Responsive to Whom?

A Critical Analysis of Risk-Based and Responsive Regulation and its Application to Australian Pharmaceutical Industry

by

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TABLE OF CONTENTS

LIST OF ABBREVIATIONS

AAT	Administrative Appeals Tribunal
ACCC	Australian Competition and Consumer Commission
ACCM	Advisory Committee on Complementary Medicines
ACM	Advisory Committee on Medicines
ACNM	Advisory Committee on Non-prescription Medicines
ACPM	Advisory Committee on Prescription Medicines
ACSOM	Advisory Committee on the Safety of Medicines
ADEC	Australian Drug Evaluation Committee
ADHD	Attention-Deficit/Hyperactivity Disorder
ADIA	Australian Dental Industry Association
ADR	Adverse drug reaction
AMA	Australian Medical Association
ANAO	Australian National Audit Office
APMA	Australian Pharmaceutical Manufacturers Association
ARTG	Australian Register for Therapeutic Goods
ASMI	Australian Self-Medication Industry
ATGAC	Australian Therapeutic Goods Advisory Council
AusPARs	Australian Public Assessment Records
CHC	Complementary Healthcare Council
CHF	Consumers Health Forum
CHOICE	Australian Consumers' Association
CMA	Complementary Medicines Australia
CMEC	Complementary Medicines Evaluation Committee
CMI	Consumer Medicines Information
CMIRG	Complementary Medicines Implementation Reference Group
CRP	Complaints Resolution Panel
DEAN	Database of Adverse Event Notifications
DPP	Commonwealth Department of Public Prosecutions
DTCA	Direct-to-consumer advertising
ELF	Electronic listing facility

FDA	Food and Drug Administration
GMiA	Generic Medicines Industry Association
GMP	Good manufacturing practice
MA	Medicines Australia
MEC	Medicines Evaluation Committee
MIMS	Monthly Index of Medical Specialists
MRA	Mutual Recognition Agreement
MSD	Merck Sharpe & Dohme Australia
MTAA	Medical Technology Association of Australia
NBSL	National Biological Standards Laboratory
NCCTG	National Coordinating Committee on Therapeutic Goods
NMP	National Medicines Policy
NPS	National Prescribing Service
NRAS	National Registration and Accreditation Scheme
NSAIDs	Non-steroidal anti-inflammatory drugs
NTGC	National Therapeutic Goods Committee
OLSS	Office of Laboratories and Scientific Services
OTC	Over-the-counter
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefits Scheme
PGA	Pharmacy Guild of Australia
PI	Product Information
PIC/S	Pharmaceutical Inspection Convention and the Pharmaceutical Inspection Cooperation Scheme
PMAA	Proprietary Medicines Association of Australia
PMP	Promotional Monitoring Panel
RACGP	Royal Australian College of General Practitioners
RMP	Risk Management Plan
SARA	System for Australian Recall Actions
SBREC	Social and Behavioural Research Ethics Committee, Flinders University
SOPs	Standard operating procedures
TGA	Therapeutic Goods Administration

TGACC	Therapeutic Goods Advertising Code Council
TGC	Therapeutic Goods Committee
TICC	TGA-Industry Consultative Committee
UK	United Kingdom
US	United States

LIST OF FIGURES

LIST OF TABLES

ABSTRACT

For close to two decades, Australia's national drug regulatory authority, the Therapeutic Goods Administration (TGA), has used both risk-based and responsive regulation theory in the regulation of the prescription and non-prescription medicines industry. These theories have been pivotal to the formation of a regulatory regime, as well as an entire field of academic scholarship, which has emphasised working cooperatively with regulated entities when non-compliance first occurs, and using deterrents only as a last resort, in order to persuade regulated entities to comply. However, data indicate that rates of non-compliance in the Australian prescription and non-prescription medicines industry are greatest in those aspects of the regime which are most reliant on these persuasive techniques and where fewer deterrents are used. For instance, in the complementary medicines sector, which largely operates under a self-regulatory arrangement, as many as 90% of products have been found to contain quality, safety, and efficacy issues. This finding led the Australian National Audit Office (2011, p. 17) to conclude that TGA regulation in this space 'has been of limited effectiveness'.

Using a combination of Marxist and Foucauldian theory within an ontological framework of critical realism, this thesis argues that an emphasis on compliance-based regulatory techniques, like risk-based and responsive regulation, has contributed to the formation of a regulatory regime congruent with neoliberal rationalities of government that aim to limit forms of market intervention by non-market forces detrimental to the accumulation of capital. In a qualitative thematic analysis, encompassing 451 submissions to public consultations and interviews with 18 participants, this thesis explores the reasons why the pharmaceutical regulatory regime in Australia, underpinned by the theories of risk-based and responsive regulation, has failed to generate compliance from sponsors. The thesis finds that the limited capacity of the regulator to act on non-compliance, and lack of opportunities for meaningful democratic participation within the regime by other non-market forces, is a direct consequence of this hybrid risk-based and responsive regulatory framework, which not only suffers from issues of incompatibility, but has rendered non-market forces less able to intervene in the regime in ways which are contrary to the interests of capital. This lack of intervention by non-market players has ultimately allowed the regime to become organised around the interests of the dominant hegemony. This thesis concludes with a discussion on the key elements necessary for enhancing the current regime, why this has not (and will not) be achieved within the current climate of neoliberalism, and why a truly alternate regime of regulation is necessary.

DECLARATION

I certify that this thesis does not incorporate without acknowledgement any material previously submitted for a degree or diploma in any university; and that to the best of my knowledge and belief it does not contain any material previously published or written by another person except where due reference is made in the text.

Signed: _____ Date: _____

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1 INTRODUCTION

Prescription and non-prescription medicines regulation in Australia has encompassed elements of both risk-based and responsive regulation theory. These theories, which form the foundations of the dominant school of thought within the regulatory literature, known as the 'compliance school' (Pearce & Tombs 1990, p. 425), place emphasis on working cooperatively with regulated entities, and using deterrents only when these persuasive techniques fail to compel regulated entities to comply. Risk-based regulation achieves this mandate by relying on the self-regulatory capacity of regulated entities and prioritising regulatory enforcement towards those sites which pose the greatest risk to regulatory objectives (Baldwin & Black 2008; Black & Baldwin 2010 & 2012). Responsive regulation, however, opts for a more graduated enforcement technique. It begins by having the regulator and regulatee working cooperatively to re-establish compliance when non-compliance first occurs, and the regulator incrementally escalating the severity of its response each time its attempts to compel compliance fails (Ayres & Braithwaite 1992). Advocates of these compliance-based regulatory techniques argue that compliance can be achieved from regulatees voluntarily without having to resort to the use of deterrents.

Australia's national drug regulatory authority, the Therapeutic Goods Administration (TGA), uses risk-based and responsive regulatory techniques to prioritise enforcement towards certain risks, the risk posed by the product and the risk of non-compliance, and then, to guide its response to these risks through graduated enforcement (TGA 2012a, 2012h, 2015a & TGA 2017a). However, this regulatory regime has consistently failed in securing the cooperation of regulatees. The regime experiences high rates of non-compliance from sponsors, the companies which import, export, manufacture, and supply medicines in Australia, particularly among the sponsors of low-risk medicines and in those aspects of the regime where persuasive techniques are most commonly used. There have also been documented cases of sponsors actively evading and defying the spirit of regulatory requirements, and ignoring and appealing TGA decisions in these aspects of the regime.

A select group of scholars argue that risk-based and responsive regulation theory are often 'severed' from their 'ideological foundation[s]' when applied in practice so that they are more amenable to the neoliberal program (Mascini 2013, p. 55). The key features of risk-based and responsive regulation, which stress the prioritisation of enforcement, intervention as a last resort, the primacy of self-regulation, and the socialisation (rather than punishment) of corporate crime and harm, share a significant degree of overlap with the neoliberal critique of excessive government. This congruence with neoliberalism has made risk-based and responsive regulation highly amenable with the

'neoliberal reflex' of limiting forms of market intervention detrimental to the accumulation of capital (Mascini 2013, p. 56). This is not to suggest that all market intervention, particularly on the part of the state, is necessarily reduced, only those forms which are contrary to the interests of capital (Tombs & Whyte 2015, p. 22). Therefore, forms of market intervention which promote market activity, something which 'cannot exist without a great deal of state work' (Tombs & Whyte 2015, p. 162), forms 'part of a hegemonic process' which attempts to sustain the interests of dominant social forces within capitalist societies (Tombs & Whyte 2015, p. 24).

This thesis provides an examination of the Australian pharmaceutical regulatory regime and its failure to compel compliance from prescription and non-prescription medicines sponsors using cooperative risk-based and responsive regulatory techniques. The central argument of this thesis is that the regime's failure to compel compliance from sponsors is due to its congruence with neoliberal rationalities of government which attempt to limit non-market forces from intervening in markets in ways detrimental to the accumulation of capital. In identifying the principle reasons for the failure of the Australian pharmaceutical regulatory regime, this thesis will demonstrate that the regime is not only organised around the interests of capital, but that the state also operates in ways which facilitates these interests.

The chapter begins by providing a brief overview of the research context for this thesis: the failure of the Australian pharmaceutical regulatory regime as a result of persistently high rates of non-compliance. It then outlines the aim, significance, and scope of this thesis, before ending on an outline of the thesis chapters.

1.1 RESEARCH CONTEXT

The Australian National Audit Office (ANAO) has documented consistently high rates of non-compliance among the sponsors of low-risk medicines. In 2011, 90% of complementary medicines, including vitamin, mineral, herbal, aromatherapy, and homoeopathic medicines, were found non-compliant with quality, safety, and efficacy requirements post-marketing (ANAO 2011, p. 15). This finding led the ANAO (2011, p. 17) to declare that the TGA's regulation of complementary medicines 'has been of limited effectiveness'. Overall, the sponsors of non-prescription medicines, which are considered lower in risk than prescription medicines, have consistently demonstrated rates of non-compliance with quality, safety, and efficacy requirements between 70 and 75% (ANAO 2011; TGA 2015). According to the ANAO (2004 & 2014), almost all audits of prescription and non-prescription medicine manufacturers reveal violations of the Code of Good Manufacturing Practice. In the case of

prescription medicine manufacturers, 60% of all audits conducted between 2008 and 2013 revealed at least one major deficiency or deviation from standards (ANAO 2014, p. 69). Just over 1% of all audits conducted for prescription medicine manufacturers during this period where classed as critical deficiencies which had the potential to cause physical harm (ANAO 2014, p. 69). Between 1999 and 2003, 20% of all audits conducted for non-prescription medicine manufacturers, which are generally subject to fewer audits than prescription medicine manufacturers, contained deficiencies where there was believed to be 'a potential risk to public health or safety' (ANAO 2004, p. 79).[1]

In the advertising space, several sponsors have been accused of withdrawing non-prescription medicines from the market and re-listing them with alternate labelling to avoid scrutiny from the regulator. For example, in the case of Undoit, a diet pill which claimed to prevent fat and carbohydrate absorption, the sponsor cancelled the product's listing, while it was still subject to a complaint and investigation by the TGA's Complaints Resolution Panel (CRP), and re-listed the same product under a different name, Undoit Plus, to terminate the investigation into the original product (Hobday 2012). Sponsors have also been accused of ignoring CRP and TGA decisions. In the case of Reckitt Benckiser and the advertising of pain-specific Nurofen products that claimed to provide 'targeted' relief from specific types of pain, Reckitt Benckiser ignored the initial determinations of the CRP (2011 & 2013), as well as requests from the TGA (2012e & 2014a) to comply with the CRP's initial determinations. It was only five years later, after a second regulator, the Australian Competition and Consumer Commission, took Reckitt Benckiser to the Federal Court of Australia, that the sponsor finally removed the offending claims and paid a AU$6 million fine (*Australian Competition and Consumer Commission v Reckitt Benckiser (Australia) Pty Ltd (No 4)* (2015) FCA 1408; *Australian Competition and Consumer Commission v Reckitt Benckiser (Australia) Pty Ltd (No 7)* (2016) FCA 424).

Concerns have also been raised with respect to misleading promotional practices and the relationships between sponsors and healthcare practitioners, all of which operates under a self-regulatory framework. Data compiled from mandatory reports made by prescription medicine sponsors between 2007 and 2012 found that sponsors in Australia spent an average of AU$1.1 million per week (and AU$58 million per year) on educational events directed to healthcare practitioners (The Global Mail 2012). The case of Merck & Co and its subsidiary Merck Sharpe & Dohme Australia (MSD) and the

[1] Information concerning TGA enforcement outcomes, including its outcomes on manufacturer audits, is rarely made available to the public. This issue has been raised at several points during the course of the thesis. It is due to this lack of publicly available information that direct comparisons between prescription and non-prescription manufacturers over the same time-frame are not possible.

promotion of the prescription pain-reliver Vioxx provides a unique insight into the types of practices sponsors will engage in to portray products in a more favourable light. Employees at the parent company allegedly produced articles for peer-reviewed journals 'without any disclosure of their interest' and also engaged in ghost-writing practices, all of which portrayed Vioxx's safety profile more favourably (Faunce 2010, pp. 47-8). In Australia, MSD used key opinion leaders and trained its sales team to minimise the safety risks associated with Vioxx (*Peterson v Merck Sharpe & Dohme (Aust) Pty Ltd* (2010) FCR 180, para. 274 & 281-3). MSD also produced its own 'fake medical journal' as a means of peddling the company's products, including Vioxx (*Peterson v Merck Sharpe & Dohme (Aust) Pty Ltd* (2010) FCR 180, para. 296).

Since 2010, the TGA and the Australian Government Department of Health have undertaken an extensive period of public consultation on proposals to reform the regulation of prescription and non-prescription medicines, conducting over 50 public consultations between the years of 2010 and 2014. Initial consultations conducted during this period, particularly the consultations entitled *Improving Advertising Arrangements for Therapeutic Goods* and the *Review to Improve the Transparency of the TGA* (also referred to as the *Transparency Review*), led to the production of the document *TGA Reforms: A Blueprint for TGA's Future* (known as the *Blueprint Reforms*), which sparked a major period of prescription and non-prescription medicine reform from 2012 onwards (see TGA 2012g). The *Blueprint Reforms* not only aimed to enhance the regulation of non-prescription medicines, and medicine advertising and promotion, acknowledging that there has been 'a poor rate of compliance with regulatory requirements' in these areas (TGA 2012g, p. 8), but also aimed to enhance the transparency of the regulator and regulatory regime to the public.

1.2 RESEARCH OUTLINE

The aim of this thesis is to examine why the pharmaceutical regulatory regime in Australia, underpinned by the theories of risk-based and responsive regulation, has been unable to generate compliance from sponsors. This thesis proceeds on the assumption that the regime has failed to generate compliance, not only because of the data and documented cases of non-compliance reported in the previous section, but because the regime has been *perceived* to be incapable of achieving compliance by a wide range of stakeholders and has since been subject to public consultation and reform by the Australian Government.

This analysis focusses upon the regulation of prescription and non-prescription medicines. It therefore excludes an analysis on generic and biological medicines, and medical and in vitro diagnostic devices,

which are regulated in a slightly different manner to prescription and non-prescription medicines. The analysis is also restricted to the post-market regulation of prescription and non-prescription medicines since medicines which fail to comply with regulatory requirements prior to marketing (generally) do not receive approval. However, the thesis does include an analysis on a range of post-market compliance issues which stem from the pre-market regulation of medicines, and lack thereof. This thesis also does not engage in a discussion on the general absence of media 'outrage' on the level of industry non-compliance even though this discussion would be highly relevant to an analysis of this type (and therefore, worth exploring for future research purposes).

Findings generated from this thesis will have both theoretical and practical implications. The thesis challenges the dominant school of thought within the regulatory literature, the compliance school, by exploring the capacity of two of its most fundamental theories, risk-based and responsive regulation, to compel compliance from regulated entities, and ultimately, their vulnerability to being weakened by the interests of the dominant hegemony. The findings also have implications for the current operation and reform of the regulatory regime. For instance, suggestions that the Australian pharmaceutical regulatory regime may be organised around the interests of the dominant hegemony, and that the state largely operates in ways to facilitate this hegemonic project, would imply that a more transformative solution is required (see 9.1.1).

1.2.1 RESEARCH SCOPE

To develop these arguments, it is necessary to outline the starting point for this thesis by situating it within the regulatory, crime and harm, and state-corporate crime literature.

1.2.1.1 Conceptualising the Regulatory Terrain

This thesis is first and foremost occupied with the analysis of *regulatory regimes* or *terrains*—the spaces which encompass 'the norms, the mechanisms of decision making, and the network of actors that are involved in regulation' (Levi-Faur 2011, p. 13). This thesis therefore goes beyond a discrete analysis of law and regulation, and regulatory agencies, actors, and networks. These regimes are analysed based on the *context* or setting in which they operate (e.g. how regulation is being enacted, how regulatory actors produce and/or are affected by regulation, and public preferences and attitudes towards regulation), as well as their *content* (e.g. the extent of investment in the regime, its institutional structure and organisation, and overall style) (Hood, Rothstein & Baldwin 2001; as cited in Levi-Faur 2011, pp. 13-4).

The Australian pharmaceutical regulatory regime is usually characterised as 'a conceptual hybrid of corporatism and neoliberalism' (Lewis & Abraham 2001, p. 66). *Corporatism* (and *neo-corporatism*) is described as the socio-political system where 'organisations representing monopolistic functional interests engage in political exchange with state agencies over public policy outputs' (Lewis & Abraham 2001, p. 55). Under corporatism, the state is conceived as a ''strong state' … capable of resisting capture by interest groups … [and] asserting its own interests' (Abraham & Lewis 2000, p. 10). Interest groups involved in this exchange are 'non-competitive' and have 'a deliberate representational monopoly' granted by the state 'in exchange for certain controls [being placed] on them' (Lewis & Abraham 2001, p. 55). The intermediation of these various interests is designed to ensure that bargaining remains two-way—that the 'state is not powerful enough to dictate policies to interest groups' and 'no interest group exercises a monopoly of representational activity' (Lewis & Abraham 2001, p. 55). Consumer and public interest groups, healthcare practitioners, practitioner associations, and public health activists participate in this exchange in the Australian pharmaceutical space. However, this exchange is typically characterised by a 'pronounced business bias' due to the amount of representation industry receive (Löfgren & de Boer 2004, p. 2398). Historically, there has also been little evidence of *tripartism*—the empowerment of public interest groups by the state to advance regulatory norms in accordance with the public interest (more on this concept in *Chapter 2*). This has particularly been the case when political exchange has been closed off to the public and policies are developed exclusively between the state and industry because its subject matter is thought to be too technical for public debate. This 'privileged access' afforded to industry has allowed industry to shape political exchange in line with its interests (Lewis & Abraham 2001, p. 75). This is not to suggest that neoliberalism has supplanted corporatism to become the dominant mode of socio-political organisation; neoliberalism has simply 'redefined the interests of the state to be more responsive to, and convergent with, industrial interests' (Lewis & Abraham 2001, pp. 73-4).

Unlike corporatism, neoliberalism is a contentious term which 'seems to mean many different things depending on one's vantage point' (Ong 2006; as cited in van Baar 2011, p. 164). As a general policy framework, neoliberalism is conceived as 'a set of policies … aim[ed] at the 'rolling back' of the state from traditional areas of intervention through measures of deregulation, privatization, and 'marketization'' (van Baar 2011, p. 153). This version of neoliberalism is often associated with neo-classical economics, 'world leaders … responsible for the 'neoliberal turn'', such as Ronald Regan and Margret Thatcher, and the conservative liberal political movement the 'New Right' (van Baar 2011, pp. 153-4). Neoliberalism can also be approached through neo-Marxist and Gramscian theory. Under Marxian political economy, neoliberalism is conceived as a capitalist mode of economic organisation and production which has been 'imposed' on those less powerful 'to maintain or

augment the class positions of 'the powerful'' (van Baar 2011, p. 154). The Gramscian concept of hegemony extends and builds upon the Marxian concept of political economy by treating neoliberalism as the ideology or discourse which underpins these specific modes of economic organisation and production. According to this view, neoliberal hegemonic ideas are disseminated throughout the social body by creating a *hegemonic project*—by articulating a set of policies or goals as being in the common interest when they actually serve the long-term interests of more dominant groups (Jessop 1990, p. 181). This hegemonic project is achieved by progressively neutralising or eliminating oppositional (or *counter-hegemonic*) forces (Jessop 1990, p. 181). It involves: taking systematic account of the interests of various social (subordinate) groups; making compromises on secondary issues, without at the same time sacrificing essential interests, to maintain the support and alliances of subordinate groups; and incorporating these interests into the dominant interest by framing these interests as part of a 'collective will', 'common worldview', or shared 'common sense' (Jessop 1990, p. 181). This project enables those with power to secure the support of those less powerful (Jessop 1990, p. 51), which explains why less powerful groups often 'consent to measures that are often mobilised against them' (van Baar 2012, p. 1293). Neoliberalism can also be conceived in Foucauldian terms as a form of governmentality, or a technique and mentality of governing (more on this concept in *Chapter 3*). This interpretation of neoliberalism is particularly prominent within the criminological literature (e.g. see Tombs 2016, p. 11).

For the purposes of this discussion, this thesis treats neoliberalism as a form of governmentality. It is argued that neoliberal governmentality forms part of a wider hegemonic project that attempts to sustain the long-term interests and dominance of more dominant forces in the pharmaceutical regulatory regime. For a detailed overview of this theoretical approach, see *Chapter 3*.

1.2.1.2 Defining Crime and Harm

This thesis also adopts a broad approach to crime by situating the analysis within a social harm, or zemiology, perspective. This social harm approach has been adopted for a number of reasons. First, corporate harms are rarely criminalised and enshrined in law. In fact, in the Australian pharmaceutical regulatory regime, most forms of corporate harm are enshrined under regulatory or civil law. These harms are rarely viewed as crime because conventional definitions and conceptions of crime are a product of their institutional framing, which is largely determined by the state and those interests which influence the state—that is, crime is 'not merely something that the state controls or organises a war against, but something that the state creates by deciding what to prioritise and what not to prioritise' (Whyte 2009, p. 2). Importantly, in terms of this research, this means that states and corporations 'play a central role in defining the boundaries of their own crime' (Whyte 2009, p. 3).

Since many of the harms explored in this analysis are not labelled as crime, not only is it necessary to adopt a broader term to describe those forms of harm which have escaped this label, but to use a term which is distinct from the label of crime to clearly distinguish between those harms which are criminalised and those which are not. Second, corporate harms are unlikely to be reported and investigated (Tombs & Whyte 2015, p. 52). This can occur for a variety of reasons, most of which stem from the fact that corporate harms are rarely treated as 'crimes', so victims may not perceive themselves as victims, and enforcement agencies may not interpret corporate harms as issues meriting their attention. Finally, not only are corporate harms rarely enshrined in law, but even when these harms are punishable by law, corporations are rarely prosecuted. This occurs for many reasons, including: a lack of resources to enable enforcement agencies to bring cases against offenders; difficulties in establishing *causation* (a connection between the act and its resulting harms); difficulties in establishing intent, especially when these harms occur during the course of everyday business activities which are generally perceived to have socially-productive ends; difficulties in establishing blame due to the diffusion of responsibility within corporations; and because cases are likely to result in settlement (Friedrichs 2010; Tombs & Whyte 2015).

In the pharmaceutical space, causation is particularly difficult to prove because of a medicine's biological effect on the human body. This can make it difficult to determine whether certain biological processes have been triggered by a medicine or some other biological factor intrinsic to the consumer. The 'hallowed status' afforded to pharmaceutical industry because it is the only provider of essential, often life-saving, medicinal products, also means that many of the negative consequences of industry practices are often treated as 'unfortunate incidents' and 'inevitable risks … we're evidently prepared to live with' (Rawlinson 2017b, p. 215). Fears that access to certain medicines may be lost if industry are treated too punitively has led to an 'unwillingness to bite the hand that heals us, or [at least] promises to' (Rawlinson 2013, p. 73). A social harm perspective is therefore well suited to analysing harmful industry practices 'operating within the framework of legality' (Rawlinson 2017b, p. 216).

In the context of this research, it is necessary to clearly establish what is meant by harm. While definitions of social harm are still subject to debate in the criminological literature, many criminologists (Garside 2013; Hillyard & Tombs 2017; Lasslett 2010; Pantazis & Pemberton 2009; Pemberton 2004 & 2007; Yar 2012) opt to define harm in line with the theory of human needs. Here, human needs are defined as the 'pre-requisites for human well-being', which 'clearly delineates needs … from subjective wants and desires' (Pemberton 2007, p. 37). Individuals are therefore harmed when these 'needs are not fulfilled' (Hillyard & Tombs 2017, p. 300). Since health and many of its underlying determinants—which includes medicines since they must be 'scientifically and medically

appropriate and of good quality' (Office of the United Nations High Commissioner for Human Rights 2008, p. 4 [emphasis removed])—are deemed an international human right, this definition is particularly well suited to studying the harmful practices of the pharmaceutical industry.

Most criminologists tend to attribute the causes of harm to capitalist, particularly neoliberal, structures (Hillyard & Tombs 2017; Pantazis & Pemberton 2009; Pemberton 2004 & 2007). Garside (2013, p. 256) believes this to be problematic because it defines harm as a product of certain forms of capitalism, not capitalism in general or other modes of social organisation, and implies that human needs are 'static' and 'exist in a state logically prior to, and independent of, the social relationships into which humans enter'. In defining social harm, Garside (2013) argues for a more relational account of harm, which views harm as something which is produced and reproduced by socially harmful arrangements. This allows harm to be conceived in ways which are not necessarily capitalistic, which Garside believes is essential for developing more transformative solutions to social harm.

For the purposes of this thesis, the term *non-compliance* will be used to describe those violations of law which do not necessarily involve a criminal law violation, such as civil law and regulation, but cause harm to the consumer nonetheless. Since non-compliance is a term that is already used by the TGA to describe these types of violations, this thesis will continue to use this term to avoid potential confusion, particularly with those forms of harm which are readily framed as crimes because they involve a violation of criminal law. This thesis also employs a relational account of power through a critical realist, Marxist and Foucauldian theoretical framework. This approach to power, and therefore, the production of harm, allows the analysis to escape the essentialist view adopted by Marxism, and to conceive power as something which is both structured and contingent on factors other than structure (more on this in *Chapter 3*). While this thesis is primarily concerned with neoliberal techniques and rationalities of government, many of the harms associated with neoliberal governmentality are also characteristic of capitalism in general since neoliberalism is an explicit form of capitalism.

1.2.1.3 The State-Corporate Paradigm

This thesis also adopts a state-corporate approach to corporate crime and harm. This state-corporate crime approach has been adopted on the grounds that 'corporate crime and harm are nothing more … than a power relationship that is guaranteed, under-written, and indeed often partly also enjoined, by states' (Tombs & Whyte 2015, p. 167). According to Tombs and Whyte (2015, pp. 167-8 [emphasis removed]):

> corporate power is a manifestation of the infrastructural power of states … Through a variety of political, legal and ideological processes—processes that are always ongoing, requiring a great deal of state work—corporations … are more or less empowered within states in ways that allow them to cause large-scale social harms with relative impunity.

It is due to this relationship between the state and corporations that the thesis adopts a state-facilitated approach to corporate crime and harm. According to Kramer, Michalowski, and Kauzlarich (2002, pp. 271-2), state-facilitated corporate crime can be conceived as the failure of 'government regulatory institutions … to restrain deviant business activities, either because of direct collusion between business and government or because they adhere to shared goals whose attainment would be hampered by aggressive regulation'. In the context of this analysis, it is argued that the state has willingly facilitated the production of the current regulatory regime, rendering the regulator less able to compel compliance, and therefore, less able to intervene in the regime in ways that are contrary to the interests of capital. As the 'political organiser' of the various interests within this regime (Mahon 1979, p. 166), the state has permitted these interests to dominate and allowed the regime to become organised around these interests.

1.3 CHAPTER OUTLINE

This thesis is comprised of nine chapters. *Chapter 2* explores the strengths and criticisms of risk-based and responsive regulation within the wider context of the deterrence and compliance debate. Though risk-based and responsive regulation have been designed with the intent of acting as a practical compromise between deterrence and compliance-based approaches, many of its key features share a significant degree of overlap with neoliberal rationalities of government. This chapter examines the strengths and limitations of the deterrence and compliance schools, and risk-based and responsive regulation, and highlights the compatibility of the theories with neoliberal rationalities of government.

Chapter 3 outlines the theoretical framework and research method employed by this thesis. The first two sections of the chapter begin by providing an overview of the Marxist and Foucauldian theoretical framework used. Section one provides an overview of Marxist and Foucauldian conceptualisations of power. Section two explores the interplay between Marxist and Foucauldian theory by using a general theory of critical realism. Here, Marxism is used to explain the structure and motivations for power relations within the pharmaceutical regulatory regime, Foucault is used to explain the

production and exercise of these relations of power, and a critical realist ontology is used to conceive these power relations as something which emerges from, but is not reducible to, social structures. The final section is dedicated to detailing the research method: a critical realist qualitative thematic analysis of public consultation submissions and interview transcripts. This thematic analysis is used to identify themes in stakeholders' and interviewees' perceptions towards the regulator and regulatory regime, particularly those aspects of the regime which they perceive to be incapable of generating compliance from sponsors.

The following chapter, *Chapter 4*¸ provides an overview of the historical emergence of the Australian pharmaceutical regulatory terrain. This chapter examines the emergence and retreat of the state with the emergence and dominance of compliance-based techniques of government, and neoliberal governmentality. The motivations and practices which led to these transformations are explored through the combined theoretical framework outlined in *Chapter 3*. The chapter explores how: state power has been decentralised through the delegation of power to a specialised apparatus of the state, the TGA, and the empowerment of industry associations; pre-market and post-market regulation has been deregulated; risk-based, cooperative, and graduated techniques of government were introduced to minimise state intervention in the regime; and technologies of citizenship were introduced to enhance stakeholder participation. The central argument of this chapter is that these transformations to the regulatory regime, which have been willingly facilitated by the state, has resulted in the production of a regime which promotes the interests of the dominant players more so than those of other regulatory players.

Chapter 5 provides an overview of the current regulatory terrain as a result of the historical processes outlined in *Chapter 4*. This chapter outlines the regime's key players, its risk-based and responsive regulatory framework, the two-tiered medicine classification scheme which dictates how prescription and non-prescription medicines enter the market, and its pre- and post-market regulatory framework. This chapter particularly focuses upon the processes involved in the post-market testing and monitoring of medicine quality, safety, and efficacy, and medicine advertising and promotion.

The two results chapters, *Chapters 6* and *7*, are organised around the two over-arching themes generated from the thematic analysis. *Chapter 6* explores the first of these two over-arching themes, *Reduced Regulatory Capacity*, and how the deterrent impact of the risk-based and responsive regulatory techniques has reduced the overall capacity of the pharmaceutical regulatory regime to compel compliance from sponsors. *Chapter 7* explores the second over-arching theme, *Reduced Capacity for Participatory Democracy*, and how participation in the regime by non-market non-

governmental players, such as consumers, public interest groups, healthcare practitioners, and practitioner associations, is limited compared to more dominant market players within the regime, namely sponsors and industry associations. *Chapter 7* ends by establishing the connections between the findings outlined in *Chapters 6* and *7*. It explains how non-market players, governmental and non-governmental alike, are rendered less able to intercede and challenge the regime in ways that are contrary to the interests of the dominant hegemony, and how this allows the regime to become organised around these dominant interests.

Chapter 8 examines the TGA's attempts to enhance the regulatory regime to better regulate industry in the period immediately following data collection for this thesis. This discussion is based on six key features that were identified during the qualitative thematic analysis, which stakeholders and interviewees believed to be necessary for enhancing the capacity of the current regime to generate compliance.

The final chapter, *Chapter 9*, provides an overview of the conclusions generated from this thesis. This chapter explains why the structural inequalities generated by the regime cannot simply be overcome with greater reform, and why a larger program of social transformation is necessary for a truly alternate regime to be realised. It also highlights the unique contributions of this thesis to the literature and presents options for future research agendas in light of its limitations.

2 THE DETERRENCE AND COMPLIANCE SCHOOLS

The dominant school of thought within the regulatory literature, known as the compliance or 'Oxford' school of regulation (Pearce & Tombs 1990 & 1997; Tombs 2016), argues that greater reliance should be placed on persuasion, rather than punishment, to generate compliance from businesses, as businesses are more likely to be socially responsible 'political citizens' committed to their community and its laws than 'amoral calculators' motivated only by profits and their self-interests (Kagan & Scholz 1984). Proponents of this school of thought argue that command-and-control styles of enforcement, most commonly associated with the deterrence school, are inefficient, expensive, a hindrance to regulatee cooperation, and to focused on 'end-of-pipe' solutions (Fairman & Yapp 2005; as cited in Tombs 2016, p. 79). Proponents of compliance therefore argue that deterrence-based approaches should only be used as a last resort in those limited number of cases where persuasion has failed (Almond & Colover 2012, p. 1000).

Two theories which feature prominently in the compliance literature are *risk-based* and *responsive regulation*. While both of these theories differ in their approach to addressing the issue of non-compliance, each share a number of common philosophies, including: a belief that the state does not and will not have sufficient resources to oversee compliance with all regulatory requirements; that resources should be targeted towards those sites and activities which present the greatest degree of risk to compliance; that regulation is best pluralised (i.e. occurring beyond the state); and that industry self-regulation is an effective and efficient alternative to state regulation because businesses have more of an innate and moral commitment to mitigate risk (Tombs 2016, p. 82). The growing affinities between these two sets of literature has only strengthened the position of the 'regulatory orthodoxy' (Tombs 2016, p. 82); in fact, Baldwin and Black (2008 & 2010), have gone so far as to combine the two theories to form *really responsive risk-based regulation* as a way of getting the best of both strategies.

This chapter explores the strengths and criticisms of risk-based and responsive regulation within the broader context of the deterrence and compliance debate. The chapter begins with overviews of the deterrence, compliance, and risk-based and responsive regulation literature to highlight each of their philosophical differences, and conceptual and empirical limitations. It concludes with a discussion of the degree of overlap between risk-based and responsive regulation and the neoliberal notion of limited market intervention. This overlap often leads risk-based and responsive regulation to become 'severed' from their 'ideological foundation[s]' so that risk-based and responsive regulation 'fits neatly into the neoliberal program' (Mascini 2013, pp. 55-6).

2.1 DETERRENCE AND THE CLASSICAL SCHOOL OF CRIMINOLOGY

The deterrence school is rooted in utilitarian philosophy which views offenders as rational and self-interested actors (Simpson 2002; Tombs & Whyte 2007). Decisions to offend are based on a rational calculation of the perceived costs and benefits of committing an offence; if the perceived costs of an offence are outweighed by its perceived benefits, individuals will be deterred from offending simply because it is more rational for them to comply (Paternoster & Simpson 1996, p. 553). Compliance is therefore achieved by increasing the probability of detection, and the celerity and severity of punishment to the point where the costs of non-compliance becomes irrational (Murphy 2017, p. 44).

In the context of the corporation, 'the decision to break the law is made by individuals … affected by the context' or 'the characteristics and imperatives of their business organization' (Paternoster & Simpson 1996, p. 553). Corporations, in turn, 'take on the characteristics of acting agents responsible for their conduct' (Paternoster & Simpson 1996, p. 553), and thus, develop their own 'corporate personality' (Tombs & Whyte 2007, p. 131), which is independent, and structurally distinct from, the decisions and actions of its agents. This means that corporations represent themselves as unified, rational, decision-making entities even when the decisions and actions of corporations, which are enacted by their directors, senior management, and employees, 'clearly fall[s] short of any standard of rational action' (Tombs & Whyte 2015, p. 101).

Corporations are 'quintessentially rational' in the sense that their sole purpose is to generate (and maximise) profit whilst at the same time minimising the costs of this pursuit (Yeager 2016, p. 439). Corporations are therefore considered to have an amoral calculative attitude towards business activity among advocates of deterrence (Pearce & Tombs 1990 & 1997; Tombs & Whyte 2007 & 2015). Expectations, then, that corporations will respect a moral commitment to act in the best interests of the public, even when this commitment conflicts with the interests of capital accumulation, is 'oxymoronic' (Rawlinson 2017a, p. 88), according to advocates of deterrence, as this 'would entail ignoring the very rationale of the corporation and the nature of the existing economic system' (Pearce & Tombs 1990, p. 425). Although corporations can be pressured to act in socially responsible ways (i.e. by consumer or environmental groups, trade unions, or political parties), Pearce and Tombs (1997, p. 83) argue that these 'counterpressures only constrain, and certainly do not remove, the pressure to maximize profits'. Pearce and Tombs (1997, pp. 83-4) state that:

> while there is a range of ways in which companies … have responded to environmental, safety and health pressures, it is difficult to conceive of any of them as representing either some form of altruism or subordination of profitability in some other (social) ends.

It is for this reason that proponents of deterrence argue that corporations need deterrents because relying on corporations alone to act in socially responsible ways is likely to result in suboptimal levels of compliance (Lexchin & Kawachi 1996, p. 225).

2.1.1 THE LIMITATIONS OF DETERRENCE

Deterrence and rational choice theories are often criticised on the grounds that offenders cannot always have perfect knowledge (as rationality is bounded) or behave in rational ways. However, Tombs and Whyte (2007, p. 169 [original emphasis]) argue that these criticisms often arise because these theories are applied 'to those who are *least* capable of acting rationally' and 'do not have any control over the social conditions that shape their present and their future'. Unlike individuals, corporations have a range of resources at their disposal to seek advice and collate information, and while the decisions of corporations can never be based on perfect knowledge, the range of 'knowledge resources' available to corporations enables corporations to make more calculated decisions than would otherwise be possible for those without such resources (Tombs & Whyte 2007, p. 170). Corporations are also susceptible to 'perceptual and computational biases and heuristics, overconfidence, and hubris', so they can never be 'perfectly rational' (Paternoster 2016, p. 386).

Opponents of deterrence also point to the lack of empirical support as proof that deterrence-based approaches are incapable of generating compliance. While there is evidence to suggest that the perceived certainty of punishment has a deterrent effect on conventional forms of crime (Bachman, Paternoster & Ward 1992; Grasmick & Bursik 1990; Grasmick & Green 1980; Kennedy & Braga 1998; Klick & Tabarrok 2005; McGarrell, Chermak, Wilson & Corsaro 2006; Nagin & Paternoster 1993; Weisburd, Einat & Kowalski 2008), more so than punishment severity and celerity (Hawken & Kleiman 2009; Weisburd, Einat & Kowalski 2008), this evidence is by no means 'solid' (Paternoster 2010, p. 766). Early research demonstrating a deterrent effect for deterrence-based approaches on conventional forms of crime has been criticised for its unsophisticated methodology (Schell-Busey, Simpson, Rorie & Alper 2016; Simpson 2002; Simpson, Rorie, Alper & Schell-Busey 2014), and contemporary studies, which have employed more sophisticated research methodologies, have failed to replicate the effects of this earlier research (Paternoster 1987). There has been even less of a deterrent effect observed for corporate and white-collar crimes: in a recent meta-analysis conducted by Simpson et al. (2014), enforcement measures aimed at deterring corporate crime (e.g.

law) showed less of a deterrent effect than regulatory and mixed intervention strategies. These findings led the authors to declare that 'we cannot conclude that law has a deterrent effect on corporate offending' (Schell-Busey et al. 2016, p. 397).

However, proponents of deterrence have argued that this does not indicate that deterrence cannot work altogether. Paternoster (2016, p. 384 [emphasis removed]) argues that the meta-analysis conducted by Simpson and her colleagues is 'greatly hampered by the paucity of good studies'. In the authors' own words:

> Out of the 25 effect sizes calculated, 16 (64%) indicated a desirable (i.e., deterrent) impact. However, none of the effects were strong in magnitude and only 4 of those effect sizes were statistically significant … most of our analyses are based on less than 10 studies … [and] most of the studies included do not use rigorous methods that would rule out spurious relationships or establish proper temporal ordering (Simpson et al. 2014, p. 31).

These 'null findings' are also not too surprising given the current state and use of deterrence-based strategies (Paternoster 2016, p. 384). Legal sanctions are rarely applied to corporate harms, because detection fails to occur, sanctions do not exist, or prosecution is deferred, and are often too small to have a deterrent effect (Paternoster 2016; Tombs 2016; Yeager 2016). In fact, it is often argued that sanctions cannot be too large since corporations will not have the capacity to pay—also referred to as the 'too big to fail' thesis (Paternoster 2016, p. 384). Tombs (2016, p. 83 [original emphasis]) has even gone so far as to argue that:

> a deterrent enforcement philosophy, transmitted via command-and-control regulation has *never* featured predominately in any liberal democratic system … empirical studies of a range of regulatory bodies across various jurisdictions overwhelmingly point to the facts that non-enforcement of the law is the most frequently found characteristic in regulatory regimes; enforcement activity tends to focus upon the smallest and weakest individuals and organisations, and sanctions following regulatory activity are invariably light.

Since there are a range of factors which impact upon the quantity and quality of studies analysing deterrence-based approaches, Tombs and Whyte (2017, p. 13) argue that the case against deterrence-based approaches is 'always made hypothetically'.

Paternoster (2016, pp. 385-6) argues that the fact that 'corporate offending takes place in the face of low certainty of punishment and even lower severity and swiftness' demonstrates that corporations

'seem to respond to both incentives and disincentives' and that 'rational choice is at work'. For example, Simpson (1986 & 1987) demonstrated that antitrust violations are more likely to occur under permissive Republican political administrations than stringent Democrat administrations in the United States (US) (Simpson 1986 & 1987). Braithwaite (2016, pp. 422-4), Yeager (2016), and Paternoster (2016, p. 384) made reference to instances where deterrence-based approaches—particularly law—have generated greater compliance from businesses. Even in the meta-analysis by Schell-Busey and colleagues, a significant deterrent effect was only found for regulatory and mixed intervention strategies 'when comparing firms subject to active regulation (hence, threat of enforcement) with those that were not so subject' (Yeager 2016, p. 440). This has led Paternoster (2010, p. 766) to conclude that 'while … there likely is a deterrent effect to the workings of the criminal justice system, it is difficult to determine how strong an effect it is'.

2.2 THE COMPLIANCE SCHOOL (THE DEVELOPMENT OF THE REGULATORY ORTHODOXY)

The compliance school encompasses a wide range of strategies, including responsive (Ayres & Braithwaite 1992), risk-based (Black & Baldwin 2010 & 2012; Hutter 2001), really responsive risk-based (Baldwin & Black 2008), smart (Gunningham & Grabosky 1998), and problem-solving regulation (Sparrow 2000). These strategies adopt a *cooperative* approach to enforcement which urges regulators to 'wait longer to pull the trigger' (Steinzor 2015, p. 67) and only use deterrence-based strategies as a 'last resort' (Hawkins 2002, p. 14). Advocates of compliance argue that emphasis should be placed on self-regulation and persuasive measures to 'advise, educate, bargain, negotiate and reach compromises with the regulated' (Tombs & Whyte 2007, p. 152).

Compliance-based approaches are based on the normative assumption that corporations are moral actors. According to Ayres and Braithwaite (1992, p. 94):

> [corporate] citizens comply with the law most of the time because it seems wrong to them to break the law. They refrain from crime not because they calculate that the costs of crime exceed its benefits; crime is simply off their deliberative agenda. … It is not that the expected utilities turn out badly; they do not know the sentence and the probability of detection to be able to calculate them. More often, it is just that the offense is unthinkable.

It is believed that if corporations act in amoral and calculative ways, this only occurs in a minority of cases, and even then, these violations are unlikely to be a result of pure economic calculation since

corporations are thought to have a 'normative commitment to the community and its laws … [which] outweighs narrow self-interested utility' (Scholz 1984, p. 181). In this respect, corporations are not intrinsically criminal, so their actions cannot be deterred by increasing the costs of non-compliance (Kagan & Scholz 1984). This makes corporate illegalities different from 'traditional crimes' (Kagan & Scholz 1984, p. 68), necessitating a different enforcement attitude than what would otherwise be the case for other types of offending. It is on this basis that advocates of compliance argue that compliance can be achieved voluntarily without actually having to resort to punitiveness (Murphy 2017, p. 45).

The compliance school is heavily influenced by republican theory which adopts a restorative, rather than punitive, approach to enforcement. Republicans advocate for a regulatory culture which is focused on 'socializing institutions' to encourage corporations to behave in ways that are more in line with the public interest (Ayres & Braithwaite 1992, p. 93). This is achieved by attempting to modify the 'deliberative habits and behavioral dispositions' of corporations by 'mobilizing social disapproval against those who sell out … and those who are unreasonable with cooperators'. It is argued that the shaming effect this disapproval generates will foster the internalisation of norms that will encourage corporations to act in the public interest more so than their own self-interest (Ayres & Braithwaite 1992, p. 93).

Compliance-oriented approaches are also influenced by concepts such as responsive law (Nonet & Selznick 1978). According to Nonet and Selznick (1978), the rigidity and strict fidelity of law reduces its capacity to compel compliance from regulated entities because legalism and criticism of authority will prompt corporations to either retaliate and counteract those measures in place, or, mount a direct attack on authority, both of which lead to the erosion of law. To generate greater compliance from regulated entities, law therefore needs to be 'more responsive to social needs' (Nonet & Selznick 1978, p. 73). To become more responsive, Nonet and Selznick (1978) have suggested that two changes are necessary to transform modern government. First, law must be given a facilitative, rather than an adjudicative, role; greater emphasis should be placed on the establishment of and adherence to norms rather than law, because law primarily acts upon pre-existing discourses and practices, and because norms 'form part of a wider scheme of regulation which has monitoring and behaviour-modifying mechanisms' (Scott 2004, p. 156). Secondly, Nonet and Selznick (1978) argue there should be a diffusion of legal responsibility and a gradual wearing down of egocentric power—essentially, a 'blending of powers and blurring of institutional boundaries' (p. 11)—to reduce the arbitrariness of law and increase the fairness of the judicial system. Delegating legal authority to a wider range of actors will allow these 'special-purpose institutions' to become 'the critical bearers of

legal responsibility and the sources of growth of law' (Nonet & Selznick 1978, p. 103). Each institution is then able to work 'in close relation with its own constituencies' to realise collective goals and use its 'broad discretionary powers' to enlist cooperation from stakeholders, rather than having to prescribe conduct (Nonet & Selznick 1978, p. 103). This 'withering away of the state' does not suggest that the state should be absent from all aspects of government (Nonet & Selznick 1978, p. 102); instead, it is argued that the state should be viewed as just one source of power and as much 'an object as well as a subject of regulation' (Braithwaite 1999, p. 90). Accordingly, the relaxation of central authority and increase in civic participation should lead to 'more effective cooperative action' (Nonet & Selznick 1978, p. 100). This will ultimately allow law to find 'consensus in general aspirations rather than in specific norms of conduct' (Nonet & Selznick 1978, p. 91).

This approach to offending has had a significant impact on the ways in which corporate crimes and harms are viewed by the literature. Corporate crimes and harms are often socialised on the basis that corporations are political citizens and any crimes or harms committed by corporations are usually conducted during the course of their everyday business activities which are believed, in the most part, to have socially-productive ends. This attitude to corporate harm has led to the disappearance of the term corporate crime from everyday vernacular in favour of terms such as non-compliance and corporate misconduct (Snider 2000, p. 171).

2.2.1 RISK-BASED REGULATION

In its simplest form, risk-based regulation involves 'the use of a broad suite of tools' which 'seek to achieve outcomes that can be characterised in risk terms' (Rothstein, Irving, Walden & Yearsley 2006, p. 1057). Although risk-based frameworks vary considerably in their design, they often share five common features: a set of objectives (i.e. a determination of the types of risks they are concerned about); a degree of tolerance (i.e. a determination of the types of risks to be tolerated and the extent to which they will be tolerated); an assessment[2] of the probability and impact of certain risks (i.e. a determination of their likely occurrence and the severity of an adverse event); a risk rating or scoring system based on the probability and impact of certain risks; and a framework which allocates resources on the basis of risk scores (Black & Baldwin 2010, pp. 184-5). Currently, there is little empirical evidence which demonstrates *how* risk-based regulation—'as an intervention strategy

[2] Risks are predominately assessed according to their degree of probability and impact but may also include an evaluation of the 'simplicity or complexity of the causal chain between hazard and harm; the degree to which [the] probability and/or impact are known or uncertain; the nature and distribution of the impacts (remediable or irremediable, concentrated or diffused); and the socio-political contestability of the risk' (Black & Baldwin 2012, p. 4).

distinct from a mechanism for allocating resources'—would operate in practice (Gunningham 2011, p. 189).

2.2.1.1 Limitations of Risk-Based Regulation

Because risk-based regulation sees resources prioritised towards those sites and activities which pose the greatest risks to regulatory objectives, it leads regulators to 'pull back' on resources dedicated to lower risks where most regulatory sites are located (Black & Baldwin 2012, p. 2). This means that the risk-based prioritisation of resources can impede regulatory agencies in responding to non-compliance because there are fewer resources available to carry out these regulatory activities. Black and Baldwin (2012, p. 6) argued that, while such risks cannot be ignored, and regulators must find cost-neutral ways to deploy their resources so that they are still able to identify low-risks before they raise problems, risk-based regulators need to develop a level of tolerance to risk because resource limitations inevitably mean that not all risks can be attended to. Black and Baldwin (2012, p. 4) argue that:

> what is a "low risk" or a "high risk" is a matter of construction … "Low risk" means, in practice, "low priority" – it is not so much a characterization of the risk itself as a statement of a risk's relative significance to the regulatory organization and, usually, its potential to attain its objectives or mandate.

Due to the prioritisation of risks, some risks are allowed 'to fall out of the regulatory net altogether' (Black & Baldwin 2012, p. 8), an outcome which, even Black and Baldwin (2012, p. 7) acknowledge, poses 'very significant dangers' for regulators.

Resource prioritisation can also have negative implications for the detection of non-compliance. According to Tombs (2016, p. 90), risk-based regulation presumes that 'offenders can be clearly identified through a series of knowable variables that allow the likelihood of offending to be predicted'. However, in his study on food, health and safety, and environmental regulation, Tombs (2016, pp. 176-8) found that low rates of inspection of businesses resulted in lower levels of intelligence gathered. The lack of inspection not only makes the prospect of detection—and therefore, the potential to bring about prosecution—less likely to occur, but it also impacts upon the ability of inspectors to develop appropriate risk ratings and scores to guide the frequency of future inspections.

The political salience of risk and presence (or absence) of political support can also have a major influence on which types of risks receive greater amounts of regulatory oversight. Threats to political legitimacy, or *political* risks, can arise in response to the perceived inadequacy of regulatory

responses (Haines 2011, p. 48). In the case of risk-based regulation, risk tolerance has the potential to expose regulators to 'problematic public scrutiny' (Black & Baldwin 2012, p. 7). '[T]he higher the political salience of a sector or risk, the less will be the regulators' tolerance of failure in that particular area'. This means that resources tend to 'go to the area which is most politically sensitive' (Black & Baldwin 2012, p. 8), irrespective of its level of *actuarial* risk, or, 'the reality of harm' (Haines 2011, p. 36). This can produce under- and over-enforcement across different sectors of the regime (Black & Baldwin 2012, p. 8).

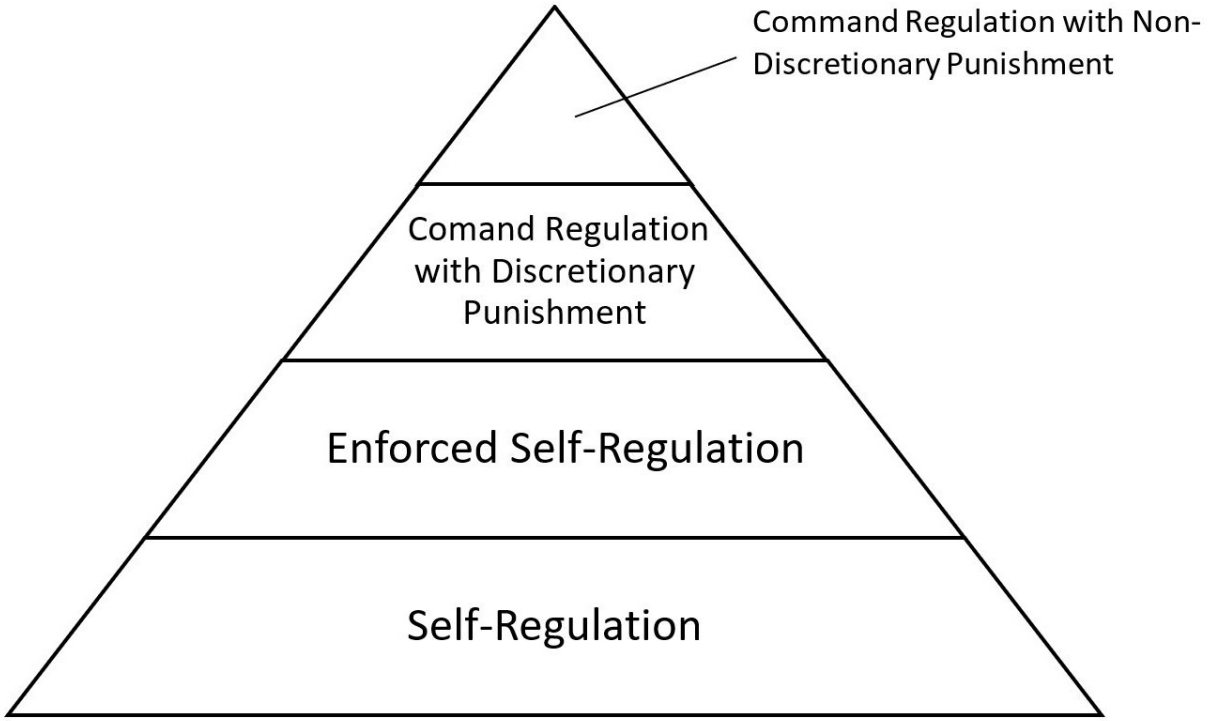
2.2.2 RESPONSIVE REGULATION

Responsive regulation is best described as 'an incrementalist and compliance-oriented strategy based on the principle of deterrence' (Tombs & Whyte 2007, p. 155). It is largely reliant on industry self-regulation and securing the cooperation of regulatees by way of persuasion. According to the theory, punitive, deterrence-based interventions only occur as a last resort when persuasive measures have failed to compel regulatees to comply with regulatory requirements (Ayres & Braithwaite 1992, p. 50). Law and adversariness therefore feature in responsive regulatory regimes, but it is not a principle mode of government. For Ayres and Braithwaite (1992, p. 39), law's primary role is to 'signal' to non-compliant entities the regulator's willingness to get tough as needed. It is this threat of punishment, according to the theory's authors, that 'usher[s] in a regulatory climate that is more voluntaristic and non-litigious' (Ayres & Braithwaite 1992, p. 39). By relying first on persuasive measures to generate compliant behaviour, the regulator avoids responding prematurely to those regulatees who are well-intentioned and are genuinely motivated to abide by the law (Ayres & Braithwaite 1992; Braithwaite 1985). However, to prevent the regime from being subject to exploitation by regulatees, the regulator can revert to more interventionist and punitive measures when the threat of escalation is insufficient to compel compliance (Ayres & Braithwaite 1992, p. 21). Once the cooperation of the regulatee has been secured, the regulator should be 'forgiving' and re-assume a cooperative posture (Ayres & Braithwaite 1992, p. 21).

This relationship between cooperative and deterrence-based enforcement is envisaged in Ayres and Braithwaite's *enforcement pyramid* (see *Figure 2.1*). Self-regulation, which represents the greatest amount of regulatory activity, is located at the pyramid's base. Regulatory intervention occurs and becomes increasingly severe as the severity of business conduct increases and dialogue fails. Regulators first use lower-level responses—persuasive tactics such as written warnings—to compel compliance from regulatees, and then progress to civil and criminal penalties, and licence suspension and revocation to punish continued non-compliance (Bandiera 2015, pp. 7-8). The greater the height to which the regulator can escalate enforcement, the more effective the regulator is said to be at

securing compliance from regulatees, and the less likely the regulator will have to resort to deterrence-based measures (Ayres & Braithwaite 1992, p. 6). This is because the height of enforcement maximises the difference between compliance (the *cooperation payoff*) and non-compliance (the *punishment payoff*), and makes cooperation appear the more economical and rational response (Ayres & Braithwaite 1992, p. 26). Companies which demonstrate acceptable levels of compliance are rewarded with the capacity to continue to self-regulate (i.e. operate with maximum dominion at the pyramid's base). The regulator's 'scare regulatory resources' can then be directed away from compliant companies and towards those companies which 'play fast and loose' (Ayres & Braithwaite 1992, p. 129).

Figure 2.1: The Pyramid of Enforcement Strategies.



Closely adapted from Ayres and Braithwaite (1992, p. 39).

By approaching corporate illegalities in this way, responsive regulation makes three broad assumptions about corporate behaviour as outlined by Braithwaite and Fisse (1987, p. 22). First, the theory assumes that corporations are largely moral actors—most corporations will obey the law voluntarily 'because to do so is ethically right, even if costly'. Second, the theory assumes that corporations are largely motivated by threats to their reputations—they 'subjugate economic rationality to [the] preservation of their good name and self-respect'. Finally, it assumes that corporations will commit to self-regulation because it 'pre-empt[s] the less palatable alternative of government' (Braithwaite & Fisse 1987, p. 22).

2.2.2.1 Tripartism

Because responsive regulation attempts to foster cooperation between the regulator and industry, it runs the risk of encouraging capture and corruption (Ayres & Braithwaite 1992, p. 54). This is because 'regulatory institutions are structured to institutionalize the power of some stakeholders (in particular those who bear the costs) … and to exclude the influence of others (those who derive the benefits)', which can allow bipartite relationships to form (Ayres & Braithwaite 1992, p. 81). Capture theorists have long argued that states and regulatory agencies can become influenced by the interests of those they seek to regulate (Stigler 1971), an argument which has some empirical support within the academic literature (Abraham & Ballinger 2012; Lexchin 2006). Rather than refrain from persuasion, Ayres and Braithwaite (1992) have argued that these types of conflicts can be managed through *tripartism*—the empowerment of a third player, such as a public interest group—as a way of counterbalancing both regulatory and industry interests. Ayres and Braithwaite (1992) argue that the introduction of a third player immediately impacts upon the firm's ability to capture the regulatory agency because the third party must now be captured in order to capture the regulator. The empowerment of a third player also places that player in a position to punish firms directly and indirectly (i.e. by punishing the regulator for failing to act upon non-compliance) (Ayres & Braithwaite 1992).

Tripartism shares much in common with democratic and empowerment theory; it aims to make citizens politically active and capable of engaging in democratic participation (Cruikshank 1999, p. 1-2). This is based on the assumption that power, participation, and knowledge is unequally distributed within regulatory regimes and that more is required to increase the regime's political equity (Ayres & Braithwaite 1992, p. 81; Cruikshank 1999). To achieve greater equity and better empower the public, Ayres and Braithwaite (1992, pp. 57-8) argue that public interest groups need to be given:

> access to all the information that is available to the regulator … a seat at the negotiating table with the firm and the agency when deals are done … [and] the same standing to sue or prosecute under the regulatory statute as the regulator.

This will allow citizens:

> (1) choices to vote with their feet in the marketplace; (2) voting rights in a representative democracy; [and] (3) opportunities and resources to participate directly in any local area of collective decision-making that has an important effect on their lives (Ayres & Braithwaite 1992, p. 17).

Ayres and Braithwaite (1992, p. 100) concede that simply empowering public interest groups will not make them 'equal partners' with government and industry but argue that this will make public interest groups 'credible watchdogs' that will help to strengthen government and industry conduct.

2.2.2.2 Limitations of Responsive Regulation

Often there are not enough repeat regular encounters between regulators and regulatees for responsive regulation to be feasible in practice (Gunningham 2011; Mascini 2013; Mascini & Van Wijk 2009; Nielsen & Parker 2009). Despite initial intentions that responsive regulation be used to regulate 'a small number of firms in a single industry' so that 'the chances of repeated regular encounters are greater' (Ayres & Braithwaite 1992, p. 55), responsive regulation is often applied in the regulation of large numbers of firms operating in highly diverse industries (for a complete list of agencies utilising responsive regulatory approaches, see Ivec, Braithwaite, Wood & Job 2015). The likelihood of regulator-regulatee interaction when responsive regulation is applied across a large regulatory terrain is therefore reduced simply by virtue of there being too many regulated entities for the regulator to confront (Gunningham 2011, p. 188). At the same time, regulatory regimes have become increasingly complex and noisy because the responsibility of enforcement is spread across different actors, and even different facets of the regulatory agency (Baldwin & Black 2008; Ford 2013; Gunningham 2011). Due to this level of decentralisation, interactions between regulators and regulatees are likely to be less intense and increasingly indirect to the point where they often involve 'one-to-many' and 'many-to-many' interactions (Ford 2013, p. 19). Resourcing, and legislative and institutional constraints can also limit the capacity of regulatory agencies to escalate enforcement, and thus, confine regulatory agencies to using soft-law approaches (Baldwin & Black 2008; Parker 2006; Scott 2004). This combination of factors has led Nielsen and Parker (2009, p. 389) to declare that 'continuing responsiveness by both parties is more a normative ideal of how parties should interact … [rather] than an actual empirical phenomenon'.

The theory also suffers from conceptual limitations. Responsive regulation largely operates on the assumption that regulator-regulatee relationships are binary and that messages can be clearly transmitted from regulator to regulatee (Baldwin & Black 2008, p. 63). However, regulatory encounters are likely to involve contact with a number of actors, which can impact upon the transmission of information and increase opportunities for miscommunication between regulators and regulated entities (e.g. by way of inconsistency, misinformation, or confusion) (Baldwin & Black 2008, p. 63). This is especially problematic for the formation of regulator-regulatee cooperation

because the regulator's capacity to clearly communicate its intentions when responding to regulatee conduct is severely reduced (Mascini 2013; Mascini & Van Wijk 2009).

Though proponents of compliance are quick to argue that deterrence leads to increased opposition and the destruction of cooperation (Kagan & Scholz 1984, p. 73), in those few studies where tit-for-tat interactions were observed and had a measurable impact on regulatee behaviour, negative attitudes towards the regulator have also been observed (Makkai & Braithwaite 1994; Mascini & Van Wijk 2009; Nielsen & Parker 2009; Parker 2006). Mascini and Van Wijk (2009, p. 40) found that inspectors switching between persuasive and coercive enforcement strategies did not prevent regulatees from developing negative attitudes towards inspectors; regulatees 'forgot' that inspectors had acted cooperatively during the initial phases of their interaction and chose instead to focus on the punitiveness of inspection outcomes (i.e. the warning or fine issued). Parker (2006) likewise found that regulatees were highly critical of the (ACCC) when it shifted from a cooperative to a deterrent enforcement approach. Respondents in the study spoke of instances where regulatees had demonstrated disengagement, resistance, and defiance towards the ACCC (Parker 2006, p. 612). Some spoke of instances where regulatees had made explicit attempts to influence the ways in which the ACCC operated by criticising the agency publicly and lodging complaints about ACCC decisions, investigations, and commissioners, including the ACCC's Chair, directly to government ministers (Parker 2006, p. 612).

Regulators can also find themselves unwilling or unable to escalate enforcement because of its potential to jeopardise regulator-regulatee cooperation—what Parker (2006) terms the *compliance trap*. Parker (2006, p. 593) argues that because adversariness is treated as a barrier to cooperation, regulators utilising cooperative enforcement strategies may find themselves trapped in situations where their actions either lack deterrent impact (because the regulator refrains from adversariness to maintain cooperation) or lack legitimacy (either because regulatees interpret adversarial enforcement as unjust and retaliate, or, regulators fail to receive the political backing of the state). Because of this trap, the regulator may refrain from using deterrence-based strategies altogether and opt instead for less-objectionable soft law options (Parker 2006). A small number of empirical studies demonstrate these types of effects on regulatory agencies. Richard and Ogus (1979; as cited in Pearce & Tombs 1990, p. 429 [added emphasis]) found that regulators sometimes had a marked tendency 'to *favour* consent conditions which were acceptable to industry' when 'control could not be achieved in the face of widespread non-cooperation'. Richardson, Ogus, and Burrows (1983; as cited in Pearce & Tombs 1990, p. 429) also found evidence of regulators who were 'prepared to bargain' to retain the cooperation of industry when they had experienced opposition.

Responsive regulation also raises issues of sanction consistency and proportionality by suggesting that punishment should only occur when regulatees fail to cooperate. Yeung (2004, p. 170) argues that:

> [i]n liberal democratic societies, punishment is legitimated not by persuasion, as Ayres and Braithwaite suggest, but by a finding of guilt determined in accordance with the requirements of procedural fairness, [redacted] Text has been removed due to copyright restrictions. [redacted] Ayres and Braithwaite neglect several essential constitutional values implicated in the enforcement process.

Yeung (2004, p. 168) believes that:

> [t]here is something seriously suspicious about a strategy in which very serious regulatory infractions causing widespread harm are not treated with the appropriate level of severity because the suspect chose at all times to co-operate fully with the regulator, whilst minor infractions are dealt with in a punitive and severe manner because the suspect refused to co-operate with the regulator.

The concept of tripartism has also been subject to some criticism in the literature. Schwarcz (2014) has argued that third parties are no less susceptible to capture then regulatory agencies, and although it is possible to have different interest groups compete for the privilege of being the third player—thus making guardianship contestable and less susceptible to becoming captured by industry—this would require having a number of interest groups to choose from, and in some regulatory regimes, there is an insufficient number of groups available with the requisite skills and expertise necessary to make tripartism and contestability viable. Whether citizens can ever be truly empowered is also subject to scepticism. Lippman (1993), for instance, argues that 'the accepted ideal of the sovereign and omnicompetent citizen' is 'unattainable' (pp. 10-1) since 'he [or she] cannot know all about everything all the time' (p. 16). Cruikshank (1999, p. 2) argues that participatory democracy 'both enables and constrains the possibilities for political action', and therefore, participatory democracy is just a mode 'of constituting and regulating citizens' (more in *Chapter 3*).

2.2.3 REALLY RESPONSIVE RISK-BASED REGULATION

As standalone approaches, Baldwin and Black (2008) have argued that neither responsive nor risk-based regulation provide a complete solution to resource constraints, institutional pressures, and the complexities of a dynamic regulatory environment. It is not always feasible, for instance, for regulators to respond to industry non-compliance by using a step-by-step approach, especially when grave health risks or amoral calculators are involved, and a more immediate, high-level response is warranted (Baldwin & Black 2008, p. 62). Regulation is also more likely to involve single points (rather than a chain) of interaction, and therefore, step-by-step escalation may not always be feasible for each regulatory encounter (Nielsen & Parker 2009). Yet, a lack of flexibility and variety in enforcement tools can also render regulators unable to respond to unforeseen risks (Baldwin & Black 2008).

Baldwin and Black argue that by employing a combination of both theories, or *really responsive risk-based regulation*, regulators can achieve the best of both strategies—specifically, access to a variety of regulatory tools, which can be used in an adaptable and flexible manner, all while being attune to risk analysis (Baldwin & Black 2008; Black & Baldwin 2010). In order to be 'really responsive', Black and Baldwin (2010, p. 186 [emphasis removed]) argue that regulators not only need to be alert to compliance risks, but also: '(1) the behavior, attitudes, and cultures of regulatory actors; (2) the institutional setting of the regulatory regime; (3) the different logics of regulatory tools and strategies (and how these interact); (4) the regime's own performance over time; and, finally, (5) changes in each of these elements'. These features of really responsive risk-based regulation enable regulators to better predict and respond to risks as they arise and to understand the contextual basis in which non-compliance occurs (Baldwin & Black 2008; Black & Baldwin 2010). The theory therefore moves beyond regulatory intervention to consider the institutional, operational, and cognitive environment in which the regulatory regime operates (Baldwin & Black 2008; Black & Baldwin 2010; Gunningham 2011).

2.2.3.1 Limitations of Really Responsive Risk-Based Regulation

However, whether these strategies accurately reflect a really responsive risk-based regulatory regime, and whether responsive and risk-based regulation can be applied effectively in practice, is questionable. Gunningham (2011, pp. 193-4) has indicated that a preoccupation with risk can trump and render meaningless all other criteria which may be used to determine the appropriateness of a regulatory response. Risk-based strategies also imply that more punitive enforcement action should be taken in those situations where high-risks or high-risk environments are involved—this is

contradictory to the underlying philosophies of responsive regulation which are premised on virtue and certainty, not the extent to which risk should impact on a decision (Gunningham 2011, p. 194). Responsive regulation also tends to appeal to the better nature of the regulatee, much unlike risk-based approaches which are predominately based on utilitarian philosophies (Gunningham 2011, p. 194). These contradictions may inhibit the operation of a regulatory approach which attempts to combine both responsive and risk-based regulation.

2.2.4 RISK-BASED AND RESPONSIVE REGULATION AND ITS CONGRUENCE WITH NEOLIBERALISM

Mascini (2013, p. 56) believes that much of the support for theories like risk-based and responsive regulation is due to their 'unintended congruence with liberal values favoring limiting the role of the state in capitalist economies'.

2.2.4.1 Risk and Neoliberal Government

Risk-based regulation allows state activity to be prioritised towards certain sites more so than others. As a result of this prioritisation, states are forced to invest in systems of government which decrease the reliance upon the state (Petersen 1997, p. xviii). For example, states often implement risk management systems to encourage responsible behaviour among actors (Gray & Hamilton 2006, p. 12). States also attempt to *responsibilise* actors by (re)allocating responsibility for government away from the state and onto individual actors by encouraging these actors to take steps to avoid or minimise risks to themselves, and thus, become self-helping and self-regulating entities (more on the concept of *responsibilisation* in 3.1.2.2). These types of strategies allow states to regulate low risks at a lower frequency and/or intensity while still managing all levels of risk. However, these features of risk-based regulation provide a means through which to redefine and redistribute the responsibilities of governing in ways consistent with the ethos of neoliberalism (Gray & Hamilton 2006, p. 10). Risk prioritisation and the underlying tenets of risk-based regulation theory which stress that not all risks are manageable—that regulators are 'overburdened by rules' and cannot be expected to 'enforce every one of these rules … at every point in time' (Black & Baldwin 2010, p. 184)—have a great deal in common with the neoliberal objective of a limited and noninterventionist state. Similarly, the responsible, self-regulating individual epitomised by the concept of responsibilisation has a significant degree of overlap with the economically-rational and utility-maximising individual epitomised by neoliberalism (see 3.1.2.1). These similarities between neoliberal forms of government and the features of risk-based regulation render risk-based regulatory strategies susceptible to being co-opted and shaped by interests sympathetic to neoliberal ideas. Thus, instead of prioritising state

intervention so that there are higher and lower levels of regulation, and all levels of risk are being managed, risk-based regulation can be used to limit state intervention altogether. For instance, governments often employ risk-based strategies in tackling issues such as illicit drug use. Drug users are commonly 'recast' as 'responsible risk takers' and 'rational choice subjects' who are responsible for governing the risks of their behaviour to themselves and others (O'Malley 2004, p. 8). Rarely are they portrayed as 'addicts' with 'impaired rationality' in need of intervention from the state (O'Malley 2004, p. 8). In the pharmaceutical space, companies are not only encouraged to become self-regulating entities, but consumers are also responsibilised in the same way by being encouraged to become better educated about their health and healthcare (known as *health literacy*) so that they can navigate their own way through the regulatory terrain, and therefore, lessen their own risk towards unscrupulous products and industry practices (more on this point in *Chapter 3*). Since these types of strategies do not involve direct coercion on the part of the state, they are considered a highly cost-efficient means of disciplinary control compared to more intensive forms of state intervention (O'Malley 1992, p. 254).

Attitudes towards risk—notions such as 'there is no such thing as a risk-free society' and 'that risk-taking entrepreneurialism is the motor of contemporary capitalism'—have also valorised risk and risk-taking behaviour (Tombs 2016, p. 88). This attitude has contributed to the socialisation of corporate crime and notion of limited market intervention by treating harmful corporate risk-taking practices as 'inevitable risks' (Rawlinson 2017b, p. 215) that form part of everyday business activities. Because business activities are generally perceived to have socially productive ends, 'the socially productive effects of private corporate activity' tend to be balanced 'against the deleterious ones' so that corporate harms (and the *right* accumulate capital) are rarely contested (Tombs 2016, p. 88).

2.2.4.2 Really Responsive?

The 'superficial similarities' between responsive and light-touch regulation have led responsive regulation to become equated with the neoliberal notion of limited market intervention (Haines 2016, p. 234). Policy-makers often reduce the theory of responsive regulation to its enforcement pyramid (*Figure 2.1*), thereby severing the pyramid from much of the underlying tenets of the original theory (Mascini 2013, p. 55). The ability to adapt the pyramid to suit a specific regulatory context also means that pyramids can become 'broken, incomplete or outside the control of instrumentally orientated agencies' (Scott 2004, p. 158). Though Ayres and Braithwaite have explicitly stated that they are not 'sympathetic to the libertarian view that the state should be kept weak because it poses a threat to freedom' (Ayres & Braithwaite 1992, p. 17), and that they are advocates for '[a] regulatory delegation

that is underwritten by escalating (and increasingly undelegated) forms of government intervention' (Ayres & Braithwaite 1992, p. 158), the absence of certain features (to ensure that regulatory intervention is kept to a minimum) often means that in practice the theory is unable to deliver an effective punishment payoff to channel regulatee behaviour towards the pyramid's base. This failure can result in the development of lax regulatory regimes which are unresponsive to corporate non-compliance 'even in the face of significant harm' (Haines 2016, p. 234).

Responsive regulation also treats punishment 'as a negative point of reference' (Mascini 2013, p. 55). By setting enforcement 'against its notional opposite: partnership' (Tombs & Whyte 2010, p. 51), enforcement is always framed 'as something that might *compromise* 'partnership'' (Tombs & Whyte 2010, p. 51 [original emphasis]). This has led responsive regulation to have an 'unintended congruence' with neoliberal ideologies which have favoured limiting the role of states (Mascini 2013, p. 56). This agreement with neoliberal rationalities of government is considered a primary reason for the theory's popularity among the political stratum (Pearce & Tombs 1990; Mascini 2013; Tombs 2016).

2.3 SUMMARY

The regulatory literature comprises of two distinct schools of thought: the deterrence school, which emphasises strict law enforcement and the use of deterrents to compel compliance from regulated entities, and the compliance school, which emphasises the use of persuasion and cooperation to achieve compliance voluntarily without the need to resort to deterrents. The deterrence school is often criticised for its rational views of offending and lack of empirical support, though proponents of deterrence have argued that corporations are more likely than other offenders to act in rational ways and that deterrent enforcement philosophies rarely feature in regulatory regimes. The compliance school, and risk-based and responsive regulation, has been criticised for its selectivity, normative conceptions of regulatory interaction, sensitivity to external pressure (from regulatees and the state), and procedural fairness.

Many of the key features of risk-based and responsive regulation—their emphasis on regulatory prioritisation, intervention as a last resort, diffusion of regulatory responsibility, and persuasion and socialisation in place of punishment—shares a significant degree of overlap with the neoliberal objective of limiting the capacity of states to intervene in markets. These features of risk-based and responsive regulation provide corroboration for the neoliberal critique of punitive and excessive government which has made the theories highly amenable to the neoliberal program.

Chapter 3 explores the ways in which the neoliberal program shapes the motives and practice of government to limit forms of market intervention by the state and other non-market forces which are detrimental to capital accumulation. This is achieved by using a combination of Marxist and Foucauldian theory and an ontological framework of critical realism to explore why and how dominant modes of social organisation come to dominate in capitalist societies. This chapter also introduces the research design and method employed for this thesis: a qualitative thematic analysis of public consultation submissions and interview transcripts which develops themes based on stakeholders' perceptions towards the TGA and pharmaceutical regulatory regime. This research method is used to identify those aspects of the regime which stakeholders perceive to be incapable of achieving compliance from sponsors.

3 THEORY AND METHODS

Only a handful of publications provide a critique on the Therapeutic Goods Administration (TGA) and Australian pharmaceutical regulatory regime (Australian National Audit Office 2004, 2011 & 2014; Doran & Löfgren 2013; Faunce, Murray, Nasu & Bowman 2008; Faunce, Townsend & McEwan 2010; Harvey 2009; Harvey, Korczak, Marron & Newgreen 2008; McCabe 2005). Not only is this previous research confined to disciplines outside the field of criminology, but few have interrogated the theory which underpins the current regulatory framework.

This thesis endeavours to return these issues to the discipline of criminology by undertaking a broader examination of the theories of risk-based and responsive regulation, and their capacity to compel compliance from regulated entities. This chapter begins with a discussion on the theoretical framework employed for this thesis—a combination of Marxist and Foucauldian theory approached through an ontological framework of critical realism. Marx and Foucault are used to explore the motivations and transformations which led to the production of the pharmaceutical regulatory regime on the grounds that 'Marx explains the "why" of power … and Foucault explains the "how" of power' (Marsden 1999, p. 26). Since Marx and Foucault approach power from two different ontological positions, critical realism is used to overcome the ontological differences between these two sets of literature by allowing power to be conceived as something which emerges from social structures but is not reducible to them.

The second half of this chapter is dedicated to a discussion on the research design and methods employed for this thesis. It provides justification for the mode of inquiry, and for the epistemological and ontological orientation of this research, and then gives a detailed overview of the specific data collection and coding procedures used. The thesis employs a qualitative thematic analysis of public consultation submissions and interview transcripts to identify stakeholders' perceptions towards the TGA and pharmaceutical regulatory regime—particularly, those aspects of the regime which stakeholders perceive to be incapable of achieving compliance from sponsors. These findings will be used to demonstrate why risk-based and responsive regulation has failed to generate compliance from sponsors, and how the pharmaceutical regulatory regime, underpinned by the theories of risk-based and responsive regulation, has become congruent with neoliberal rationalities of government which aim to limit the capacity of non-market forces to intervene in markets in ways that are detrimental to the interests of capital.

3.1 THE ROLE OF POWER IN THE PRODUCTION OF SOCIAL HARM

According to Garside (2013), it is not enough to examine social harms in terms of their effects and consequences; a discussion on social harm must also include an explanation of its underlying causes. Though Marxism provides the best explanation for the motivations behind dominant modes of social organisation within capitalist societies (i.e. the drive to accumulate capital), it is unable to explain the processes which led to the production of these modes of organisation (i.e. 'the mechanics of capital's motion') (Marsden 1999, p. 135). Garside (2013, p. 252) argues that '[u]nderstanding the production of social harm under capitalism means placing the production of harm within the context of the underlying dynamics of the processes of capital accumulation as these have developed across time and space, and continue to do so'. This is best achieved by using Foucauldian conceptualisations of power which 'explore the actual practices of subjugation rather than the intentions that guide attempts at domination' (Jessop 2007, p. 36). However, Foucauldian conceptualisations of power cannot be considered in isolation, as something more is required to explain 'how these … practices come to work the way they do' (Joseph 2010, p. 223). If, then, 'Marx's *explicandum* is a cluster of conclusions in search of a premise, … [and] Foucault's *explicans* is a cluster of premises in search of a conclusion' (Marsden 1999, p. 135 [original emphasis]), a Marxist analysis of capital and its inherent tendencies must be situated within the wider context of a Foucauldian analysis of government and its exercise.

3.1.1 MARX ON POWER AND THE ANTAGONISMS OF CLASS

For Marx, power is exercised in the struggle and conflict between classes— 'the capacity of one class to realize its own interests through its practice … in opposition to the capacity and interests of other classes' (Poulantzas 1973 p. 105 [emphasis removed]). According to Marx, society is generally comprised of two antagonistic classes or coalition of classes: a *dominant* or *ruling* class, and a *dominated* class. Each class comes to be defined by the struggle between classes; classes do not exist prior to struggle with clear identities or interests; individuals are integrated into their respective class based on their economic function (Milos 2000, pp. 285-90). The structure of society, and where and with whom power is predominantly located, is generally determined by the nature of its economy, or, the *economic base* of society. In capitalist economies, this means that power is largely located with the capitalist class; by exchanging their labour for a wage, the working class (the dominated class) give primary ownership over the means of production to the capitalists (the dominant class), who purchase this labour power along with the rights to the social relations of production (i.e. the allocation of resources and its resulting surpluses) (Jessop 2012, p. 4). However, power is also a 'conjunctural phenomenon' which is 'contingent on specific actions by specific agents in specific circumstances', and not something which is 'guaranteed by [the] unequal social relations of

production' (Jessop 2012, pp. 4-5). Thus, power is also located with and exercised by the dominated class, a primary example being working-class labour resistance (Jessop 2012, p. 4).

The state, while considered its own entity and structurally distinct from the rest of civil society, is often conceived in instrumentalist terms by most Marxists. According to this view, the state is viewed as a neutral and passive instrument of class rule which can be readily seized to advance the interests of those which appropriate it (Jessop 1982, p. 12). Marx, however, held both instrumentalist and anti-instrumentalist views of the state, and avoided any attempt to form a theory of the state and state power (Jessop 1982 & 1998). While Marx agreed that the state can be conceived as a tool of the dominant class appropriated for the purposes of furthering the dominant interest, he has also argued that the state is its own 'independent force', which stands 'outside and above society' (Jessop 1982, p. 16), and which seeks to regulate class struggle either 'in the public interest or … manipulate it to the private advantage of the political stratum' (Jessop 1998, p. 28).[3] Several Marxists (Jessop 1982, 1990, 1998, 2010 & 2012; Mahon 1979; Poulantzas 1978) therefore conceive the state as a 'form-determined condensation of the changing balance of [class] forces' (Jessop 2010, p. 45), a theoretical position which Jessop has labelled the strategic-relational approach. According to these scholars, the state is 'an ensemble of power centres' (Jessop 2010, p. 45) with an 'unequal structure of representation' (Mahon 1979, p. 163), and it is this 'structural' and/or 'strategic selectivity' (Jessop 2008, p. 36 & 125) which renders the state more amenable to certain interests than others. This 'bias' of the state allows certain class interests to dominate, as it is 'the articulation of the class struggle in the state … which 'produces' the authority of the hegemonic class or fraction' (Mahon 1979, p. 165). This authority is used by the dominant class 'to assert a general common sense' for the purposes of gaining 'dominance in, over and through mainstream social institutions' (Tombs 2016, p. 20).

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[3] Jessop justified this argument based on his interpretations of the work of Marx and Engel. Jessop (1982, pp. 15-6) argues:

> if the state is a simple instrument of class rule, it is necessary to explain how the dominant mode of production is successfully reproduced when the economically dominant class does not actually occupy the key positions in the state system.
>
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These observations led Jessop (1982, p. 25) to conclude that Marx felt it was 'incorrect to adopt an essentialist approach to the state' and that it was 'necessary to examine each state [form] in its own terms'.

It is on this basis that criminologists, like Tombs and Whyte (2015, p. 25 [original emphasis]), argue that the state-corporate relationship in capitalist economies is not 'one of *opposition* and *externality*', but a *symbiotic* relationship. States establish and maintain the conditions that enable corporations to produce and accumulate capital, and therefore, to 'cause harm … with relative impunity' (Tombs & Whyte 2015, p. 159). States too are reliant on corporations since corporations are integral to the infrastructure of the capitalist state and capitalist production (Tombs & Whyte 2015, p. 27). Hence, the relationship between the state and corporations is not one of antagonism—'the power of one does not decline at the expense of the other … [as] the power of the corporation rests upon the power of states, and vice-versa' (Tombs & Whyte 2015, p. 162). States therefore:

> bear some culpability … for their formal legislation of much of this [corporate] harm, their failures to develop adequate law and regulation which might mitigate these, their failures to enforce adequately such laws as do exist, and/or their failures to impose effective sanctions where violations of law are proven … any recognition of corporate harm, let alone crime, cannot proceed adequately without understanding the role of the state as bystander, facilitator and even conspirator (Tombs 2016, p. 28).

3.1.2 FOUCAULT ON THE RELATIONS OF POWER

Foucault was highly critical of Marxism because of its preoccupation with class rather than the nature of struggle itself (Marsden 1999, p. 20). Foucault (1979; as cited in Joseph 2004, p. 152) believed power to be something that was 'exercised rather than possessed', meaning that:

> nothing in society … [would] be changed if the mechanisms of power that function outside, below and alongside the State apparatuses, on a much more minute and everyday level, are not changed also (Foucault 1980, p. 60).

Seizing the state, then, as Marxists suggest as the solution to overcoming the dominant class, will not destroy power because 'power is … diffused through the entire social structure' (Turner 1997, p. xii). For Foucault (1980, p. 97), power therefore emanates, not from the state, a distinct class, or the underlying structure of society, but 'at the extreme points of its exercise' in the very techniques and practices which operate throughout the social body. Foucault (2004; as cited in Jessop 2007, p. 37 [Jessop's translation]) believed power was best understood:

> as the multiplicity of force relations immanent in the sphere in which they operate and that constitute their own organization; as the process which, through ceaseless struggles and confrontations, transforms, strengthens, or reverses them; as the support which these force relations find in one

> another, thus forming a chain or a system, or, on the contrary, the disjunctions and contradictions that isolate them from each other; and, lastly, as the strategies in which they take effect, whose general design or institutional crystallization is embodied in the state apparatus, in the formulation of the law, in various social hegemonies.

Power can therefore be conceived as 'something which circulates'; power 'is never localised…, never in anybody's hands, [and] never appropriated as a commodity or a piece of wealth' (Foucault 1980, p. 98).

Because Foucault believed power to be exercised beyond the centres of the state, classes, and capitalist production, Foucault argued that it was the codification, consolidation, and institutionalisation of these practices within society which produced a capitalist social order (Jessop 2007, p. 39). Foucault therefore conceived class domination to be a 'terminal form' of power and entities like the state and classes to be its 'emergent effects' (Jessop 2007, pp. 37-8); they are 'the vehicles of power' (Foucault 1980, p. 98), which have been organised through these practices in ways which conform with the key features of a capitalist economy (Jessop 2007, p. 40). It is on this basis that Foucault (1980, p. 97) argued that any analysis of power should:

> refrain from posing the labyrinthine and unanswerable question: Who then has power and what has he in mind? What is the aim of someone who possesses power?
>
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>
> Let us ask, instead, how things work at the level of on-going subjugation, at the level of those continuous and uninterrupted processes which subject our bodies, govern our gestures, dictate our behaviours etc.

3.1.2.1 Governmentality

One way in which Foucault explores the exercise of power is through the exercise of government. Foucault (2008, p. 192) defines government as 'the way in which one conducts people's conduct'. It entails 'any attempt to shape with some degree of deliberation aspects of our behaviour according to particular sets of norms and for a variety of ends' (Dean 2010, p. 18). Government is therefore a 'multifarious' act which operates both internally and externally to the state—from the level of 'oneself', to 'the father of a family, the superior in a convent, the teacher, the master in relation to the child or disciple', to 'that of government … applied to the state as a whole' (Foucault 2007, p. 93). Foucault used the term *governmentality* to refer to the activity or practice of government (the *technique* or *technology of government*) and ways of thinking about the activity or practice of

government (the *mentality* or *rationality of government*) (Petersen 2003, pp. 190-1). It is best described as the 'semantic linking' of the practice of government ('gouverner') with the mentalities which underpin its exercise ('mentalité') (Lemke 2001, p. 191).

3.1.2.2 Neoliberal Governmentality and Rationality of Government

In his lectures during the mid-to-late 1970s, Foucault argued that neoliberalism, as a form of governmentality, had taken on an entirely different form to classical liberal governmentality epitomised by 18th century Western Europe. According to Foucault, all forms of liberalism share a common concern for freedom from encroachment by the state—'freedom of the market, freedom to buy and sell, the free exercise of property rights, freedom of discussion, possible freedom of expression, and so on' (Foucault 2008, p. 63). In classical liberalism, these freedoms are defined and supervised by the state. Here:

> [t]he model and principle of the market was exchange, and the freedom of the market, the non-intervention of a third party, of any authority whatsoever, and a fortiori of state authority, was … applied so that the market was valid and equivalence really was equivalence. The most that was asked of the state was that it supervise the smooth running of the market … [to] ensure respect for the freedom of those involved in the exchange (Foucault 2008, p. 118).

Freedom was also a 'precondition for rational government'; government could not constrain these freedoms since this would effectively undermine its own foundations (Lemke 2001, p. 200).

However, neoliberalism, which emerged in the late 20th century, rests upon the notion that the market is the 'organizing and regulating principle of the state' (Foucault 2008, p. 116). Like classical liberalism, neoliberalism suggests that 'the market can only function through free and full competition' and that 'the state must … refrain from altering the existing state of competition and … avoid introducing elements that will alter this state of competition through phenomena of monopoly, control, and so forth' (Foucault 2008, p. 119). However, far from markets being free and left to operate naturally, the state is placed in 'direct service to the economy' (Brown 2005, p. 44), and charged with directing, buttressing, and protecting the market through law and policy, and through 'the dissemination of social norms designed to facilitate competition, free trade, and rational economic action' (Brown 2005, p. 41). The rationalities of government which underpin neoliberal governmentality are therefore premised on a *market discipline* or 'state under the supervision of the market rather than a market supervised by the state' (Foucault 2008, p. 116).

Neoliberalism also departs from the notion that government should respect the natural freedoms of individuals. Instead, government is predicated upon an 'artificially arranged liberty' where individual freedom is simultaneously encouraged and controlled by the state (Lemke 2001, p. 200). Here, individuals are viewed as self-interested, economically-rational beings (or *homo œconomicus*) who are capable of calculating the costs and benefits of their actions, and therefore, systematically navigating the variables of their environment (Lemke 2001, p. 200). This rationality of government enables the state to generate a 'responsibilized autonomy' (Garland 1997, p. 180), which allows the state to shift the responsibility of government onto individuals, and thus, 'transform their status' to become 'active' citizens capable of self-government (Dean 2010, p. 197). This responsibilisation enables the state to govern individuals from a distance, 'without at the same time being responsible for them', in ways which conform with neoliberal rationality of limited government by the state—by 'supplying' individuals with the 'scope for self-determination and desired autonomy … with the possibility of actively participating in the solution of specific matters and problems which had hitherto been the domain of state agencies' (Lemke 2001, pp. 201-2). This has made *homo œconomicus* 'a behaviouristically manipulable being'; she/he is a 'correlative of a governmentality' which attempts to construct and shape active subjects so that they are aligned with neoliberal objectives of government (Lemke 2001, p. 200).

Neoliberal rationalities of government have effectively dissolved the distinction between the economy and the social by re-defining 'the social sphere as a form of economic domain' so that 'all forms of human action and behaviour … [are] deciphered using economic criteria and within economic terms of their intelligibility' (Lemke 2001, pp. 197-8). This encourages individuals 'to give their lives a specific entrepreneurial form' (Lemke 2001, p. 202). The state's performance is indexed against market concepts which measure its success (and failure) in accordance to 'its ability to sustain and foster the market' (Brown 2005, p. 41). This extends to the state's social responsibilities, which must 'meet profitability tests, incite and unblock competition, and produce rational subjects' (Brown 2005, p. 44), all in accordance with the market principle of 'equal inequality for all' (Lemke 2001, p. 195). Because 'a generalized calculation of cost and benefit becomes the measure of all state practices', this too gives the state an entrepreneurial form where it is made to 'think and behave like a market actor' (Brown 2005, p. 42). This 'rationality to which state practices have been submitted' makes 'the health and growth of the economy … *the* basis of state legitimacy' (Brown 2005, p. 42 [original emphasis]).

Neoliberal governmentality involves both direct and indirect forms of state intervention. Direct interventions, which occur by way of 'empowered and specialized state apparatuses' (Lemke 2001,

p. 201), are designed to make 'dint' interventions in the market to bolster market conditions (Lemke 2001, p. 193). Indirect interventions occur from both above and below (Dean 1998, pp. 35-6). The former, referred to as *technologies of performance*, involve those mechanisms of government which shape conduct to optimise the performance of individual agents, such as in the case of a risk-management plan or framework (Dean 1998, p. 36). The latter, known as *technologies of agency*, refers to those mechanisms of government which deploy the agency of individuals (Dean 1998, pp. 35-6), such as self-regulation and those mechanisms which encourage consumers to become health literate. Technologies of agency also involve those mechanisms which empower individuals to maximise their capacity for democratic participation—what Cruikshank (1999, p. 67) refers to as *technologies of citizenship*. Technologies of citizenship include tripartite forms of government.

3.1.3 OTHER RATIONALITIES OF GOVERNMENT

According to Foucault, neoliberal governmentality can also be underpinned by risk, biopolitics, and power-knowledge relations.

3.1.3.1 Risk

Governmentality—particularly its neoliberal varieties—has been influenced by risk rationalities. Risk provides a means 'of ordering reality' and 'rendering it into a calculable form' so that risks can be brought under greater control (Dean 2010, p. 206). When risk rationalities are 'tethered' with techniques of government, it provides a means of regulating, managing, and shaping conduct 'in the service of specific ends and with definite, but to some extent unforeseen, effects' (Dean 2010, p. 207).

Under neoliberalism, the decentralisation and deregulation of markets generates greater levels of uncertainty which warrant greater investment in micro-level forms of governmentality (Turner 1997, p. xvii). At the micro-level, the costs and benefits of individual decisions are calculated with the intent of insulating the decision-maker from potential risks. As individuals are responsible for mitigating their own risks, 'neoliberalism equates moral responsibility with rational action', and therefore, the individual with 'full responsibility for the consequences of his or her action[s] no matter how severe the constraints on this action' (Brown 2005, pp. 42-3). This is because risk is treated as an inevitable side-effect of economic progress, and in neoliberal regimes, 'the production of risks is subordinate to the production of wealth' (Dean 2010, p. 210). When an individual is unable to navigate these risks, or engages in risky behaviour, it is framed as a failure on the part of the individual—'a failure of the self to take care of itself' (Greco 1993; as cited in Petersen 1997, p. 198). In the case of participatory democracy, the mismanagement of risk becomes a new mode of disorganising and depoliticising

democratic powers as it 'reduces political citizenship to … passivity and political complacency' (Brown 2005, pp. 42-3). This 'separates those who deserve to succeed from those who will fail' (Crawford 1994; as cited in Petersen 1997, p. 198) in line with the neoliberal rationality of freedom of competition.

3.1.3.2 Biopolitics

Biopolitics is a mode of politics and form of political power concerned with the administration of life at the level of the population—where the 'life' of the population is the 'object' of politics (Lemke 2011, p. 165). This not only includes all politics concerning the health of the population, but also the politics governing the quality, safety, and efficacy of medicines, the quality use of medicines, and medicines access. While biopolitics can be conceived as a rationality of government, it is distinct to governmentality in the sense that it is a form of power which both guides and is refined by techniques of governmentality (Dean 2010; Joseph 2010). It can therefore be conceived as one of many forms of government rationality which shapes the exercise of government.

There are two different dimensions to biopolitics: one which is centred upon 'individual disciplining' (Lemke 2011, p. 174), specifically, 'the disciplining of the individual body' (Lemke 2011, pp. 165-6); the other on 'regulating the populace' (Lemke 2011, p. 166). Prior to the mid-20th century, biopolitics was primarily concerned with disciplining individual bodies as a means of regulating the populace. Here, biopolitics was instrumental to state power because 'guaranteeing health' ensured 'the preservation of national physical strength, the work force and its capacity of production' (Foucault 2004, p. 6). It also led to modern forms of state racism—healthiness was associated with 'cleanliness' and 'hygiene' (Foucault 2004, p. 7), so external populations, or 'foreign bodies' (Bashford 1998, p. 391), had to be kept out of the population entirely. At the height of state welfarism, the body (and health) of the individual increasingly became a site of state intervention because of its expense to the state and implications for productivity (Foucault 2004, pp. 6-7). This led to the reversal of 'the healthy individual in the service of the State … [to] that of the State in the service of the healthy individual' (Foucault 2004, p. 6), and the portrayal of health as a *right* and quintessential human need. In the late 20th century, the increasing portrayal of health-as-right led health to acquire an 'economic and market value' and become a 'consumer object' which could be reproduced by 'pharmaceutical laboratories, doctors, etc., and consumed by both potential and actual patients' (Foucault 2004, p. 16). Here, biopolitics was 'indispensable' to capitalism and neoliberal governmentality; 'first, in terms of disciplining bodies to fit into the machinery of capitalist production, and second, on a more general scale, facilitating the regulation of various population trends to economic processes' (Novas 2016, p. 189).

3.1.3.3 Power-Knowledge

Power and knowledge relations also underpin neoliberal techniques and rationalities of governing. Foucault used the term *power-knowledge* to denote the relationship between knowledge and the exercise of power. According to Foucault (1977, pp. 27-8):

> power and knowledge directly imply one another … there is no power relation without the correlative constitution of a field of knowledge, nor any knowledge that does not presuppose and constitute at the same time power relations. … 'power-knowledge relations' are to be analysed, therefore, not on the basis of a subject of knowledge who is or is not free in relation to the power system, but, on the contrary, the subject who knows, the objects to be known and modalities of knowledge must be regarded as so many effects of these fundamental implications of power-knowledge and their historical transformations.

In the pharmaceutical space, medical knowledge, a form of 'esoteric' (Fleck 1979; as cited in Bunton 1997, p. 233) or technical knowledge, has generated power imbalances between those who possess knowledge of pharmaceutical products, such as pharmaceutical companies and healthcare practitioners, and those who do not, such as consumers. The same is true of regulatory knowledge. Those aware of the TGA and the extent of its remit, and who understand the regulatory regime, how it operates, and its various rules, such as the TGA, industry associations, and pharmaceutical companies, are better placed to exercise power within the regime than those who do not possess this knowledge, namely healthcare practitioners and consumers. These imbalances have the capacity to generate what Rose and Miller (1992, p. 188) call *enclosures*—'bounded locales or types of judgement within which … power and authority is concentrated, intensified and defended'. For consumers, enclosures generate a dependence on those with technical knowledge to make medical and regulatory decisions—the TGA, pharmaceutical industry, and healthcare practitioners. Enclosures also have the capacity to exclude and therefore dis-empower consumers. For example, consumers are often placed in less of a position to independently scrutinise product claims because the information which is used to substantiate each claim, such as clinical studies and journal articles, is regularly produced by and for those with medical knowledge, often in the absence of consumer-friendly, intermediary information sources (Bunton 1997). This denies consumers the capacity to employ individual agency for the purposes of developing health literacy, exercising greater control over their healthcare, and voting with their feet.

3.1.4 THE INTERPLAY BETWEEN MARX AND FOUCAULT

Foucault's departure from Marx could be interpreted in either one of two ways: as a radical critique of Marx, or, as 'an additional sociological question' which can be understood alongside the work of Marx (Paolucci 2003, p. 32). Many scholars (Jessop 2007; Joseph 2004 & 2010; Lemke 2001 & 2002; Marsden 1999; Paolucci 2003) have opted for the latter of these arguments on the grounds that Foucauldian conceptualisations of power are primarily occupied with 'the *how* of economic exploitation and political domination' (Jessop 2007, p. 40 [original emphasis]), or, 'the actual practices of subjugation rather than the intentions that guide attempts at domination' (Jessop 2007, p. 36). To better understand the reasons behind harmful social arrangements—essentially, 'the *why* of capital accumulation and state power' (Jessop 2007, p. 40 [original emphasis])—several scholars (Jessop 2007; Joseph 2004 & 2010; Larner 2000; Lemke 2001 & 2002; Marsden 1999; Paolucci 2003) have argued that Marxist and Foucauldian approaches should be used together to enhance one other.

Both Marxist and Foucauldian conceptualisations of power suffer from limitations. Marxism grounds power in the structure of society, specifically the classes and the relations between classes, without considering the wider context in which power operates (Jessop 2007; Joseph 2004 & 2010). Foucauldian concepts like governmentality, risk, biopolitics, and power-knowledge therefore add to Marxism by allowing these structures to be viewed within their wider context—'that the development of society is not exclusively economic ... [and] that the economic is interwoven with other social factors' (Joseph 2004, p. 156). Unlike Marxism, Foucault adopts a relational view of power within society, but because there is no one dominant power relation, entities like the state and classes are 'dissolved into the social body' to the point where they are 'just one more locus of power among many' (Joseph 2004, p. 158). This lack of structuralism and hierarchisation means that 'it is never clear exactly what power is exercised for and … what it is that any possible resistance may be exercised against' (Joseph 2004, p. 153). Foucauldian approaches are therefore at risk of having 'a flat ontology that remains at the level of the surface play of power relations' (Joseph 2004, p. 154). Placing Foucault within a Marxist framework would therefore provide the level of 'stratification' necessary to build on concepts like governmentality, risk, biopolitics, and power-knowledge (Joseph 2004, p. 159).

This thesis implements the following five features from Marxist and Foucauldian theory. First, it adopts the view that there is no one locus of power and that there are multiple centres or sources of power. Power is therefore something which is exercised by both dominated and dominant forces, the

only difference being the sum of that power. Second, it views power as a relational phenomenon. However, unlike Foucauldian conceptualisations of power, it does not treat power as something that exists in isolation and without order. That is:

> we cannot say that one individual, or group, or institution is powerful [i.e. has power] *unless* its power is defined in relation to other, less powerful, individuals, groups or institutions. … [A] prison is a powerful institution in relation to the people that it imprisons … [b]ut in relation to the government department that runs the prison or the government minister responsible for the prison who has the power to close it down or to take action to curtail its activities, it does not appear very powerful at all (Whyte 2009, p. 3 [added emphasis]).

In this respect, power is conceived as structured because it is in part a consequence of the relationships between different forces. Third, this thesis conceives the state, and more importantly, state power, as an ensemble of forces and the coalescence of the relations within and between these various forces. Because these relations are often unequally structured, and some forces are more dominant than others, it is the 'structuration of … [these] relations 'inside' the state' (Mahon 1979, p. 163) which produces the authority of dominant social forces and renders the state more amenable to certain types of forces than others. The state is therefore an 'asymmetrical institutional terrain' expressive of the relations among forces (Jessop 2008, p. 31). Fourth, the authority generated by the structure of these power relations is used by dominant forces to assert its interests and 'maintain its hegemony (or, at least, its dominance) over subaltern groups' (Jessop 2012, p. 8). This hegemony (or dominance) is not something which is forcibly imposed by dominant forces onto those who are less dominant, as this could galvanise subordinate forces and reinforce a counter-hegemonic (revolutionary) movement (Jessop 1990, p. 181). Instead, it involves the development of a hegemonic project which attempts to secure the support of the subordinate faction by mobilising:

> support behind a … programme of action which asserts a general interest in the pursuit of objectives that, explicitly or implicitly, advance the long-term interest of the hegemonic class (fraction)
>
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>
> (Jessop 1990, pp. 161-2).

Finally, this hegemony is produced and reproduced through governmentality. Here, governmentality is viewed as a set of micro-level techniques and rationalities of government which form part of a much larger macro-level (or hegemonic) strategy (Joseph 2014, p. 8). Governmentality shapes and is shaped by hegemony, and hegemony, likewise, 'is shaped by already existing practices', but also 'determines how governmentality develops and why' (Joseph 2014, p. 15).

For the purposes of this thesis, neoliberalism, along with regulatory strategies like risk-based and responsive regulation, are conceived as forms of governmentality, or techniques and rationalities of governing. Neoliberal governmentality is a product of a hegemonic project which attempts to maintain the dominance of the dominant faction by privileging those interests 'compatible with its conception of the general interest' and derogating those which are competing or contradictory (Jessop 2008, p. 30). These interests are fundamentally capitalist since neoliberalism is one of many varieties of capitalism. Risk-based and responsive regulatory forms of governmentality have been shaped by this hegemonic project so that they are congruent with a neoliberal governmentality (i.e. neoliberal techniques and rationalities of governing) and, by extension, the dominant hegemony. Industry, which comprises of sponsors and industry associations, form the dominant faction in the Australian pharmaceutical regulatory regime, however, healthcare practitioners and practitioner associations, and consumers and public interest groups also exercise various (but usually lesser) degrees of power in this space. The TGA can be conceived as one of many *apparatuses of the state*, defined as 'a distinct ensemble of institutions and organizations whose socially accepted function is to define and enforce collectively binding decisions on the members of a society in the name of their common interest or general will' (Jessop 1990, p. 341). This state apparatus often 'functions as an 'instrument of hegemony'' (Mahon 1979, p. 192) because it is essentially an expression of the unequal structure of representation inside the state. In this respect, state apparatuses like the TGA are institutionalised (as in neoliberalised); however, this does not mean they are captured by industry. Regulatory agencies 'simultaneously represent and regulate' (Mahon 1979, p. 163); they ''represent' the interests of a particular fraction' while also ''disciplining' that fraction in the name of the 'national interest'' (Mahon 1979, p. 171).

Because Marxist and Foucauldian theory approach power from different ontological positions (i.e. a structuralist and post-structuralist perspective), scholars like Marsden (1999), Jessop (2007), and Joseph (2004 & 2010) argue that a combined Marxist and Foucauldian theoretical framework is only achievable when approached through a critical realist ontology.

3.1.4.1 Critical Realism

Critical realism 'conceives the world as being structured' and social phenomena as 'the product of a plurality of structures' (Bhaskar 1989, pp. 2-3). Structure is considered by critical realists as a necessary condition of agency, but it is also treated as an 'emergent property' (Cruickshank 2002 & 2003), which is 'continually reproduced and occasionally transformed' through agency (Joseph 2004, p. 151). This interpretation of reality implies that '[t]he structure of an object', not only bestows 'an object's capacity to act' but is also a 'material cause of the events it generates' (Marsden 1999, p. 27). More importantly, it implies that 'the actions of individuals … have causal properties in their own right' (Cruickshank 2003, p. 3). Because structure and agency are both treated as *transformational* phenomena (Bhaskar 1989, p. 3), critical realists can maintain an account for both structure and agency without reducing social phenomena to either structure *or* agency—a common problem among postmodernist and constructionist ontologies (Cruickshank 2003, p. 3).

Using a general theory of critical realism, 'it is possible to argue for a social hierarchy of power without reducing power to some essential basis' (Joseph 2004, p. 159). Through critical realism, it is possible to escape the essentialist view adopted by Marxism by arguing 'for a more plural conception of different social structures' while also maintaining that 'structures exist within some sort of structured hierarchy with some structures and relations more important or influential than others'. It is also possible to escape the materialist view adopted by Foucauldian theory by arguing for a micro-level and plural configuration of power while at the same time treating power as 'something akin to a *conatus* or tendency to persist' (Joseph 2004, p. 159 [original emphasis]).

In the context of this research, and 'by virtue of the internal relations they constitute' (Marsden 1999, p. 38), it is therefore possible to argue that the structure and formation of social forces within society gives rise to certain relations of power. Each force acts as a medium which facilitates and constrains power, whilst also being an effect of that power. The relations between these forces are often asymmetrical and bestows an unequal capacity to act and exert power. However, social forces can use their agency to effect change in the relations of power. Power relations are therefore contingent on factors *other* than structure—for example, '[a] capacity to act may not be exercised, or it may be exercised without producing an empirical effect … because of a countervailing power *or* the ineptitude of the actor' (Marsden 1999, p. 38 [added emphasis]). This means that, although power relations do emerge from social structures, they are not reducible to them (Joseph 2004, p. 159). The practice of power can therefore be understood as 'the reproduction and transformation of social

structures … [where] people are not merely docile bodies or discursive constructs, but … active and dynamic agents' (Joseph 2004, p. 163).

3.2 RESEARCH DESIGN

Despite the amount of literature endorsing risk-based and responsive regulation, few empirical studies have examined risk-based and responsive regulation in practice as distinct or as hybrid strategies (Gunningham 2011). Of the studies available, there has been little consistency in the methods employed by researchers. As a result, researchers use a wide-range of quantitative and qualitative methods, including, interview (Job & Honaker 2002; Mascini & Van Wijk 2009; Waller 2007), case-study (Baldwin & Black 2008; Parker 2006), survey (Makkai & Braithwaite 1994; Mascini & Van Wijk 2009; Nielsen & Parker 2005 & 2009), observational (Mascini & Van Wijk 2009; Waller 2007), and secondary analysis (Makkai & Braithwaite 1994; Nielsen 2006). Despite the absence of a clear and consistent methodology within the regulatory literature, common themes can be drawn from this literature to guide prospective research. The compliance school assumes that cooperation—underpinned by deterrents—leads to the development of compliance. When compliance-based regulatory regimes are operating successfully, researchers should therefore be able to identify regulatees who demonstrate positive attitudes towards the regulator and regulatory enforcement, along with high rates of compliance (Ayres & Braithwaite 1992; Nielsen & Parker 2009). In the case of responsive regulation, there should be chains of interaction between the regulator and regulatee, and greater cooperation and compliance from regulatees following these interactions (Nielsen & Parker 2009, pp. 379-80). Risk-based regulation should also generate cooperation, and therefore greater levels of compliance, in spite of its utilitarian foundations, when the risk-basis for enforcement and precedence for risk-based decisions is clearly communicated to, and understood by, regulatees. Since non-market actors also play a role in shaping compliance, there must also be evidence of a third (even a fourth) player capable of participating effectively within the regime to mediate the relationship between regulator and regulatee. In this case, third players include public interest groups and consumers, and fourth players, healthcare practitioners and practitioner associations (see 5.1 for further information). The extent to which these interactions, attitudes, and range of players are present (or absent) from the regime will determine the extent to which risk-based and responsive regulation is able to generate cooperation and compliance from regulatees.

3.2.1 MODE OF INQUIRY

In the context of this research, information exists—in the form of Australian National Audit Office (ANAO) audit reports and notable case studies (see 1.1)—to suggest that non-compliance is high in

many facets of the regime, specifically in those areas which rely most on cooperative techniques. The recent spate of consultations and reforms reinforces this conclusion that rates are, or, at the very least, are perceived to be, substantial; so much so, that a major overhaul of the regime by the Australian Government has been warranted. The purpose of this research, and therefore, its potential value to the literature, does not lie in a deductive approach which aims to examine how risk-based and responsive regulation generates (or fails to generate) compliance, but in an abductive approach which aims to examine *why* risk-based and responsive regulation has failed, or has been perceived to be unable, to generate compliance in this particular regime. Since the literature suggests that these failures of regulation may be a direct consequence of neoliberalising (capitalist) processes, this research develops theory 'in reverse' as 'a cluster of conclusions in search of a premise' (Hanson 1961, p. 90).

A qualitative research design has been employed for this project since such modes of inquiry are able to provide the level of contextual information necessary to examine how this regime operates in practice. A qualitative design has also been selected for practical reasons. Based on the data currently made available to the public, it is not possible to measure the impact of risk-based and responsive regulatory strategies on rates of compliance using quantitative methods. Prior audits have revealed that the TGA often fails to maintain records of its enforcement activities (see ANAO 2004, pp. 83, 106, 118-9, 121-2; ANAO 2011, pp. 96-8; ANAO 2014, p. 77), let alone permit this information to be released publicly. Small amounts of quantitative data have been made freely accessible through the Department of Health's Annual Reports, the TGA's Half Yearly Performance Reports, and from information published on the TGA's website (e.g. notices on Regulation 9 Orders, compliance undertakings, suspensions, cancellations, and court actions undertaken by the TGA). However, there are several limitations to these sources of data. First, with the exclusion of the Department's Annual Reports, most of the data available was published after 2013: it therefore excludes data from the period immediately prior to the regime's reform (and which prompted the regime's reform in the first place). Second, the data provided lacks the level of detail necessary to analyse the impact of the regime on regulatee compliance. For instance, the identity of the corporation, details of the offence, the product(s) involved, whether compliance was achieved, and whether further action was necessary from the regulator, is often absent from Annual and Half-Yearly Reports[4]. Third, the reporting of this data has been inconsistent; the same indicators are not always reported in Annual and Half-Yearly

[4] Annual and Half-Yearly Reports are geared towards reporting on the performance of the TGA against statutory time frames rather than enforcement outcomes.

Reports,[5] and reporting can occur on either a fiscal or calendar year basis. This inconsistency has diminished any potential to carry out year-by-year comparisons. Finally, there is reason to be sceptical about the accuracy of the information supplied by the TGA, particularly via its website. Not only is the TGA notorious for delaying the release of information to the public,[6] but it also only publishes *certain* outcomes on its website.[7] This lack of accuracy could distort any analysis reliant on this information.

3.2.2 EPISTEMOLOGICAL AND ONTOLOGICAL APPROACH

Because 'all research is guided by certain assumptions' (Cruickshank 2002, p. 49), researchers must be explicit in stating their epistemological and ontological position. This research raises ontological questions concerning the relationship between structure and agency—how the structure of power relations influences social forces and how these forces can act back and change these prevailing relations of power (Cruickshank 2002, p. 49). Researchers who find themselves in this position must adopt a general theory which explains 'how individuals' agency is both enabled and constrained by [this] social reality' (Cruickshank 2002, p. 49), so as 'to avoid the problems of overemphasising agency, overemphasising structure, or arbitrarily overemphasising both' (Cruickshank 2003, p. 2). This thesis therefore adopts a general theory of critical realism.

Adopting a realist ontology has epistemological implications. Critical realists assume that 'ontology (i.e. what is real, the nature of reality) is not reducible to epistemology (i.e. our knowledge of reality)' (Fletcher 2017, p. 182), and that reality is *intransitive* and exists independently of our knowledge and awareness (Bhaskar 1989). This means that not all objects of study are 'directly amenable to observation' and that conceptualisations of reality are only 'a way of knowing that reality' (Bryman 2012, p. 29). It is for these reasons that critical realists distinguish between different levels of reality: the *empirical*, or, what is conceptually mediated through human experience and interpretation; the *actual*, what occurs irrespective of whether it is mediated through human experience and interpretation; and the *real*, the causal mechanisms and structures which produce the actual (Fletcher

[5] For example, the Half-Yearly Reports for January-June and July-December of 2015 list the number of non-conformities identified during compliance reviews and the number and type of response undertaken by the regulator following the review outcome. However, only the January-June Report provides a detailed breakdown of the types of compliance issues identified (see TGA 2015a & 2015b).

[6] For example, between November 2010 and August 2013, the TGA had only published outcomes on its website for 14 of the 88 complaints it investigated after the complaint was referred from the CRP (Harvey 2013, para. 9).

[7] Complaints which have been investigated by the TGA upon referral from the CRP are published online, but not those which are received and investigated independently of the CRP by the TGA (see TGA 2017e, para. 3). Suspensions and cancellations are also only reported for complementary medicines, medical devices, and IVDs, not for other kinds of therapeutic goods.

2017; Marsden 1999). Since ‘the world … and the knowledge we have of it are not one and the same thing’ (Joseph 2004, p. 144), it is necessary to look beyond what is reported by stakeholders and interviewees to identify those structures and forces underlying the regime which ‘are not spontaneously apparent in the observable pattern of events’ (Bhaskar 1989, p. 2).

Though postmodernists tend to treat knowledge and reality as ‘one and the same thing’ (Joseph 2004, p. 144), Joseph (2004, pp. 146-7) argues that Foucault ‘does not reduce reality to discourse’ on the basis that ‘discourse, or the discursive formation within which it develops, refers not only to knowledge and language, but also to the bodies, institutions and material practices within which or alongside which this knowledge develops’. It is therefore possible to use Foucauldian concepts like power-knowledge while at the same time treating knowledge as an ‘independent intransitive realm’ (Joseph 2004, p. 145).

3.3 RESEARCH METHOD

This section outlines the procedures used in the collection and analysis of interview and submission data. It begins with a discussion on thematic analysis and how it is being operationalised within a general framework of critical realism. It then outlines the steps used in the selection of public consultations and interview participants, and the coding of submission and interview data.

3.3.1 THEMATIC ANALYSIS

Thematic analysis involves the encoding of qualitative data to form themes. Boyatzis (1998, p. 4) defines a *theme* as ‘a pattern found in the information that at minimum describes and organizes the possible observations and at maximum interprets aspects of the phenomenon’. The formation and ‘keyness’ of a theme depends, not on its size or prevalence within the data, but on its capacity to capture ‘something important in relation to the overall research question’ (Braun & Clarke 2006, p. 82). Themes therefore receive ‘considerable space in some data items, and little or none in others, or … might appear in relatively little of the data set [overall]’ (Braun & Clarke 2006, p. 82). Themes can be identified at a *semantic* level ‘within the explicit or surface meanings of the data’, or, at a *latent* level ‘beyond the semantic content of the data’ to determine the features which give the semantic content its form or meaning (Braun & Clarke 2006, p. 84). Theme identification is therefore an active process on the part of the researcher; themes do not reside within the data, but ‘in our heads from our thinking about our data and creating links as we understand them’ (Ely, Vinz, Downing & Anzul 1997; as cited in Braun & Clarke 2006, p. 80).

A thematic analysis is typically characterised by three distinct phases: the observation of a perceived pattern (or *theme*) within the data; the classification (*encoding*) of the pattern by way of a label, definition, or description; and the interpretation (*analysis*) of the pattern within the context of a theory and/or the conceptual framework being used (Boyatzis 1998, pp. 3-4). However, little guidance is provided to researchers on how best to conduct a thematic analysis. This is partly because researchers have not been explicit in stating the use of thematic analysis when carrying out research; researchers often claim to have used other methods, a discourse or content analysis, when a thematic analysis is actually being used, or, have neglected to mention its use entirely by simply stating that a 'qualitative analysis for commonly recurring themes' has been conducted (Braun & Clarke 2006, p. 80). Researchers also often fail to provide the level of detail necessary to enable other researchers to determine how data has been analysed and what assumptions have been used to inform the analysis (Braun & Clarke 2006, p. 80). Braun and Clarke (2006) therefore urge researchers to be explicit when stating the type of procedure used.

For the purposes of this thesis, themes were developed based on the semantic content of the data to limit the potential for researcher bias. A 'unidirectional relationship' has therefore been assumed between the data and its meaning (Braun & Clarke 2006, p. 85). In line with a critical realist approach, themes which have been derived directly from the data (referred herein as lower-order themes) will be assumed to be a direct representation of the 'realities' reported by stakeholders and interviewees. In progressing from a level of *description*, 'where the data have simply been organized to show patterns in the semantic content', to a level of *interpretation*, '[the] attempt to theorize the significance of the patterns and their broader meanings and implications', over-arching themes (referred herein as higher-order themes) will be constructed based on their connection with the theoretical framework adopted for this project (Braun & Clarke 2006, p. 84). The six-stage coding procedure developed by Braun and Clarke (2006) has been used to analyse the data, details of which are discussed in section 3.3.4.

3.3.2 PUBLIC CONSULTATIONS

Since 2010, the Australian Government and TGA have conducted a series of public consultations to obtain feedback on the regulations associated with prescription and non-prescription medicines. Analysing submissions to these consultations allows us to examine the broad range of stakeholder attitudes towards the regime prior to the regime's reform.

3.3.2.1 Data Collection and Research Parameters

Consultations which had been carried out and published on the TGA, Department of Health, and Australian Parliamentary websites between the 1st of January 2010 and 30th of June 2014 were selected on the basis that they best reflect the state of stakeholder attitudes towards the regulator and regime prior to the regime's reform. 12 public consultations on the post-market regulation of prescription and non-prescription medicines were selected from this period. A list of these consultations is provided in *Table 3.1*.

Table 3.1: Consultations Conducted by the TGA, Department of Health and Australian Parliament between 1 January 2010 and 30 June 2014.

TGA Consultations	DoHA Consultations	Senate Consultations
Draft TGA Approach to Disclosure of Commercially Confidential Information. Evidence Required to Support Indications for Listed Medicines (Consultation 1). Evidence Required to Support Indications for Listed Medicines (Consultation 2). Evaluating the Feasibility of a New-to-Market Risk Communication Scheme for Therapeutic Goods. Improving Advertising Arrangements for Therapeutic Goods. Mechanisms to Maintain the Currency of Approved Product Information (PI) and Consumer Medicines Information (CMI). Regulation Impact Statement: Regulating the Advertising of Therapeutic Goods to the General Public. TGA Guidance on Release for Supply for Medicines Manufacturers. Transparency Review of the TGA.	Position Paper on Promotion of Therapeutic Goods.	Therapeutic Goods Amendment (2013 Measures No. 1) Bill 2013 Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013

Consultations which concerned pre-market and administrative processes, generic and biological medicines, and medical and in vitro diagnostic devices were immediately excluded from the sample. All consultations (three in total) conducted and listed on the Department of Health and Australian Parliamentary website and nine of the 50 consultations conducted and listed on the TGA website were included in the final sample.[8] A detailed list of the consultations conducted by the TGA during this period and the reasons for their inclusion or exclusion from the analysis is provided in *Appendix A*.

A total of 451 (out of a possible 1,657) submissions were published for the 12 consultations analysed. The proportion of submissions received for each consultation has been outlined in *Table 3.2*. Most of the unpublished submissions were from a single consultation, *Regulation Impact Statement: Regulating the Advertising of Therapeutic Goods to the General Public*. The TGA (2014b, para. 2) has alleged that most of these submissions were written by complementary healthcare practitioners who opposed the proposal which would see the term healthcare practitioner restricted to practitioners with a National Registration and Accreditation Scheme (NRAS) accreditation, which currently excludes complementary healthcare practitioners. The proposal therefore had the potential to exclude non-NRAS practitioners from receiving promotional material directly from industry. At the time of the consultation, the TGA had received significant criticism for this proposed change—three separate petitions condemning the changes were organised by naturopaths, homoeopaths, and herbalists with the support of Blackmores.[9] An attempt was made to access the remaining submissions from the TGA, but these requests went unanswered. The TGA (2014b, para. 3) stated that the 94 submissions that were published had addressed some or all the proposals of the consultation document, including the controversial proposal to restrict advertising to certain healthcare practitioners. It was therefore possible to access some, but not all, of the submissions. Apart from this consultation, most of the submissions were made available for all remaining consultations—a small number were not published by the TGA because they were explicitly marked as confidential by the stakeholder at the time of submission.

A total of 96 individuals and 188 organisations were represented in the consultations analysed. A breakdown of the number of stakeholders and submissions per occupational and organisational category is presented in *Tables 3.3* and *3.4*.

[8] Submissions were only published for 60% (30 out of 50) of the consultations conducted by the TGA.
[9] Blackmores is an Australian company which produces non-prescription medicines, particularly vitamins and supplements.

Table 3.2: Proportion of the Submissions Available per Consultation.

Consultation Name	No. of Sub.	Total Sub.
Draft TGA Approach to Disclosure of Commercially Confidential Information.	13	13
Evaluating the Feasibility of a New-to-Market Risk Communication Scheme for Therapeutic Goods.	20	Unknown
Evidence required to support indications for listed medicines (excluding sunscreens and disinfectants) Consultation 1.	40	50
Evidence required to support indications for listed medicines (excluding sunscreens and disinfectants) Consultation 2.	24	26
Improving Advertising Arrangements for Therapeutic Goods in Australia.	36	39
Mechanisms to Maintain the Currency of Approved Product Information (PI) and Consumer Medicines Information (CMI).	23	25
Position Paper on Promotion of Therapeutic Goods	32	39
Regulation Impact Statement: Regulating the Advertising of Therapeutic Goods to the General Public.	94	1,276
TGA Guidance on Release for Supply for Medicines Manufacturers.	16	16
Therapeutic Goods Amendment (2013 Measures No. 1) Bill 2013.	11	11
Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013.	25	25
Transparency Review of the TGA.	117	117
Total:	**451**	**1,657**

Table 3.3: Number of Individuals and Submissions per Occupational Category.

Occupation of the Individual	No. of Ind.	No. of Sub.
Unknown	42	43
Academics	21	26
Practitioners	18	21
Consumers	8	9
Consumer Representatives	3	3
Business Owners	1	1
Information Providers	1	1
Journalists	1	1
Regulatory Consultants	1	1
Total:	97	106

Table 3.4: Number of Organisations and Submissions per Organisational Category.

Organisation Type	No. of Org.	No. of Sub.
Sponsors, Manufacturers, Importers, Exporters & Suppliers	57	95
Practitioner Associations	33	66
Industry Associations	25	80
State & Federal Governmental Bodies	13	15
Health Advocacy Groups	9	13
Industry Consultants	8	10
Patient Advocacy Groups	8	9
Sceptic Organisations	6	10
Advisory Committees	4	5
Uncategorised	4	4
Complaints Bodies	3	3
Information Providers	3	7
Professional Development Bodies	3	3
Consumer Organisations	2	13
Healthcare Providers	2	2
Hospices	2	2
Public Advocacy Groups	2	9
Tertiary Institutions	2	2
Media Organisations	1	1
Steering Committee	1	1
Total:	188	345

Apart from those submissions made anonymously or where the occupation of the individual was unknown, most individuals identified as being an academic or healthcare practitioner. The majority of organisations represented in the consultations identified as being a sponsor, a practitioner association, or an industry association. A complete list of those organisations which made submissions to these consultations is available in *Appendix B*. Due to the number of anonymous submissions received, an equivalent list has not been generated for submissions made by individuals.

Many of the individuals and organisations represented in the sample had made submissions to more than one consultation. At least 25 of the 54 individuals who could be identified had made two or more submissions (no single individual made more than four submissions). Of the organisations represented, 55 of the 188 organisations made two or more submissions. A list of these organisations is provided in *Appendix C*. Again, due to the number of anonymous submissions received, no equivalent list has been generated for individual submissions.

Each submission was given a four-digit number unique to its consultation. The numerical range used for each consultation (and submission) is listed in *Table 3.5*. Consultation submissions were then coded using the coding procedure outlined in section 3.3.4.

Table 3.5: Numerical Range Used for Each Consultation.

Cons. No.	Consultation Name
1000-1119	Transparency Review of the TGA.
2000-2037	Improving Advertising Arrangements for Therapeutic Goods in Australia.
3000-3040	Evidence required to support indications for listed medicines (excluding sunscreens and disinfectants) Consultation 1.
3100-3124	Evidence required to support indications for listed medicines (excluding sunscreens and disinfectants) Consultation 2.
4000-4023	Position Paper on Promotion of Therapeutic Goods.
5000-5025	Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013.
6000-6020	Evaluating the Feasibility of a New-to-Market Risk Communication Scheme for Therapeutic Goods.
7000-7095	Regulation Impact Statement: Regulating the Advertising of Therapeutic Goods to the General Public.
8000-8023	Mechanisms to Maintain the Currency of Approved Product Information (PI) and Consumer Medicines Information (CMI).
9000-9013	Draft TGA Approach to Disclosure of Commercially Confidential Information.
9100-9116	TGA Guidance on Release for Supply for Medicines Manufacturers.
9200-9211	Therapeutic Goods Amendment (2013 Measures No. 1) Bill 2013.

3.3.2.2 Limitations

The biggest issue posed by the use of consultation submissions is their generalisability as several biases affect the representativeness of the consultation process. For example, the complexity of the issues requiring stakeholder input may be better understood by those stakeholders with medical and regulatory knowledge, which is likely to impact upon which stakeholders make submissions, and lead to an under- and/or over-representation of certain stakeholder groups. The number of consultations conducted over the period, many of which were conducted concurrently, is likely to have prohibited some stakeholders from being able to make submissions to each consultation conducted. Resourcing is likely to have impacted upon which stakeholders are able to make submissions and finally, a lack of awareness that a consultation is being conducted would have prohibited some stakeholder groups from making a submission altogether.

To reduce the impact of these biases, care was taken to select consultations with the greatest degree of representativeness (i.e. consultations which dealt with issues that would affect a wide range of

stakeholders). The number of consultations analysed also helped to ensure that a wide range of stakeholder groups was represented. Employing a qualitative, rather than quantitative, thematic analysis also enabled themes to be generated based on their importance to the overall research question rather than their size or frequency within the data. This helped to remove any potential biases that may have arisen from stakeholders with greater input into the consultation process.

There was also a concern that the data obtained from the consultation submissions would not contain enough depth to adequately develop themes. It was common, for example, for submissions to make recommendations without elaborating on why they were in fact needed. A handful of submissions had also been modelled on one another to the point where their content was practically identical. To combat these effects, a large number of submissions was used to make up the sample to ensure that there would be enough variety in responses to run a robust thematic analysis. Interviews were also used to provide extra depth and corroboration (triangulation) for the themes generated.

3.3.3 INTERVIEWS

Interviews were used to supplement and add greater depth to the data obtained from the consultation submissions. This thesis employed a semi-structured, open-ended interview format to create the flexibility necessary to pursue different lines of inquiry specific to each participant's area of expertise. Approval for this project was obtained from the Flinders University Social and Behavioural Research Ethics Committee (SBREC) (Project Number 5588). Participants were selected based on their direct association and/or involvement in the post-market regulation of prescription and non-prescription medicines in Australia. Interviews were carried out between the 1st of February and the 31st of July 2013 following five pilot interviews. Data obtained from the interviews was coded using the coding procedure outlined in section 3.3.4.

3.3.3.1 Interview Sample

Participants were sampled from the Therapeutic Goods Administration (TGA), along with the TGA's Advisory Committee on the Safety of Medicines (ACSOM), the Therapeutic Goods Committee (TGC), and the Australian Therapeutic Goods Advisory Council (ATGAC).[10] Each of the relevant

[10] The ACSOM, TGC, and ATGAC comprised 12, 10, and 15 members respectively at the time of interview. Committee members represented a diverse range of employment backgrounds, including the private and public sectors, consumer organisations, academia, healthcare (e.g. medicine, pharmacy, and nursing), and the medical research sector. As of January 2017, all three committees had been disbanded. This was due to the introduction of the Therapeutic Goods Amendment (Advisory Committees and Other Measures) Regulation 2016 (Cwlth) and a push by the Australian Government to streamline the advisory committee structure.

industry associations, the Australian Self-Medication Industry (ASMI), the Complementary Healthcare Council (CHC) (now Complementary Medicines Australia or CMA), and Medicines Australia (MA), were contacted.[11] Law firms involved in cases against the TGA were approached, along with the Commonwealth Department of Public Prosecutions (DPP) and Administrative Appeals Tribunal (AAT).

All participants were approached by email using contact details which had been made freely available online[12] or had been provided to the researcher through snowballing techniques. Some of the participants were approached indirectly via their employer or a fellow employee within their workplace. Under these circumstances, the organisation was contacted via a general enquiries address listed on the organisation's website. The initial email and paperwork used was addressed to the organisation; this email and paperwork contained an outline of the study and a request to speak to someone within the organisation. The employer/employee who responded to the initial email then placed the researcher in contact with an appropriate employee. This employee was then provided with their own separate paperwork and was free to choose whether or not they would participate in an interview. Those employers/employees who put the researcher in contact with the employee did not receive confirmation as to whether the employee chose to respond to the email or consent to an interview.

Of the 44 individuals and/or organisations approached, 20 were willing to either participate in an interview (18 participants) or to provide a written statement (two participants). Seven of the participants were from the TGA and all seven were interviewed as a group. A former employee of the TGA also agreed to participate. Five members of TGA regulatory committees agreed to interview participation; two members from both ACSOM and the ATGAC, and one from the TGC. Of the five committee members, two were pharmacists (one practicing, one retired), two were doctors (one with a private practice, one from a hospital), and one participant identified as a full-time consumer advocate. Interviews were conducted with two members of industry associations (ASMI and MA); a statement was obtained by the CMA via phone. Two academics who identified as consumer advocates committed to interviews, as did a lawyer who had provided counsel to companies in cases against the

[11] The Generic Medicines Industry Association (GMiA) were excluded from the interview sample on the grounds that the post-market regulation of generic medicines differed in some respects to the post-market regulation of prescription and non-prescription medicines. Issues that overlapped with the regulation of generic medicines were captured in consultation submissions made by the GMiA and the sponsors, manufacturers, importers, exporters, and suppliers of generic medicines.

[12] Not all individuals within the population were able to be contacted since their contact details were not publicly available. This was particularly the case with some members of the TGA regulatory committees; five of the 37 committee members could not be contacted at all.

TGA. Written statements were received from the DPP and the TGA in response to additional questions. Five of the 18 participants interviewed made up part of the original committee for the Transparency Review of the TGA.

It was hoped that sponsors would also form part of the interview sample through snowballing techniques as most belong to one of the three industry associations sampled. However, access to this population was significantly hampered by the fact that two of the three industry associations sampled (the CMA and MA) did not respond to participation requests until well after the main interviewing period had ended (June 2013). ASMI had agreed to place an advertisement inviting companies to participate in the project in their weekly and monthly newsletters, however, none of ASMI's members responded to these requests.[13] Despite these difficulties, and as *Table 3.4* demonstrates, the views of sponsors are well represented through the number of consultation submissions received and their industry associations.

Avenues for obtaining consent differed depending on whether a participant consented to the audio recording of the interview. Written consent was obtained from each participant who agreed to be audio recorded (10 out of the 18 participants). These participants were asked to complete a consent form prior to commencing the interview. For those participants who did not wish to be recorded (one out of the 18 participants), written consent was obtained through email. In the group interview (seven out of the 18 participants), written consent was obtained from the TGA via email prior to the group interview. Due to reasons cited by the TGA, participants of the group interview were not permitted to sign a consent form or give written consent via email but were permitted to give verbal consent prior to commencing the group interview. The TGA initially consented to the audio recording of the proceedings, but this was later declined, and a scribe had to be negotiated.[14] These accommodations required two separate ethics modification requests. Following the interview and the development of the transcript, all participants were supplied with a PDF copy of their transcript and were asked to provide written feedback—this was for the purposes of identifying any information which may have been mis-transcribed or that would require de-identification. Written consent was obtained from each participant (and from the TGA in the case of the group interview) to approve the use of the transcript

[13] This advertisement had been published in March 2013 prior to the Easter long weekend. This most likely would have impacted on response rates. It is possible that response rates may have also been impacted by the sensitivity of the subject matter to industry, however, this did not appear to be an issue for industry associations, who were willing to participate.

[14] Although these proceedings could not be recorded, a transcript was compiled based on the written notes recorded by myself and the scribe. This transcript was sighted and approved for use by the TGA and those present on the basis that the comments transcribed from the group interview were an accurate reflection of the comments made during the proceedings.

in the thesis and in subsequent publications. Participants were given two weeks in which they could access and comment on their transcripts; a time limit imposed to ensure the timely completion of the thesis. All participants took the opportunity to access and read through their transcript prior to consenting to its use. Some participants chose to redact information which they believed to be identifiable and/or confidential, including information on the name, active ingredients, mechanism of action, and side effects of a medicine, the name of a company which produced or manufactured a medicine, and information concerning the nature of a participant's line of work. For this reason, some extracts used in the thesis contain this identifiable information while others do not. Those extracts where identifiable/confidential information has been removed are identified in text by footnote.

3.3.3.2 Interview Schedule

Participants were asked to take part in a 45-minute interview. All interviews exceeded this time frame and ranged between 50 to 90 minutes in length. Five pilot interviews were conducted in Adelaide between the 11th of February and the 31st of March 2013. Interviews were carried out in three further phases; in Sydney (between the 8th and 12th of April 2013), Melbourne (on the 22nd and 23rd of April 2013) and in Canberra (between the 28th of May and 3rd of June 2013). A final interview was conducted by phone in July of 2013.

3.3.3.3 Interview Format

Interviews were conducted in a variety of locations but were most often conducted in cafes. Cafes were the location of choice when interviewees did not wish to be interviewed at their workplace (and therefore, to be identifiable to their colleagues). Before commencing each interview, each participant was provided with a brief overview of the research project, as well as information regarding the grounds of their participation. Audio recording of the proceedings would then commence in those interviews where a participant had signed a consent form, as per ethics requirements.

Rather than follow a sequential line of questioning, interview questions were arranged in a matrix according to subject area. This matrix was devised during the piloting phase to increase the ease of moving between subject areas as the interviews evolved. Many of the questions and subject areas were consistent for all participants—this provided some structure to the interviews and enabled some comparisons to be drawn between each participant's responses. Interviews would often begin with a question about why the participant chose to participate in the study (i.e. what sparked their interest) or the participant's initial interpretations of the regulatory framework (i.e. what aspects they perceived to be appropriately rigorous). Subsequent lines of inquiry varied depending on how each participant

responded. During audio recorded interviews, I would take notes to prompt future lines of questioning, but I mostly relied on the digital recorder so that I could give my full attention to the interviewee. In the interview were there was no audio recording, I would pause between each question to copy down excerpts stated by the participant. These excerpts were then read out loud to the participant to confirm that they were copied correctly before I moved onto the next question.[15] In the case of the group interview, these excerpts were taken by myself and the scribe.

Each interview would finish with the opportunity for participants to ask additional questions or make any further statements. It was at this point that I was often asked more about my project, previous research, and the progress I had made with the PhD. This would sometimes lead to further discussions on regulatory issues and suggestions as to who else I could speak to. Recording ceased for audio recorded interviews following this discussion.

3.3.3.4 Limitations

It is possible that those individuals who elected to be interviewed chose to do so because they had a greater investment in the regulatory issues being examined. This may mean that the data provided by some of the participants may not be truly representative of the views of the greater population. Participants, particularly in the group interview with the TGA, would have also been motivated to provide information that would place themselves, and their organisation, in a favourable light as the project revisits certain actions and decision-making processes which undermined the regulator and regulatory regime. To reduce these effects, participants were sampled across a range of stakeholder groups so that a variety of views were captured. Data obtained from the interviews was also triangulated with the data obtained from the consultations submissions to verify the themes that had been generated.

Since the interview and transcription process requires an element of interpretation, there is potential for researcher bias. To combat these effects, themes were generated based on the semantic content of the data. Triangulation was also used to corroborate data across different sources to ensure that the initial themes generated had factual accuracy, and therefore, greater descriptive validity (Johnson 1997, pp. 284-5). Investigator triangulation—using multiple researchers to assist in the collection and corroboration of data (Johnson 1997, p. 285)—was specifically implemented for the group meeting

[15] Although this interview was not recorded, a transcript was compiled based on the notes made during the interview. This transcript was sighted and approved for use by the participant on the basis that the comments transcribed were an accurate reflection of the comments made during the proceedings.

since it could not be recorded. The scribe acted as a second observer to the proceedings, which allowed notes, which would go on to form the final transcript, and accounts of the discussion to be compared with my own. Feedback on the interview transcript was also sought for each of the interview participants to increase its interpretative validity (Johnson 1997, p. 285).

Power-imbalances were only apparent during my pre- and post-interview interactions and group interview with the TGA, something which I discuss in detail in section 7.1.1.9 of the thesis. Most participants were willing to discuss problem areas associated with the regulatory regime, a willingness which was reflected in the participation response rate and participants' overall receptiveness towards this project. Because this research coincided with an extensive period of public consultation and reform, many of the problems associated with the regulatory regime were well documented and publicised. This timing meant that most participants were open to discussing why certain aspects of the regime were prone to failure. As the subject matter of this thesis centred upon the government's regulation of industry, the discussion rarely required an intricate knowledge of the formulation and action of medicinal products. Experience in the disciplines of medicine and pharmacy was therefore not necessary to understanding the key regulatory issues being examined, and certainly did not inhibit my interactions with participants. Even when such experience was required, most participants were more than willing to explain this information to me. I also felt my position as a PhD student was beneficial (rather than detrimental) to this research. Interview participants generally perceived this research as less threatening when it was framed as a PhD thesis, mostly due to the belief that PhD research was less likely to be published for wider and more public audiences. Many of the interview participants also had PhDs or held adjunct or lecturing positions at Australian universities. These participants expressed sympathy towards PhD students because they were aware of the difficulties associated with obtaining interview participants for the purposes of PhD research. Two participants also offered encouragement, grateful for the fact that a young female researcher was carrying out research in a space where relatively little emerging research was being conducted.

3.3.4 CODING

To generate themes from the submission and interview data, this thesis has adopted the six-stage coding procedure developed by Braun and Clarke (2006).

Stage 1: Familiarisation

According to Braun and Clarke (2006, p. 87), researchers must first immerse themselves in the data so that they are familiar with its content and are able to begin to identify themes. This specifically

involves active and repeated reading of the entire data set on the part of the researcher. Immersion can begin as early as the transcription phase since the transcription process requires researchers to go back and forth between the recording and transcript to ensure its accuracy. As the transcripts were also amended to incorporate any clarifications from participants, this provided an additional layer of reading and familiarisation. Data which has not been collected first hand or by interactive means, requires a greater level of familiarisation since the researcher would not have prior knowledge of its content. For this reason, consultation submissions were read through twice and interview transcripts once prior to coding. To increase work flow, hard copies were made of each consultation submission and interview transcript. Submissions and transcripts were then placed into arch lever folders and numbered; submissions were numbered in accordance with the numerical range assigned to the consultation (see *Table 3.5*), interviews were numbered sequentially in order of conduct. Because coding was conducted electronically, digital copies of each submission and transcript were also made and stored in the program NVivo.

On the first reading, I noted any interesting points and thoughts by hand in a separate notebook. On the second reading, points of interest were underlined or noted in pencil on the submissions and transcripts directly. Any potential codes or themes generated at this point were listed separately in the notebook.

Stage 2: Initial Coding

Researchers can begin generating initial codes once they are familiarised with the content of the data items. Initial codes represent 'the most basic segment, or element, of the raw data or information that can be assessed in a meaningful way regarding the phenomenon' (Boyatzis 1998, p. 63). It is this coded data which is grouped together to form each unit of analysis (i.e. themes).

For this project, the researcher highlighted segments of text—first by hand on hard copy submissions and transcripts, then electronically using NVivo—to clearly capture data within the surrounding text. Each segment of text was tagged and assigned a unique label. As advised by Braun and Clarke (2006, p. 89), data was coded for as many potential themes as possible. Some of the surrounding text was also captured to ensure that the context of each code was not lost.

Stage 3: Forming Themes

Once codes have been generated, researchers must sort and group each code to form preliminary themes (Braun & Clarke 2006, p. 89). Each individual code generated was collated with similar codes, and then given a label based on its semantic meaning when three or more codes could be grouped

together. Higher-order themes were constructed based on the relationships between these themes and relevant theory. It is through forming these connections that a thematic map was developed. Lower-order themes which did not appear to bear a connection with other themes within the data set were temporarily housed under a 'miscellaneous' theme.

Stage 4: Reviewing Themes

Once the initial themes have been developed, each theme must undergo refinement to ensure its fit with the coded data. Braun and Clarke (2006, p. 91) recommend a two-step approach to refining themes. First, researchers are advised to read all coded extracts under each theme to determine whether they 'accurately capture the contours of the coded data' (Braun & Clarke 2006, p. 91). Should any of the extracts fail to fit, this may mean that the 'theme itself is problematic' (i.e. it needs to be reworked) or that the extract 'simply do[es] not fit there' (i.e. the extract needs to be moved to a new theme, a pre-existing theme, or discarded entirely) (Braun & Clarke 2006, p. 91). Once researchers are satisfied that each coded extract is an accurate fit for each theme, researchers must determine the fit of each theme within the entire data set. This involves a re-reading of the extracts to determine whether themes 'cohere together meaningfully' whilst remaining clear and identifiably distinct (Braun & Clarke 2006, p. 91). At this stage, researchers should also be on the lookout for new themes—any aspects of the phenomenon being studied which may have been missed during the earlier stages of coding (Braun & Clarke 2006, p. 91). The aim is to develop a map which accurately reflects the data set.

Given the size of the data set, step one was conducted twice to ensure coded extracts were an accurate reflection of each prescribed theme. The initial thematic map was also re-worked on several occasions to streamline and condense the number of themes overall.

Stage Five: Further Defining and Reviewing Themes

At this stage, researchers are advised to 'define and refine' themes for the purposes of identifying the 'essence' of individual themes (Braun & Clarke 2006, p. 92). Braun and Clarke (2006, p. 92) state that each theme must be clearly defined so that it is clear 'what your themes are and what they are not'.

Since themes have been developed based on the semantic content of the data (and have therefore involved little interpretation), the essence of each theme can be summarised by its label. An outline of each theme is provided as part of the results in *Chapters 6* and *7*.

Stage Six: Producing the Final Results

The final stage involves the write up and reporting of the results. Here, extracts are used to illustrate the narrative of the analysis and provide sufficient support for the themes generated (Braun & Clarke 2006, p. 93). This reporting has been carried out and is explained over *Chapters 6* and *7*.

3.3.4.1 Limitations

Although thematic analysis is considered a 'relatively straightforward' method of analysis (Braun & Clarke 2006, p. 94), it is prone to failure when researchers fail to actually analyse the data (i.e. when there is no analysis and the researcher simply describes the content), when the analysis is weak (i.e. it fails to provide adequate examples, is incoherent, or does not work together), when the analysis is unfounded (i.e. it is not supported by the data and/or suggests an alternate narrative), and when the analysis bears little connection to theory or the overall research question (Braun & Clarke 2006, pp. 94-5). Many of these issues arise because researchers fail to adhere to a prescribed method of thematic analysis. By adopting the six-stage approach developed by Braun and Clarke (2006), themes can be generated and refined with a significant degree of thoroughness to ensure their fit with the coded data. Since this research was abductive in nature, themes, especially higher-order themes, were developed in close concert with theory.

3.4 SUMMARY

This chapter outlined the theoretical framework, and research design and method employed for this thesis. The thesis applies a critical realist, Marxist, and Foucauldian framework on the grounds that: Marxism provides the best explanation for the structure and motivations behind dominant modes of social organisation within capitalist societies; Foucauldian approaches provide the best explanation for the production and exercise of power; and critical realism provides an ontology of social phenomena both structured and plural in configuration. This realist, Marxist, and Foucauldian framework allows power relations to be conceived as something which can emerge from dominant modes of social organisation, such as social structures, while not being reducible to them.

Given the lack of access to quantitative sources of data and the benefits of qualitative inquiry for developing contextual accounts of social phenomena, this thesis employs a qualitative thematic analysis of submissions to public consultations and interview transcripts. These consultation submissions and interview transcripts are used to determine why a regime utilising risk-based and responsive regulation has failed to generate compliance from regulated entities, and how the regime has become congruent with neoliberal rationalities of government which aim to limit forms of market

intervention detrimental to capital accumulation. This thesis adopts an abductive line of reasoning based on scholarship which argues that risk-based and responsive regulatory strategies are congruent with neoliberal rationalities of government. To protect against biases that may arise from this research approach, themes are generated based on the semantic content of the data, and prior to interpreting and theorising their broader meanings and implications. This approach ensures that themes best reflect the realities reported by stakeholders and interviewees while allowing the underlying structures of the regime to be analysed.

The theoretical framework developed in this chapter is employed in *Chapter 4* to explore the emergence and dominance of compliance-based regulatory strategies in the Australian pharmaceutical regulatory regime. This chapter maps the emergence of compliance-based strategies with the emergence and subsequent retreat of the state, the emergence of the TGA, and the advent of neoliberalism.

4 THE HISTORICAL DEVELOPMENT OF THE AUSTRALIAN PHARMACEUTICAL REGULATORY TERRAIN

The Department of Health—and by extension, the Therapeutic Goods Administration (TGA)—first formed when public health and welfare were conflated with economic and security concerns in the late 19th century (Bashford 1998, p. 388). It had been during the country's initial attempts to secure its borders and population from the threat of foreign disease that federal laws and policies aimed at prohibiting the entry of harmful and contaminated therapeutic products into the country were first developed. For most of the 20th century, the Australian pharmaceutical terrain was oriented towards the protection of public health and welfare, resembling what Löfgren and de Boer (2004, p. 2398) labelled a protectionist Keynesian-welfare state. However, in the late 1980s, as political attitudes in Australia, like in many Western countries at the time, shifted towards the privatisation, decentralisation, and deregulation of markets, the pharmaceutical terrain evolved and became increasingly predicated upon the notions of cooperation, risk-management, and self-regulation.

The state's role in the regulation of the pharmaceutical industry has varied over this period to contend with the competing objectives of public health and welfare, and viability of industry. It is only by studying these transformations to the pharmaceutical terrain that we 'learn more about how political-economic institutions shape policy choices and ... how these choices in turn reshape the institution' (Vogel 1996, p. 9). This chapter seeks to analyse the emergence—and dominance—of compliance-oriented regulatory techniques in the regulation of the Australian pharmaceutical industry. This is achieved by examining the historical development of the Australian pharmaceutical regulatory terrain, and by tracing the emergence and subsequent retreat of the state with the advent of neoliberalism and development of the TGA. In the context of the Australian pharmaceutical terrain, the transition from welfarism to a neo-corporatist regime congruent with neoliberalism is best viewed as successive phases of governmentality, which have been influenced, not only by changing attitudes in biopolitics and rationalities of government, but a hegemony perpetuated by the dominant faction which privileges the accumulation of capital. Analysing government within this realist, Marxist, and Foucauldian framework provides greater avenues in which to explore the restructuring of governmental processes than would otherwise be possible using stand-alone approaches. The chapter finds that these transformations have contributed to the production of a regime which has seen: the decentralisation and delegation of Commonwealth powers to specialised state and non-state apparatuses; the growth of technologies of agency as a result of the deregulation of pre-market and post-market regulation; the adoption of risk-based, cooperative, and graduated techniques of

government reminiscent of risk-based and responsive regulation theory; and the creation of technologies of citizenship to increase tripartism within the regime.

Literature documenting the historical development of this terrain is relatively scarce; few scholars have been able to provide a comprehensive overview of law and policy changes in this space due to its historical complexity and the lack of publicly available information. This chapter should therefore not be construed as a complete overview of the historical development of the Australian pharmaceutical regime—although, it is likely to be one of the more comprehensive accounts of the historical development of the regime to date. Since the Department of Health has undergone several changes in name throughout its history, to avoid potential confusion, references to the Department and Minister will mean the Department and Minister of Health, regardless of whichever nomenclature was in place at any time.

4.1 THE EMERGENCE OF STATE WELFARISM

Australia's first public health policies arose from the country's early quarantine controls which aimed to restrict immigration—and thus, safeguard the country's racial and national identity—on biopolitical grounds. It was during this period that population health was increasingly being 'articulated as a problem of government' and 'a new citizenry was being deliberately shaped' (Bashford 1998, p. 388). Here, the state was exercising power over and through the population with the intent of regulating and ordering the population (Dean 2010, p. 29).

4.1.1 THE EMERGENCE OF THE DEPARTMENT OF HEALTH

Prior to Federation in 1901, the lack of inter-colonial quarantine and consequent failure by colonial governments to control the spread of disease, particularly at ports of entry, was perceived by many colonial governments to be a substantial threat to 'national healthiness' and 'purity', especially at a time when the Australian continent had been the only continent free of endemic disease (Bashford 2002, p. 350). Although colonial governments were not opposed to cooperative action on quarantine matters, attempts to develop uniform legislation across the colonies in the 1880s never achieved fruition (Roe 1976, p. 176). It was only after a continent-wide plague in 1900—which would last until 1909—that unanimous support for a national system of quarantine under a central government was achieved (Roe 1976, p. 177). Under the Constitution, the newly formed Australian Government was granted the power to develop laws on all matters concerning quarantine (Brew & Burton 2004, p. 7). Each of the Australian States, however, continued to exercise its own quarantine controls, and

retained the power to legislate and control the manufacture and sale of medicinal products, a privilege which was protected by the Constitution.

The elevation of quarantine control to the national level enabled the Australian Government to exercise greater control over the spread of disease by way of the movement of people. This allowed the Australian Government to reinforce the boundaries between internal (clean and pure) and external (dirty and impure) populations (Bashford 1998, p. 389). The 'new, pure, healthy and white' Australia was located in an Asia-Pacific region which had been construed as 'dirty, diseased and all that was not white' (Bashford 1998, p. 393), and fears of unrestricted immigration and potential invasion by Australia's Asian neighbours fuelled concerns about the spread of disease. Particular concern was raised with respect to Australia's Chinese population which had rapidly increased following the gold rushes of the late 19th century—Chinese men were regularly portrayed as 'sexual' and 'moral' threats to white Australian women, as well as 'purveyors of disease' (Bashford 1998, p. 397). In 1906, within the climate of the burgeoning plague crisis, the Australian Government took its first steps towards legislating its Constitutional powers by gaining formal support from the Australian States to develop quarantine controls at ports of entry and to take the lead on internal quarantine arrangements (Brew & Burton 2004, p. 6). The Australian Government, under Prime Minister Alfred Deakin, introduced the *Quarantine Act 1908* (Cwlth), which, in combination with the *Immigration Restriction Act 1901* (Cwlth) introduced shortly after Federation, gave the Australian Government powers to legally pursue infectious disease control by way of immigration regulation (Bashford 2002, p. 346). This legislation was not only pivotal to legislating state racism—the *Quarantine Act* was a technology of the White Australia Policy (Bashford 1998, p. 398)—but it was also pivotal to the development of the modern-day pharmaceutical regulatory regime. It led to the formation of the Quarantine Service—the first governmental body in Australia charged with protecting and promoting public health, and the governmental body which would eventually go on to form the modern-day Department of Health (Roe 1976, p. 177). The Quarantine Service, which was situated within the Department of Trade and Customs, was controlled by the Australian Government, but operated by the Chief Health Officers from each of the Australian State Governments (Castles 1988). Its primary purpose was to 'vest' Australian State health authorities with Federal quarantine powers (Roe 1976, p. 177), an act which many Australian State Governments perceived to be an attack on their independent control of internal health regulation (Wright 1970; as cited in Roe 1976, p. 177). The imposition caused by the Quarantine Service generated so much tension between the Australian State and Federal Governments that between 1910 and 1929, many of the Australian States ceased all cooperation with the Service (Roe 1976, p. 177).

The Australian Government, nevertheless, through the Quarantine Service, attempted to expand its influence over issues incidental to the life of the population in the period immediately following the First World War. The then Acting Prime Minister W. A. Watt used a number of key events, including the global influenza pandemic of 1918, the return of Australian Imperial Force personnel, and Australia's expanding interests in the Asia-Pacific region, to pressure Australian State Governments to consider formally conferring their quarantine powers—albeit with little success, as the Australian States remained resistant to a formal transfer of power (Roe 1976, p. 179). At the same time, external pressure was increasingly being applied on the Australian Government to develop a national health department in line with other countries. The greatest source of pressure came in the form of the Rockefeller Foundation's International Health Board, whose Director, physician Victor G. Heiser, had lobbied the Prime Minister directly as well as the current and former director of the Quarantine Service, J.S.C. Elkington and J.H.L. Cumpston (Roe 1976, p. 180). The Australian Government eventually gave into this pressure and agreed to establish a department of health in early 1921 (Roe 1976, p. 181). The Australian Department of Health emerged institutionally out of what remained of the Quarantine Service and ultimately went on to administer many of its duties under the *Quarantine Act*. Unlike its predecessor, the Department of Health had a much broader public health mandate. Their role included: primary co-ordination of public health and disease prevention measures; primary investigation of the cause of death and disease, as well as powers to create and control laboratories to carry out these purposes; a primary role in public health education; and control of the Commonwealth Serum Laboratories (CSL), the government body responsible for the production of the nation's vaccines and the commercial distribution of products (National Archives of Australia 2016).

4.1.2 THE SOCIALISATION OF MEDICINE

Up until the mid-20th century, the rationality of government had been to manage the health of the population to ensure that individuals remained in the service of the state (Foucault 2004, p. 6). However, it was during the mid-20th century that the Australian Government, under the auspices of quarantine, gradually expanded its biopower with the intention of safeguarding the population from the anti-social effects of the pharmaceutical market. This movement coincided with the historical period identified by Foucault (2004, p. 8) as the socialisation of medicine—where the body of the individual increasingly became a site for state intervention (Foucault 2004, pp. 6-7). Here, preserving health was 'not for the benefit of the State, but for the benefit of individuals' since it was '[m]an's right to maintain his body in good health' (Foucault 2004, p. 6).

In a referendum held in 1946, the Australian Government was granted constitutional powers to legislate on all issues concerning social service provisions, including health benefits. The

Pharmaceutical Benefits Scheme (PBS), which would become the centrepiece of the welfare state apparatus, was developed in 1948 with the passing of the *Pharmaceutical Benefits Act 1947* (Cwlth) to increase the accessibility of medicines to the public, subsidising the cost of up to 70 per cent of the prescription medicines available on the Australian market (Löfgren 2009, p. 129). The passing of the *National Health Act 1953* (Cwlth) also enabled the Australian Government to supply medicines to pensioners free of charge (McEwen 2007, p. 20). These apparatuses of the state aimed to correct inequalities within the Australian population to ensure that all its members had the same opportunities to access medicinal products (Foucault 2004, p. 7).

Suspicions that many of the medicines imported into Australia and supplied on the PBS were substandard,[16] and, that exporting countries were 'not very interested in the quality of drugs exported' (McEwen 2007, p. 24), led to the development of further apparatuses intended to increase the state's biopolitical control over pharmaceutical products. This first came in the form of the *Therapeutic Substances Act 1953* (Cwlth) which prohibited goods imported, traded via interstate trade, included on the PBS, or supplied to the Commonwealth under contract which did not conform with standards (McEwen 2007, p. 29). The *Therapeutic Substances Act* also saw the development of the first therapeutic goods expert advisory committees at the national level.[17] The development of the Therapeutic Substance Regulations 1956 (Cwlth) made it a requirement for companies and manufacturers of imported therapeutic goods to produce a certificate upon entry to Australia declaring that each good contained no health or quarantine objections (McEwen 2007, p. 37). A National Biological Standards Laboratory (NBSL) was also formed in 1958 to test the integrity of imported and PBS medicines against the British Pharmacopeia—the good manufacturing practice (GMP) standard used in Australia at the time (de Somer, Monk & Hirshorn 2013, p. 557).

The Thalidomide disaster[18] in the 1960s prompted the Australian Government to develop more robust state apparatuses to secure the supply chain and population from the 'negative effects of the market

[16] According to McEwen (2007, p. 24), the Australian Senate was presented with data in 1953 indicating that 41% (45 out of 110) of products (presumed to be on the PBS) failed to meet pharmacopoeial requirements.
[17] These committees were: the Therapeutic Substances Advisory Committee, which advised the Minister on matters concerning the Therapeutic Substances Act and Therapeutic Substance Regulations; the Biological Standards Committee, which advised the Minister on standards relating to antibiotics, insulin products, vaccines and other biological products; and the Therapeutic Substances Standards Committee, which advised on standards relating to therapeutic substances that did not fall in the remit of the Biological Standards Committee (McEwen 2007, pp. 36-7).
[18] Thalidomide was an over-the-counter sedative and hypnotic drug marketed world-wide by the West German company Chemie Grüinenthal (Dukes, Braithwaite & Moloney 2014, pp. 23-5). Thalidomide was specifically marketed to pregnant women as an anti-nausea medicine, even though no testing had been conducted by the company on the effects of Thalidomide on a foetus in utero. In the late 1950s and early 60s, doctors had reported an increase in rates of phocomelia—an extremely rare birth defect where infants were born with

economy' (Löfgren & de Boer 2004, p. 2041). The Australian Drug Evaluation Committee (ADEC) was established in 1963 to provide medical and scientific advice to the Minister on therapeutic goods intended for marketing (de Somer, Monk & Hirshorn, p. 557). A year later, an adverse drug reaction (ADR) reporting scheme was developed and overseen by the ADEC (McEwen 2007, p. 129). The Australian Government introduced the *Therapeutic Goods Act 1966* (Cwlth) which gave the Department powers to command companies to supply data to demonstrate the quality, safety, and efficacy of an imported medicine prior to marketing (de Somer, Monk & Hirshorn, p. 557). The *Therapeutic Goods Act* also led to the expansion of general requirements for labelling and packaging of all therapeutic goods (McEwen 2007, pp. 47-8). A Code of GMP was also established in the late 1960s to create a minimum set of standards for Australian manufacturers (de Somer, Monk & Hirshorn, p. 557).

The Department's increasing role in matters concerning therapeutic goods led to the creation of a dedicated therapeutics section, separate from the NBSL, within the Department of Health in 1964 (McEwen 2007). The Therapeutics Substances Section—later renamed the Therapeutics Division in 1974—was initially charged with the coordination of activities under the *Therapeutic Goods Act* (McEwen 2007, p. 51). However, this mandate was gradually expanded throughout the 1970s. Between 1971 and 1974, the National Therapeutic Goods Committee (NTGC), comprising representatives from Australian State and Federal Health Departments, expressed repeated concerns over the lack of information provided to healthcare practitioners in the advertising for prescription medicines and to consumers in the advertising of non-prescription medicines (McEwen 2007, p. 102). The lack of Commonwealth controls over these forms of advertising led the Minister to delegate responsibility to the Therapeutics Division for pre-approving direct-to-consumer advertising materials for radio and television, and product information and promotional materials (McEwen 2007, p. 103). Subsequently this led to the establishment of the Voluntary Code for the Advertising of Goods for Therapeutic Use in 1977. The Code, which was later renamed the Therapeutic Goods Advertising Code, continues to remain in use. In the same period, the NTGC also expressed concerns

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deformed or underdeveloped limbs (Dukes, Braithwaite & Moloney 2014, p. 24). Despite early links being established between Thalidomide and phocomelia, the company made a concerted effort to discredit those who produced evidence of such connection (including threats of legal action) (Dukes, Braithwaite & Moloney 2014, p. 37). It was only after two independent studies published in 1961—one by German paediatrician Widukind Lenz, the other by Australian obstetrician William McBride—that unequivocal evidence of the link between Thalidomide and phocomelia came to light (Dukes, Braithwaite & Moloney 2014, p. 24). The Thalidomide Trust (2017), based in the United Kingdom, estimates that approximately 10,000 infants world-wide were born with Thalidomide-induced phocomelia, however, this figure is likely to be larger since many women terminated their pregnancies, had stillbirths, or had infants who died shortly after birth.

about the lack of Commonwealth controls for *all* therapeutic goods supplied in Australia, not just goods imported into the country or which crossed interstate boundaries, and proposed the introduction of a national registration scheme for pharmaceutical products (McEwen 2007, p. 53). The *Therapeutic Goods Act* was again amended in 1981 to establish a national register of therapeutic goods, to require manufacturers and suppliers to supply information for all therapeutic goods, excluding complementary and homoeopathic medicines, to the Register, and to increase penalties for breaches of the Act (McEwen 2007, p. 54). The first notices requesting manufacturers and suppliers to supply information to the Register were issued by the Therapeutics Division in 1984, but compliance was variable since 'entry on the National Register was not central to the lawful supply of therapeutic goods' (McEwen 2007, p. 55). A series of reviews in the late 1980s, including *The Public Service Board Review of Drug Evaluation Procedures* (1987) and the *Therapeutic Goods – A Review of Therapeutic Goods Evaluation and Testing Program* (1988), reiterated concerns about the capacity of manufacturers and suppliers to evade these requirements and calls were made for the creation of national legislation which unified standards for all therapeutic goods (McEwen 2007, pp. 55-6).

4.2 THE RISE OF NEOCORPORATISM AND NEOLIBERAL BIAS

Up until the late 1980s, the Department of Health had traditionally dealt with the pharmaceutical industry at an arm's length (Löfgren & de Boer 2004, p. 2399); the chief object of biopolitical concern had been the health and safety of the population. Local industry in Australia was relatively weak (Löfgren & de Boer 2004, p. 2399), and the market was dominated by multinational pharmaceutical companies whose chief operations in Australia involved secondary forms of manufacturing—namely, the formulation of imported ingredients and repackaging of imported medicines to conform with Australian requirements (Industry Commission 1996, p. XXXIV). Australian pharmaceutical exports were considered relatively 'insignificant' compared with other countries as 'almost no R&D was undertaken' (Löfgren & de Boer 2004, p. 2399). Many of the state apparatuses and technologies of government introduced during this period of welfarism were therefore perceived by industry and its supporters to be a major imposition. The introduction of the PBS, and the costs placed on local manufacturing and export, were thought to have reduced the profitability and growth of the sector (Davies & Tatchell 1992; McEwen 2007). The lack of industry representation on expert advisory committees was also a concern; representation had dwindled to just one representative on a single committee at the time the Therapeutic Goods Bill 1966 (Cwlth) was introduced to the House of Representatives in 1966 (McEwen 2007, p. 49). When these concerns were raised by members of the House during the reading of the Therapeutic Goods Bill, the Minister argued that industry representation had declined because 'it just did not work' and was perceived to be 'impracticable'

because ‘nobody could represent the whole industry’ (Senator Forbes 1966; as cited in McEwen 2007, p. 49).

The Department of Health was placed under increasing pressure by pro-business interests within industry and government to adopt a more business-friendly attitude to the pharmaceutical industry (de Somer, Monk & Hirshorn; Löfgren & de Boer 2004). For example, the prescription medicines’ industry association, the Australian Pharmaceutical Manufacturers Association (APMA), had been openly critical of the Department’s adversarial treatment of industry (Löfgren & de Boer 2004 pp. 2401-2). The Australian Government’s Industry Assistance Commission (now the Productivity Commission) had carried out three separate reports in to the productivity of the pharmaceutical sector (in 1974, 1976, and 1986), all of which criticised the stringency of current requirements and advocated for greater deregulation of the sector. The Australian Department of Industry also condoned the Department publicly for its entrenched views, arguing that the Department often prioritised consumer welfare ‘without primary concern for the profits of multinational drug manufacturers’ (Johnston 1986; as cited in Löfgren & de Boer 2004, p. 2400). This *power bloc* represented ‘a fairly stable alliance of dominant classes or class fractions’, whose unity was founded upon ‘a modicum of mutual self-sacrifice of immediate interests and … [a] commitment to a common world outlook’ (Jessop 1990, p. 42).

It was during the late 1980s and early 1990s that the overall rationality of government shifted in favour of a neoliberal governmentality. This triggered a number of transformations to the pharmaceutical regulatory terrain: the creation of laws which saw Australian Government powers decentralised and delegated to a regulatory agency and industry associations; the introduction of cost-recovery and a decreased reliance upon the state; greater deregulation, including reduced approval times and fewer pre-market hurdles; the implementation of risk-based regulation to compensate for deregulatory reforms (i.e. for drug safety problems which would arise during post-marketing); and an increased emphasis on participatory democracy. Many of these changes were the product of the successful articulation of private interest issues as the general (public) health interest by the dominant faction. For example, the failure of the Government to introduce clinical trial reforms, which had until then discouraged industry investment in research and development of new drugs, was said, at the time, to have negatively impacted upon patients ‘who were unable to access possible treatments for potentially life-threatening illnesses’ (de Sommer, Monk & Hirshorn 2013, p. 558). This framing allowed the power bloc to secure wider support for changes which generally favoured the dominant interest. These changes can also be conceived in biopolitical terms. Because private interests, such as product innovation and timely drug approvals, were fused with the needs of the population, health

came to be associated with therapeutic advance and market supply and demand. Since the administration of health was conceived as the domain of the state, this made private interest issues framed as the general public health interest the responsibility of the state. The successful articulation of this dominant hegemony as an object of biopolitical concern has been key to the formation of a neoliberal governmentality.

4.2.1 THE EMERGENCE OF THE THERAPEUTIC GOODS ADMINISTRATION

The first of the major transformations that occurred during this period involved the introduction of the *Therapeutic Goods Act 1989* (Cwlth), which replaced the complex mix of Australian State and Territory, and Commonwealth legislation to give the Australian Government primary control over therapeutic goods from the point of supply on the Australian market, rather than at the point of import as previously occurred. The new *Therapeutic Goods Act* saw the introduction of an Australian Register for Therapeutic Goods (ARTG or Register) and a two-tiered system for market entry—one for high-risk medicines, another for low-risk medicines (explored in detail in *Chapter 5*). Provisions were created within the Act to compel companies to supply certain information with applications for entry onto the Register, to demand that companies supply information when it was requested by the Secretary of the Department of Health, and to cancel an entry when companies failed to comply with these provisions (McEwen 2007, p. 57). Provisions were also created to require each manufacturer in Australia and overseas to be licenced and adhere to the Code of GMP (McEwen 2007, pp. 57-8).

The *Therapeutic Goods Act* was both a centralising and decentralising technique of government. Through the *Therapeutic Goods Act*, the Australian Government was able to delegate its powers to a newly formed national regulatory authority, the TGA—a product of the former NBSL and the Therapeutics Division within the Department of Health (McEwen 2007, p. 51). It is through this apparatus of the state that the state is able to make direct interventions into the pharmaceutical regulatory terrain. The responsibility for regulating the promotion of prescription medicines to healthcare practitioners was formally delegated to the APMA[19] with the introduction of the *Therapeutic Goods Act* (McEwen 2007, p. 103). The passing of the Therapeutic Goods Regulations 1990 (Cwlth) saw responsibility for the approval of advertisements for non-prescription medicines delegated to the Proprietary Medicines Association of Australia (PMAA) for print and electronic

[19] The APMA had been given permission by the Trade Practices Commission (now the Australian Competition and Consumer Commission) to trial a self-regulatory scheme for prescription medicine promotion between 1987 and 1989 (McEwen 2007, p. 103). Though this arrangement was 'reluctantly' agreed to by public interest groups at the time—according to Braithwaite, there was 'no practical hope of the government providing the resources to regulate marketing claims effectively'—self-regulation had been found to be 'more effective than government regulation had ever been … even if still inadequate' (Braithwaite 1995, p. 66).

media; however, these provisions would only apply to PMAA members, meaning non-members would not be subject to these standards (McEwen 2007, pp. 103-4). These technologies of agency empowered industry associations and pharmaceutical companies to become self-regulating entities so that the overall responsibility of the state in regulating industry conduct could be decreased. Licencing fees for manufacturers, and registration and listing charges were also introduced under the *Therapeutic Goods Act* as a means of increasing organisational resources for the TGA, and therefore, for decreasing the agency's reliance upon the state (Lexchin 2006, p. 2216). Initially, fees and charges were established to recover just 50% of the TGA's running costs, a feat which would not be achieved until 1996 (McEwen 2007, p. 144). However, in the 1997-98 Budget, the Australian Government increased cost-recovery levels to 75%, and then 100% in 1998 (McEwen 2007, p. 44).

Despite these changes to the regulatory framework, the TGA, like the earlier Department, continued to receive criticism for its adversarial nature, science-driven culture, and general distrust of industry (Löfgren & de Boer 2004). In 1991, the APMA argued that:

> [m]ost senior TGA officers have a strongly negative attitude towards the industry and this philosophy has permeated relatively low levels of the agency (Löfgren & de Boer 2004, p. 2401).

Attempts to secure the support of the TGA by framing private and public interests as one and the same is clear from this APMA quote:

> The role of the TGA officers has been emphasised as being the protectors of the public's safety rather than its health and welfare. Sponsor companies are seen as adversaries rather than organisations which share many of the TGA's goals and with considerable expertise to offer (Löfgren & de Boer 2004, pp. 2401-2).

This framing was also aided from below through 'the incorporation of certain interests and aspirations of the 'people' into the dominant ideology' (Jessop 1990, p. 42). For instance, the inter-governmental committee the Australian National Council on AIDS had publicly advocated for the liberalisation of the prescription medicines sector during this period to increase public access to new HIV/AIDS treatments (de Sommer, Monk & Hirshorn 2013, p. 558). The culmination of this pressure, from industry and within government, prompted the Minister to commission an inquiry into the drug evaluation system. The successful articulation of private interests as public interest issues is evident in the Minister's justification for the inquiry below:

> Protect[ing] the public from unsafe, ineffective and poor quality drugs … *needs to be balanced against the public's interest in gaining access to new and possibly life-saving medications. ... Streamlining should be seen as maximising public access to improved drugs in the minimum time* ensuring the public interest is paramount in regards to safety, quality and efficacy (Australian National Audit Office 1996, p. 9 [added emphasis]).

The *Baume Report* made a total of 164 recommendations to better streamline the drug evaluation process, most of which aimed to reduce approval times and enhance TGA performance on key performance indicators. Adopting these types of recommendations would ensure that 'neoliberal rationality extended to the state itself' by indexing 'the state's success according to its ability to sustain and foster the market' (Brown 2005, p. 41). The principle recommendation to come out of the *Baume Report*, however, was the proposed adoption of a risk-management approach to pharmaceutical regulation which prioritised regulatory resources towards therapeutic goods based on product risk. These risk-based regulatory techniques would force the state to 'think and behave like a market actor' by rendering all decision-making processes to cost-benefit calculations (Brown 2005, p. 42).

In the years that followed the *Baume Report*, there were several 'purposeful interventions' by successive Labor and Liberal Governments to bolster the regulatory regime in ways that favoured the dominant hegemony (Löfgren & de Boer 2004, p. 2399). Statutory time frames were immediately introduced to reduce the time it would take for prescription medicine companies to obtain marketing approval through the high-risk pathway—if the TGA failed to finalise an application within the mandated time frame, the TGA would forfeit 25% of the total application fee (Australian National Audit Office 1996, p. 9). A Standing Arbitration Committee was also established within the TGA to arbitrate on 'the reasonableness of TGA requests to industry for further data' (McEwen 2007, p. 143). Unrest from the non-prescription medicines industry over the application process for low-risk medicines led to an amendment of the *Therapeutic Goods Act* in 1996 to have applications self-assessed by the applicant by way of online lodgement (Australian National Audit Office 2011, p. 39), significantly reducing the time it took for non-prescription medicines to enter the market. In 1997 an amendment to the *Therapeutic Goods Act* and Therapeutic Goods Regulations saw the establishment of a Therapeutic Goods Advertising Code Council (TGACC), the Complaints Resolution Panel (CRP), and an approval process for mainstream print media advertisements for non-industry association members (TGACC 2016). The introduction of these amendments also permitted advertising approvals and complaints for non-prescription medicines to operate under a self-regulatory arrangement for PMAA and Complementary Healthcare Council (CHC) members, and under a co-regulatory arrangement for non-members and for broadcast media. Mutual Recognition

Agreements were created under the *Therapeutic Goods Act* in 1997, allowing products already approved in Europe to receive accelerated approval in Australia (McEwen 2007); a move which was viewed as mutually beneficial for consumers and industry because it increased the accessibility of treatments readily available elsewhere. The creation of the *National Medicines Policy* (NMP) in 1999, premised on a 'partnership approach' to policy development (Department of Health and Aged Care 1999b, p. 6), has also been pivotal in shaping the general public health interest to align with private interests. The NMP not only emphasises the 'quality use of medicines' and achieving appropriate standards of quality, safety, and efficacy of medicines for the benefit of consumers, but also timely access to medicines—'at a cost individuals and the community can afford'—all while maintaining a viable pharmaceutical industry (Department of Health and Aged Care 1999b, p. 1). These 'conflicting imperatives' have generated a 'paradox of regulation' (Haines 2011, p. 2) where public interest-based objectives have to be balanced against the private interest-based objectives of the NMP. The NMP has also led to the development of a more cooperative rationality of government which treats sponsors and industry associations as partners and cooperative, law-abiding entities, more so than adversaries. This cooperative rationality has produced a regime which avoids administering punishment and instead emphasises working cooperatively with industry as a means of coercing order.

Throughout the 1990s, technologies of citizenship were also increased through the formation of expert advisory committees. These technologies included the formation of a stakeholder advisory committee in 1997 called the TGA-Industry Consultative Committee (TICC) (Evans 2004, p. 7). The TICC meet with the TGA annually to discuss TGA policies, fees and charges, and its performance on key performance indicators (Evans 2004, p. 7). Initially, the TICC comprised only of representatives from industry associations; a consumer representative was not formally admitted to the Committee until 2001 (Evans 2004, p. 7). An expert advisory committee, called the Therapeutic Goods Committee (TGC), was also developed to advise the Minister directly on therapeutic goods standards, such as labelling and packaging requirements, and product manufacture (TGA 2011c). Members of this Committee are either selected by the Minister directly or nominated by the prescription and non-prescription medicine industries (TGA 2011c). Non-industry committees were also developed to provide technical advice and input into the TGA's decision-making processes (Evans 2004, p. 8). These committees include: an expanded and reinvigorated ADEC; the Complementary Medicines Evaluation Committee (CMEC) to advise on the supply and use of complementary medicines; the Medicines Evaluation Committee (MEC) to advise on over-the-counter (OTC) medicines; the National Coordinating Committee on Therapeutic Goods (NCCTG), a committee comprising of Australian State, Territory, and Federal representatives which advise on regulatory controls; and the Therapeutic Goods Committee (TGC), which advises on labelling,

packaging, and manufacturing standards (Evans 2004, pp. 8-10). These technologies of citizenship have increased the degree of representation competing interests receive within the regime, however, the overall structure of representation has largely favoured more dominant (market) forces (e.g. see 7.2.2.2).

This period of decentralisation and deregulation did not result in less regulation or a roll-back of the state. Neoliberal techniques and rationalities of government, which were construed as beneficial for *both* consumers and industry, have only generated more regulation which has *promoted* the interests of the dominant faction (Tombs 2016, p. 19). For instance, the introduction of statutory time frames not only saw a reduction in the number of days it took the TGA to approve new drug applications—from 702 days to 106 working days between 1990 and 1995 (255 working days were allowed by the legislation) (Australian National Audit Office 1996)—but also resulted in a higher proportion of positive review decisions, particularly as industry contributions via cost-recovery increased (Lexchin 2006). Neoliberal governmentality has also led to substantial prosperity for multinational pharmaceutical companies. Global prescription drugs sales, which had remained relatively steady between 1960 and 1980, tripled to US$400 billion between 1980 and 2002—the main beneficiary being the US pharmaceutical industry, where sales have generated up to US$200 billion (Davis & Abraham 2013, p. 2). Global sales increased to US$600 billion in 2007 and have continued to increase at a rate of 10% each year (Davis & Abraham 2013, p. 2). Although welfare-state apparatuses like the PBS continue to operate—albeit, under much scrutiny from industry (Doran & Löfgren 2013; Galbally 2000; Löfgren 1998; Low, Hattingh & Forrester 2010)—these transformations to the pharmaceutical regulatory regime generally demonstrate the increasing role of the state in shaping the regime to align with the interests of the dominant faction. This state work has ultimately resulted in the production of a regime which promotes the interests of the regime's most dominant players.

4.3 THE MODERN-DAY REGULATORY TERRAIN

In the 21st century, the Australian pharmaceutical regulatory regime has continued to place emphasis on a rationality of government which prioritises risk-management and cooperation. However, under-enforcement as a result of risk-based and cooperative techniques of government has led to several notable regulatory failures which have directly contributed to the shaping and reshaping of the regime. Two of the most notable failures involve the TGA's dealings with Pan Pharmaceuticals (Pan) over the non-prescription drug Travacalm, and Merck & Co (Merck) and Merck Sharpe & Dohme Australia (MSD) over the prescription drug Vioxx. The criticism the TGA received for its heavy-handed response to Pan and lack of response to Merck and MSD, not only led to the adoption of

graduated techniques of government typified by responsive regulation theory, but also provided further support for a neoliberal governmentality.

4.3.1 TGA ENCOUNTERS WITH PAN

Pan Pharmaceuticals and its Director James Selim had an extensive history of law and regulatory violations dating back to the late 1970s, including incidents involving: the substitution of active ingredients for cheaper alternatives (e.g. lactose for paracetamol); the falsification of documents of manufacture; the improper storage and handling of medicines; and the supply and export of unapproved medicines (Dalley 2003, para. 61-76). Between February 1992 and January 2003, Pan's laboratories and manufacturing facilities were audited by the TGA on 12 occasions (Commonwealth of Australia & Others 2010, para. 30(a)). Most of these audits had been announced; Pan had not undergone an unannounced audit since 1994 (Eagle, Rose, Kitchen & Hawkins 2005, p. 453). According to a former Pan employee, the TGA regularly informed the company of impending audits, meaning, by the time TGA audit officers arrived, the premises were often 'cleaned up neat and tidy' (Dalley 2003, para. 3). The TGA's Principle Medical Advisor claimed that the TGA informed companies of an upcoming audit because it needed the cooperation of the staff to access a company's facilities, arguing that:

> [i]f you're going to go through a pharmaceutical plant and ask to observe a production run of tablets, if you want to have access to their computers to get old batch records, you need their cooperation (Dalley 2003, para. 4).

In ten of the 12 audits conducted, critical deficiencies—practices or processes which would cause serious risk or (lethal) harm to consumers—were found by the TGA (Commonwealth of Australia & Others 2010, para. 30(b)).[20] Despite the presence of these critical deficiencies, certificates of compliance were issued to Pan by the TGA between 1992 and 2001 and no further corrective action was taken (Commonwealth of Australia & Others 2010, para. 30(d)).

It was only after several consumers experienced adverse reactions to the travel-sickness drug Travacalm in 2003 that the TGA brought business-impacting prosecution against Pan—the largest in

[20] These included incidences involving the manipulation of batch records, particularly to conceal instances where the decisions of a Quality Control or Assurance Manager had been overridden by Pan Management. Records were alleged to contain unauthorised deviations in the manufacturing procedures in the formulation of goods. As the audits were announced, it was alleged that Pan would close its facilities the day prior to the audit to 'clean-up' the premises and update operating procedures and production specification to appear compliant with regulatory standards (Commonwealth of Australia & Others 2010, para 30(c)).

the agency's history—and fined the company AU$10 million (*R v Pan Pharmaceuticals Pty Ltd* (2008) NSWDC 221, para. 39). Travacalm varied between 0 and 700% in strength because the company used an unapproved method for mixing batches of product to cut down on costs (Bandiera & Marmo 2017, p. 11). Several of Pan's employees were also prosecuted for the manipulation of data and fabrication of manufacturing certificates (*R v Jain* (Unreported, District Court of New South Wales, Walmsley SC, 2 September 2005)). The suspension of Pan's manufacturing licence, cancellation of all its products from the register, recall of all products it manufactured, and court-imposed fine, ultimately culminated in the company's financial collapse.

TGA regulatory practices were heavily scrutinised following this incident. Other businesses impacted by the Pan recall, including those companies who had their products manufactured by or sourced from Pan, were quick to criticise the agency for its handling of the incident (Eagle et al. 2005, p. 453). The Australian Government was also scrutinised in the Australian media for failing to release the official TGA audit report on the grounds of 'commercial sensitivity' (Eagle et al. 2005, p. 453). The most notable criticisms, however, came in the form of an Australian National Audit Office (ANAO) report which found TGA corrective action against non-prescription medicine manufacturers to be largely 'inadequate' (ANAO 2004, p. 16).

In 2005, this external pressure culminated in the development of civil and administrative penalties under the *Therapeutic Goods Act 1989* (Cwlth) to complement pre-existing criminal penalties. Although the TGA had been given some administrative powers when the *Therapeutic Goods Act* was first introduced—the *Therapeutic Goods Act* allowed the TGA to cancel an entry on the ARTG and to revoke or suspend a manufacturing licence—infringement notices, strict liability provisions, and higher-level penalties were added to the Act to create a tiered and graduated approach to enforcement (TGA 2012a, p. 36). Although the term *responsive regulation* was not explicitly used to describe this new technique of government, responsive regulation theory was having an impact on the Australian public sector at the time.[21] Agencies, such as the Australian Securities and Investment Commission, had been implementing tiered-like techniques of government since the early 1990s (Gilligan, Bird & Ramsay 1999). In 2007, the ANAO published the *Better Practice Guide to Administering Regulation*

[21] In a personal communication, the TGA indicated that they have utilised many of the powers provided to them under the Therapeutic Goods Act in a responsive manner since the Therapeutic Goods Act first came into effect. However, the Act did not come into effect until the 15th of February 1991, which predates Ayres and Braithwaite's original 1992 publication. While responsive regulation theory may have had an influence on the Australian pharmaceutical regulatory framework prior to the 2000s — it had certainly had an impact on other Commonwealth agencies at the time—evidence of its use by the TGA was not explicit until the mid-2000s.

to encourage regulatory agencies to implement strategies based on risk-based, principles-based, and responsive regulation. The document not only instructed Australian regulatory agencies on how to manage risk and resourcing issues, but also on how to establish relationships with regulated entities to 'more effectively elicit compliance' (ANAO 2007, p. 25).

In 2008, there were further repercussions following the TGA's handling of the Pan Pharmaceuticals case. To justify the initial suspension of Pan's manufacturing licence, cancel from the register all products manufactured by Pan, and undertake a mandatory recall of all products manufactured by Pan, all without notice, the TGA, had to demonstrate that Pan products constituted an imminent risk of death, or serious illness or injury. However, an expert advisory group assembled by the TGA to advise on the matter found that these products did not constitute such risk (Moran 2008, para. 23-5). Despite this advice, it was alleged that the TGA pressed forward with the revocation of Pan's licence and recall of Pan products (Moran 2008, para. 26). Notes taken during the meeting of the expert advisory group were allegedly destroyed by the TGA's Director of the Office of Complementary Medicines (Moran 2008, para. 21-2). Senior TGA staff were alleged to have misrepresented the risks posed by Pan products when seeking approval from the Minister and Prime Minister to close Pan's manufacturing facilities (Moran 2008, para. 27). It was also alleged in court documents (Pharm-a-Care Laboratories 2010, para. 40-1, 45, 47, 49, 52, & 70) that the TGA's audit report findings were illegitimate on the basis that they were essentially two separate audits—the TGA had simply combined the findings from two different audit periods, conducted between the 24th and 25th of February (referred herein as the February Audit) and the 7th and 14th of April 2003 (herein the April Audit), into a single audit report/finding. Even though the claim was denied by the defence on the grounds that the February Audit was an 'incomplete audit' (see Commonwealth of Australia & Others 2010, para. 40), the February Audit itself was problematic for the TGA's cooperative rationality of government because it denied Pan any prior opportunity to respond to and amend those deficiencies identified during the February Audit period. Combining the audit findings also appeared to have exaggerated the total number of deficiencies identified—it was alleged that at least one of the deficiencies identified in the February Audit had been rectified prior to the conduct of the April Audit, yet remained listed as a deficiency in the April Audit Report (Pharm-a-Care Laboratories 2010, para. 148(c) to (e)). The TGA—who were publicly condemned for the lack of action it took against Pan prior to the 2003 recall—were then criticised by Parliament for its heavy-handed response in dealing with Travacalm (Australia, Senate 2005b, pp. 159-60).

The Company Director, James Selim, brought a AU$200 million case against the Australian Government for negligence and abuse of power. In August 2008, the Commonwealth paid Selim

AU$55 million in an out-of-court settlement, but publicly stated that the payment should not be construed as an admission of fault (TGA 2008, para. 3). The Commonwealth also agreed to a further AU$67.5 million in an out-of-court settlement to the 162 creditors, distributors, and retailers financially impacted by Pan's collapse (Hall 2011, para. 2). In 2010, the *Therapeutic Goods Act* was amended to provide the TGA with immunity from civil sanctions. Section 61A of the Act now reads:

> No civil action, suit or proceeding lies against: (a) the Commonwealth; or (b) a protected person; in respect of loss, damage or injury of any kind suffered by another person as a result of anything done, or omitted to be done, by a protected person in relation to the performance or purported performance, or in relation to the exercise or purported exercise, of a protected person's functions, duties or powers under this Act or the regulations… [this] does not apply to an act or omission in bad faith … [or in] reference to a failure to make a decision.

Outside a very small number of well publicised cases, very little evidence exists of the TGA ever resorting to the use of civil or criminal penalties for breaches of the *Therapeutic Goods Act* since Pan. On many occasions when the TGA has administered a recall, suspended or revoked a licence, or a form of penalty, the TGA's decision has been overturned on appeal by the Administrative Appeals Tribunal (see *Aspen Pharmacare Australia Pty Ltd and Minister for Health and Ageing* (2012) AATA 362 & 376; *Ego Pharmaceuticals Pty Ltd and Minister for Health and Ageing* (2012) AATA 210; *Health World Limited and Minister for Health and Ageing* (2013) AATA 388). Back in 2009, Shirlow and Faunce (2009, p. 767) argued that this level of scrutiny may 'increasingly influence' TGA decisions to the point where 'decisions will be made in a context in which the concerns of public safety will come to be balanced equally against consideration of the financial impact of the decision on companies and industry'. Ultimately these conflicts 'could undermine the TGA's ability to pursue actions which protect the health of the Australian public yet cause detriment to the company against which they are taken' (Shirlow & Faunce 2009, p. 767).

4.3.2 TGA ENCOUNTERS WITH MERCK/MERCK SHARPE & DOHME (MSD)

The TGA's handling of Vioxx at the same time as the Travacalm incident raised serious concerns about the consistency of TGA enforcement, and the punishment and rewarding of compliance based on a regulatee's perceived cooperativeness. Vioxx, a prescription pain reliever (and COX-2 inhibitor) produced by the US company Merck and supplied in Australia by its subsidiary MSD, was granted approval by the TGA, like many other drug regulatory agencies at the time, based on a single short-term study (Vitry, Lexchin & Mansfield 2007, p. 736). This study showed that Vioxx had a small safety benefit compared with other non-steroidal anti-inflammatory drugs (NSAIDs) on the market

which were known to cause gastrointestinal side-effects—particularly an increased risk of stomach ulcers and gastric bleeding (Vitry, Lexchin & Mansfield. 2007, p. 736). However, the study did not compare Vioxx with other common forms of treatment (e.g. paracetamol, less selective NSAIDs, or cytoprotective agents) and registration data released by the United States' (US) Food and Drug Administration (FDA) showed that Vioxx had no clinical advantage over existing NSAIDs (Vitry, Lexchin & Mansfield 2007, p. 736). In 2000, a post-market study (known as the VIGOR study) conducted by the company found that participants taking high doses of Vioxx (at 50 mg per day) had half the gastrointestinal side-effects of participants using Naproxen in the comparative sample group, but a four-to-fivefold increase of myocardial infarcts[22] (Faunce, Townsend & McEwan 2010, p. 38). Merck originally attributed this increase to the aspirin-like effects of Naproxen (Faunce, Townsend & McEwan 2010, p. 39). Sceptics, however, argued that Naproxen could only reduce this cardiovascular risk by up to 30%, and therefore, could not explain an almost 500% increase in cardiovascular events (Holmes 2005, para. 116).

Since the VIGOR study 'did not provide any evidence of an increased cardiovascular risk' for the maximum dose prescribed in Australia (25 mg per day) (Australia, Senate 2005b, p. 160), Vioxx continued to remain available on the Australia market with very few safety warnings. The product information was amended voluntarily by the company 11 months after the findings of the VIGOR study were released, but some have claimed that the revisions minimised the cardiovascular risks posed by the drug.[23] No formal warnings were issued by the TGA until 2003 when it released an article in the Adverse Drug Reactions Advisory Committee bulletin. Again, the article appeared to minimise the cardiovascular risks associated with Vioxx by concluding that 'evidence for an association between rofecoxib and a risk of cardiovascular events is inconclusive and indirect' (Vitry, Lexchin & Mansfield 2007, p. 736). No larger safety trials were ever insisted on by the TGA—the TGA's Principle Medical Adviser was quoted saying that 'it's in dispute that we [the TGA] would have the power to force those studies once a drug is on the market' (Vitry, Lexchin & Mansfield 2007, p. 737).

In the US, Merck invested heavily in advertising Vioxx directly to consumers, spending approximately US$160.8 million in 2000 alone—more than PepsiCo had spent on advertising Pepsi in the same year (US$125 million) (Vitry, Lexchin & Mansfield 2007, p. 738). The company

[22] Heart attacks brought on by spasms of the coronary artery (Faunce, Townsend & McEwan 2010, p. 38).
[23] Vitry, Lexchin, and Mansfield (2007, p. 376) stated that the product information was simply amended to say that 'the risk of serious cardiovascular thromboembolic adverse events was significantly lower in patients receiving Naproxen'.

published sponsored articles[24] and engaged in ghost-writing practices,[25] all of which downplayed, and often neglected, the cardiovascular risks posed by the drug. In Australia, it was alleged that MSD trained drug reps to emphasise Vioxx's cardiovascular benefits and withhold information about the VIGOR study (Faunce, Townsend & McEwan 2010, p. 48). MSD also had its very own publication, *The Australian Journal of Bone and Joint Medicine*, which was found to have:

> the setup of a peer-reviewed, independent, journal… [h]owever it was neither peer-reviewed nor independent. It was effectively a highbrow means of promoting some of MSDA's products (including Vioxx) within the medical profession. The journal ostensibly had an editorial board, but there is reason to be sceptical about the reality of that institution: Dr Bertouch was named as a member of it, but he was unaware of that membership, and had never attended a meeting of the board (*Peterson v Merck Sharpe & Dohme (Aust) Pty Ltd* (2010) FCR 180, para. 296).

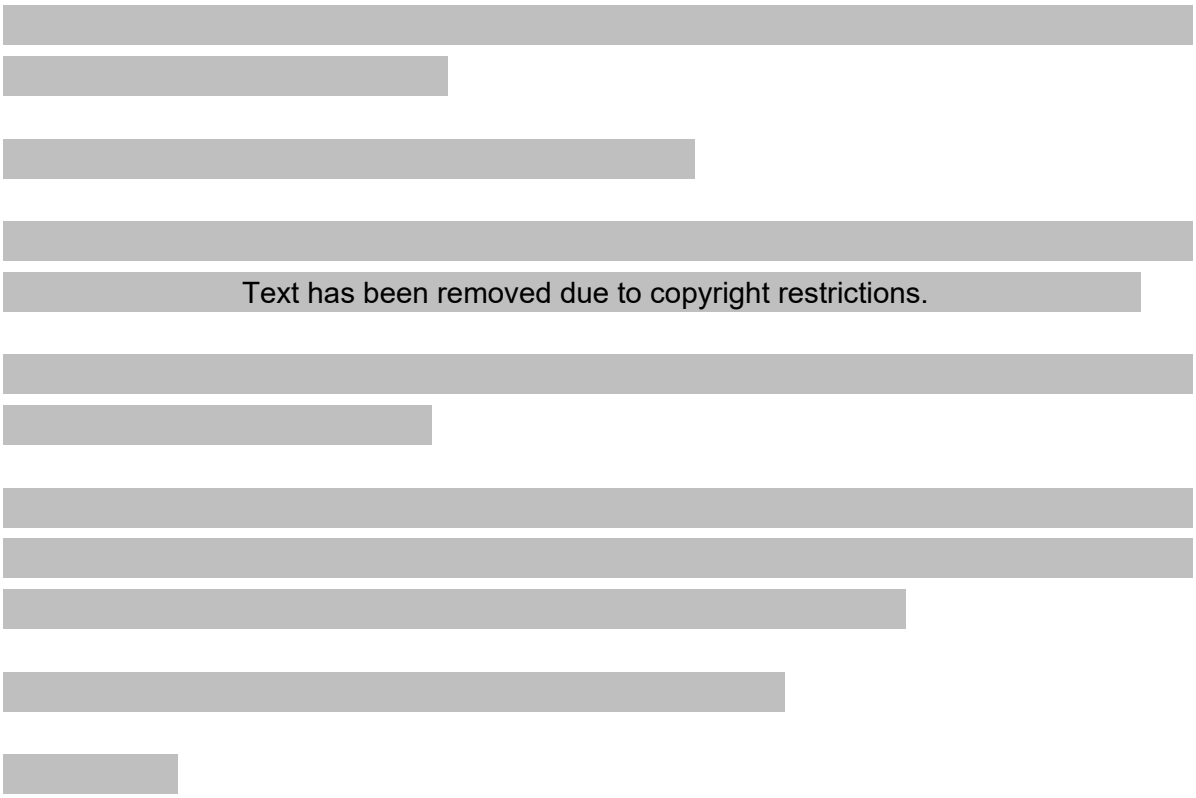
It was only after an independent cumulative meta-analysis, published in 2004, made up of 18 randomised controlled trials and 11 observational studies, that it was concluded that an increased cardiovascular risk was evident for patients taking both the 25 and 50 mg dose of Vioxx as early as 2000, and that 'the effect was both substantial and unlikely to be a chance finding' (Jüni, Nartey, Reichenbach, Sterchi, Dieppe & Egger 2004, p. 5). The study also concluded that the Naproxen effects initially detected in the VIGOR study were 'probably small' and 'not large enough to explain the findings of the VIGOR study' (Jüni et al. 2004, p. 5). It was on these grounds that Merck and MSD conducted a voluntary recall of the drug. Prior to this recall, the TGA had received 959 adverse drug reaction reports in relation to Vioxx, 319 were classified as serious, 18 of these were described as heart attacks (Australia, Senate 2005b, p. 160). In the US, it is estimated that Vioxx caused anywhere between 88,000 and 140,000 cardiovascular events (Faunce, Townsend & McEwan 2010, p. 47). This is in stark contrast to the 66 adverse drug reaction reports and 19 hospitalisations resulting from *all* products manufactured by Pan Pharmaceuticals in the 12 months preceding the recall of all of Pan's product lines (Australia, Senate 2005a, p. 156).

[24] For example, the article 'Cardiovascular Thrombotic Events in Controlled, Clinical Trials of Rofecoxib' published in the journal Circulation was written entirely by Merck employees and did not disclose the authors' interests (Faunce, Townsend & McEwan 2010, p. 47).

[25] Jeffrey Lisse was listed as the lead author on an article published in the Annals of Internal Medicine when 'Merck [had] designed the trial, paid for the trial, ran the trial … the initial paper was written by Merck and sent to me for editing' (Berenson 2005; as cited in Faunce, Townsend & McEwan 2010, p. 47).

4.3.3 THE TGA'S HANDLING OF PAN VERSUS MERCK AND MSD

While the Vioxx and Travacalm cases are by no means comparable in nature or seriousness, comparisons can be drawn between the cases based on the level of cooperativeness each company demonstrated towards the TGA and the TGA's subsequent response. Pan had made explicit attempts to obstruct the TGA from investigating the adverse reactions emanating from Pan products; the company and its CEO also had an extensive history of law and regulatory violations. On the other hand, Merck (and its subsidiary MSD) had largely complied with the spirit of Australian quality, safety and efficacy requirements; the company had voluntarily undertaken a post-marketing study, revised the product information in light of its findings, and withdrew its drug from circulation when compelling evidence of the drug's cardiovascular risks came to light—albeit, only after an independent study was conducted and definitively repudiated the conclusions drawn by the VIGOR study. MSD was fined AU$10,000 by Medicines Australia (formerly the Australian Pharmaceutical Manufacturers Association) in 2001 for unethical marketing practices in the promotion of Vioxx to healthcare practitioners (Vitry, Lexchin & Mansfield 2007, p. 739). This compares with Pan's licence suspension and eventual revocation, a world-wide recall of all Pan products, a AU$10 million fine, and jail terms for some of its employees. The lack of culpability, and balance of interest in favour of those companies which are cooperative, is best demonstrated by the following exert between Jonathan Holmes of the Four Corners (ABC) program and the TGA's Principle Medical Adviser Dr James McEwen:



Text has been removed due to copyright restrictions.

(Holmes 2005, para. 155-63).

Many of the safety risks posed by Vioxx could also be downplayed by the Australian Government on the basis that these types of risks are unpredictable and difficult to control. For instance, when questioned in a Senate Hearing on the TGA's response to Vioxx (a Class 2 Recall) compared with Pan Pharmaceuticals (a Class 1 Recall), Senator Patterson, the Health Minister at the time, explained that:

> Those adverse events [Pan] arose from quality control failures in manufacturing and are readily distinguishable clinically from unwanted events not caused by a medicine. In contrast, the role of Vioxx in increasing the rate of heart attacks was only established unequivocally through the conduct of a rigorous clinical trial and did not arise as a result of failures in manufacturing quality processes… The basis for that [Pan] recall related to assessed risks of deficient manufacturing and is not comparable to the basis for the recall of Vioxx (Australia, Senate 2005b, p. 160).

These cooperative and risk rationalities have reinforced and provided continued corroboration for a neoliberal governmentality. Regulatee cooperativeness and the unpredictability of risk reinforce the notion that government by the state should be minimal and that regulated entities should be responsible for their own governance. These rationalities of government, which are more neoliberal (rather than responsive and risk-based) in nature, ultimately help to shape the regulatory regime in ways which more closely align with a neoliberal governmentality, and therefore, the principle interests of the dominant hegemony.

4.4 SUMMARY

This chapter has analysed the historical emergence of risk-based and responsive regulation and a neoliberal governmentality within the Australian pharmaceutical regulatory regime. It was Australia's initial preoccupation with quarantine, and later, population health, which led to the formation of a biopolitics and rationality of government which prioritised the administration of the general public health interest over the private interests of industry. However, the capacity of this coalition of forces to articulate private interests as the general public health interest has allowed private interest issues to become an object of biopolitical concern. As a result, health administration

has increasingly been viewed in economic terms which has warranted the implementation of specific techniques and rationalities of government consistent with a neoliberal governmentality. Many of the key features of risk-based and responsive regulation theory which were compatible with neoliberal rationalities of government, particularly, risk and cooperative rationality, and graduated enforcement techniques, were therefore implemented in the regime with the intent of minimising forms of state intervention that inhibited the accumulation of capital. This neoliberal governmentality has had four major implications for the Australian pharmaceutical regulatory terrain. First, the decentralisation and delegation of Commonwealth powers led to the development of a specialised state apparatus in the form of the TGA—designed with the intent of making dint interventions in the regime on the part of the state in ways that would not be disruptive to capital accumulation. Second, the decentralisation and delegation of Commonwealth powers led to an increased reliance on technologies of agency which have empowered industry associations and sponsors to take primary responsibility for their own governance. Third, the deregulation of pre-market and post-market pharmaceutical regulation has increased the responsibility on individual consumers to play a greater role in regulating their own healthcare. Finally, technologies of citizenship were created through the formation of expert advisory committees to increase stakeholder participation in the regime. These transformations were willingly facilitated by the state—and by extension, the Department of Health and TGA.

As the cases of Travacalm and Vioxx demonstrate, cooperation and risk rationality have only entrenched neoliberal governmentality by reinforcing the notions that regulatees do cooperate and risks are unpredictable and outside of state control. These rationalities therefore provide continued support for the dominant ideology that state intervention in the regime should be minimal and that regulated entities must be responsible for their own regulation.

Chapter 5 builds upon this discussion by detailing the specific outcomes of this historical process. It outlines the regime's major players, the TGA's risk-based and responsive regulatory framework, and the processes involved in the pre- and post-market regulation of prescription and non-prescription medicine quality, safety, and efficacy, and advertising and promotion.

5 OVERVIEW OF THE AUSTRALIAN PHARMACEUTICAL REGULATORY TERRAIN

This chapter builds on *Chapter 4* by providing a detailed overview of the regulatory techniques currently used in the Australian pharmaceutical regulatory regime. These techniques are a direct product of the historical processes outlined in this previous chapter. This overview is organised in six parts. Part one begins by identifying the various social forces (or what I refer to as *players*) operating within the regime, briefly outlining their different roles and responsibilities. Part two provides a detailed overview of the risk-based and responsive regulatory framework employed by the Therapeutic Goods Administration (TGA). Because this framework is unique to the TGA and differs slightly in philosophy and design to risk-based and responsive regulation theory, it is necessary to explain how the TGA applies risk-based and responsive regulatory techniques in practice. Parts three and four are dedicated to providing an overview of the two-tiered medicine classification scheme which dictates how prescription and non-prescription medicines enter the market. Part four also details the processes involved in the licencing of Australian and overseas manufacturers prior to manufacturing prescription and non-prescription medicines for the Australian market. Part five is concerned with the post-market regulation of prescription and non-prescription medicines once they have entered the market. This section includes an overview of product testing and monitoring (e.g. adverse drug reaction (ADR) reporting, manufacturer inspections, laboratory testing, and compliance reviews), and advertising and promotional activities (e.g. evidence requirements, and pre-approval and complaints procedures). This chapter concludes with a summary of the current pharmaceutical regulatory terrain.

5.1 THE REGULATORY PLAYERS

Regulatory interactions, conventionally conceived, are usually characterised as a two-player game between regulator and regulatee (Ayres & Braithwaite 1992, p. 54). However, regulatory regimes—and the Australian pharmaceutical regulatory regime, in particular—are generally comprised of and shaped by a wide range of regulatory players. It is the overall structuration of these various players within the regulatory regime which dictates the authority of the regime's most dominant player or group of players. In the Australian pharmaceutical regulatory regime, these players can generally be organised into five different groups: government, industry, consumers, public interest groups, and healthcare practitioners and practitioner associations.

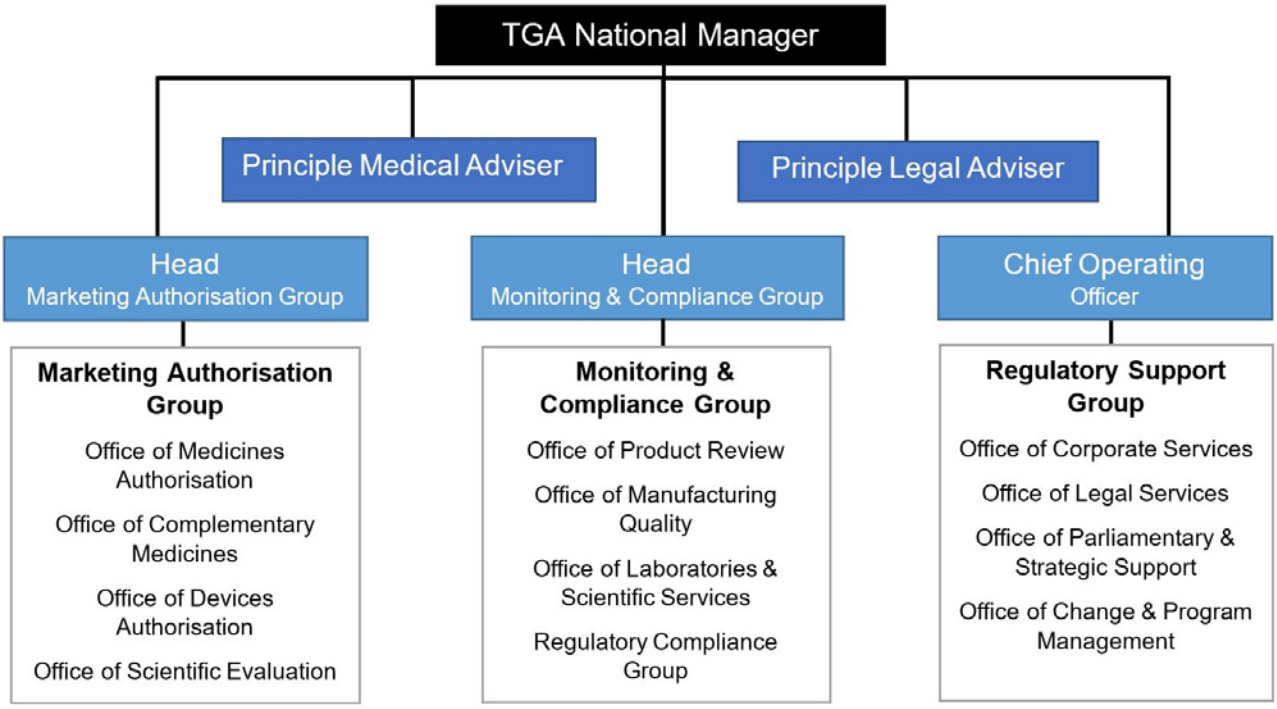
5.1.1 GOVERNMENT

The state's role in the pharmaceutical regulatory regime is generally limited to its national drug regulatory agency, the Therapeutic Goods Administration. This apparatus of the state is as a 'division' of the Australian Government's Department of Health (Australian National Audit Office 2004, p. 33), though it receives little funding from the state and operates on a 100% cost-recovery basis based on the fees it charges to sponsors. Prior to the reform of the regime (see 1.1), the TGA was made up of three internal units. These units comprised of: the Market Authorisation Group; the Monitoring and Compliance Group; and the Regulatory Support Group. The TGA is no longer composed of these units; as of 2018, the internal units of the TGA have been restructured and renamed to the Medicines Regulation Division, Medical Devices and Product Quality Division, and the Regulatory Practice and Support Division. Prior to this change, the Market Authorisation Group was charged with all things concerning pre-market regulation; it undertook evaluations and approved applications for therapeutic goods imported, exported, manufactured, and/or supplied in Australia (TGA 2014e, p. 3). The Monitoring and Compliance Group was charged with all things post-market regulation, including the monitoring of manufacturer compliance, while the Regulatory Support Group contained the TGA's legal, financial, information technology, communications, parliamentary, and human resource services (TGA 2014e p. 3). These units reported to the executive branch of the TGA. The executive branch, which has remained unchanged following the reform of the regime, is composed of the Head of each group, the Chief Operating Officer, the Principle Medical and Legal Adviser, and the National Manager. The TGA's National Manager reports directly to the Secretary of the Department of Health (and the Secretary to the Minister for Health). A visual representation of the structure of the TGA is provided in *Figure 5.1*.

The TGA also had several expert advisory committees which provided recommendations to the Market Authorisation and Monitoring and Compliance Groups. These committees were not only an extension of the TGA apparatus, but also functioned as technologies of citizenship, or, 'instruments of 'voice' and 'representation' by which … [certain] groups can enter into the negotiation over needs' (Dean 2010, p. 196). These expert advisory committees included: the Advisory Committee on Prescription Medicines (ACPM) (formally the Australian Drug Evaluation Committee); the Advisory Committee on Non-prescription Medicines (ACNM); the Advisory Committee on Complementary Medicines (ACCM) (formally the Complementary Medicines Evaluation Committee); the Advisory Committee on the Safety of Medicines (ACSOM) (formally the Adverse Drug Reactions Advisory Committee); the Therapeutic Goods Committee (TGC); and the Australian Therapeutic Goods Advisory Council (ATGAC). All committees, excluding ACSOM, TGC, and ATGAC, provided

recommendations on the approval of therapeutic goods for the Australian market. Of the three remaining committees, ACSOM was responsible for making recommendations to the TGA on the safety of a given medicine, and its risk assessment and management. These recommendations would have a major bearing on whether a product remained or would be removed from the market. The TGC provided advice to the Minister for Health on issues relating to manufacturing, labelling, and packaging standards. The ATGAC was a stakeholder committee established to provide advice and oversee the implementation of the TGA's *Blueprint Reforms* (see 1.1). All these committees, excluding the ACCM, have now been disbanded. In 2017, the ACPM, ACNM, and ACSOM were replaced by a new committee called the Advisory Committee on Medicines (ACM).[26]

Figure 5.1: The Structure of the TGA.



Closely adapted from TGA (2012f, p. 17).

5.1.2 INDUSTRY

Industry comprises of the sponsors of therapeutic goods (i.e. the companies which import, export, manufacture, and supply therapeutic goods in Australia, or which arrange the import, export, manufacture, and supply of goods in Australia)[27] and their industry associations. Sponsors are

[26] This was due to a recent push by the Australian Government to 'streamline' the advisory committee structure.
[27] The term sponsor can also apply to an individual who imports, exports, manufacturers, or supplies goods, or arranges the import, export, manufacture, or supply of goods in Australia. However, in the context of this research, the term sponsor will mean a company.

charged with their own self-regulation. They are also incentivised to monitor and be mindful of how other sponsors are operating within the regime because defiance of the regime can undermine competition and the capacity of other sponsors to compete. Most sponsors are represented by one of six industry associations; those representing the prescription and non-prescription medicines industry are: Medicines Australia (MA) (formerly the Australian Pharmaceutical Manufacturers Association); the Australian Self-Medication Industry (ASMI) (formerly the Proprietary Medicines Association of Australian); Complementary Medicines Australia (CMA) (formerly the Complementary Healthcare Council); and the Generic Medicines Industry Association (GMiA). Industry associations perform regulatory functions on behalf of the regulator (and state), mostly in product advertising and promotion (see 5.5.2). Industry associations also provide an additional layer of regulation by monitoring the self-regulation of their members against their own regulatory norms or codes of conduct. These technologies of agency—sponsor self-regulation and industry association regulation—form a multi-tiered system of governance commonly referred to as *networked governance* within the literature (Braithwaite 2008, pp. 1-4).

5.1.3 CONSUMERS

As individuals, consumers are rarely elevated to the level of player within the regulatory literature because their participation in regulatory regimes is generally perceived to be limited to the groups and organisations that represent them. Assumptions that individual consumers can and do participate in meaningful ways is usually based on normative conceptions of their abilities—that they have the level of knowledge necessary to participate and all operate in ways that represent the common interest. However, it is necessary to elevate consumers to the level of player for the purposes of this thesis—irrespective of whether they can in fact participate meaningfully or behave rationally according to neoliberal rationalities of government—because consumers in the Australian pharmaceutical regulatory regime are generally perceived to be capable of their own government. In certain aspects of the regulatory regime, consumers are responsibilised. They are often charged with making their own decisions about their healthcare without needing to consult with a healthcare practitioner, particularly when it comes to medicines which are widely available without prescription. Consumers are primarily responsible for their own health education—in fact, their failure to become health literate is generally perceived as an indictment on their duties to become fully autonomous and responsibilised citizens (Petersen 1997, p. 198). Consumers are also tasked with important regulatory functions—namely, to report any ADRs they experience and false and misleading claims they come across. These technologies of agency make consumers integral to the operation of the Australian pharmaceutical regulatory regime, irrespective of whether they perform this role well.

5.1.4 PUBLIC INTEREST GROUPS

Public interest groups represent a concentrated interest which enables them to act on behalf of consumers. Public interest groups are well placed to oversee the interactions of regulator and industry (i.e. to ensure the regulator performs its role and that industry complies), and to hold the regulator and industry to account in ways which are not always possible for individual consumers (i.e. they have staying power which enables them to hold out longer for more tangible rewards). The two most dominant public interest groups in this space are the Consumers Health Forum (CHF) and Australian Consumers' Association (CHOICE). Representatives from CHF and CHOICE sit on a number of regulatory committees, including many of the TGA's expert advisory committees. This representation intends to empower these public interest groups so that they are active participants in the regulatory regime.

5.1.5 HEALTHCARE PRACTITIONERS AND PRACTITIONER ASSOCIATIONS

Healthcare practitioners include *registered* healthcare practitioners, such as medical practitioners, clinicians, nurses, pharmacists, and dentists, as well as *unregistered* healthcare practitioners who are not required to be registered under Australian law, such as naturopaths and other complementary medicine practitioners. Healthcare practitioners and practitioner associations act as mediators between the regulator and industry, but unlike consumers and public interest groups, their specialist (medical) knowledge places them in a greater position to hold the regulator and industry to account, and therefore, to pressure the regulator and industry to substantiate certain actions. Since healthcare practitioners also act as intermediaries to consumers (i.e. they advise and prescribe medicines to consumers), industry have added incentive to keep practitioners on side. Healthcare practitioners regulate their own interactions with industry according to codes of conduct developed by practitioner associations. These technologies of agency contribute to the overall system of networked governance in the pharmaceutical regulatory regime. Practitioner associations regulate practitioners' compliance with the code of conduct and will field complaints regarding inappropriate conduct with industry. There are numerous practitioner associations operating in Australia, including the Australian Medical Association (AMA), the Royal Australian College of General Practitioners (RACGP), and the Australian Dental Industry Association (ADIA).

5.2 REGULATORY FRAMEWORK

The TGA employs a combination of risk-based and responsive regulation. The TGA first uses risk-based techniques to prioritise enforcement towards those regulatory sites which pose the greatest risk

to the regulatory regime. It then uses responsive regulatory techniques to guide its response to risks within these spaces, and to escalate its response when initial responses are unable to compel compliance from regulatees.

5.2.1 RISK-BASED APPROACH

The TGA regulates for two types of risk: those risks inherent to the product (*product risks*) and those risks posed by regulatees who fail to comply with regulatory requirements (*compliance risks*) (TGA 2012h, p. 6). This means that medicines with greater product risk receive more oversight than those medicines with a lower product risk. The regulated entity's attitude towards compliance, and therefore their likeliness to comply with the regulatory requirements, also determines the degree to which regulation is prioritised; those sponsors which are perceived by the TGA to be intentionally non-compliant receive greater oversight than those sponsors which the TGA has perceived to be unintentionally non-compliant and voluntarily compliant (see *Figure 5.2* below for an overview).

Figure 5.2: Overview of the TGA Approach to Compliance Risk.

Regulated Entity's Attitude towards Compliance			
Voluntarily Compliant	**Accidentally Non-Compliant**	**Opportunistically Non-Compliant**	**Intentionally Non-Compliant**
Committed to doing the right thing.	Trying to do the right thing but does not always succeed.	Does not want to comply but will if made to.	Chooses not to comply.
Self-regulating.	Ineffective and/or developing a system of self-regulation.	Resistant to self-regulation.	No self-regulation.

TGA's Response			
Help and Support	**Inform and Advise**	**Correct Behaviour**	**Enforcement Action**
Help to maintain compliance.	Help to become compliant.	Deter by detection.	Deter by punishment.

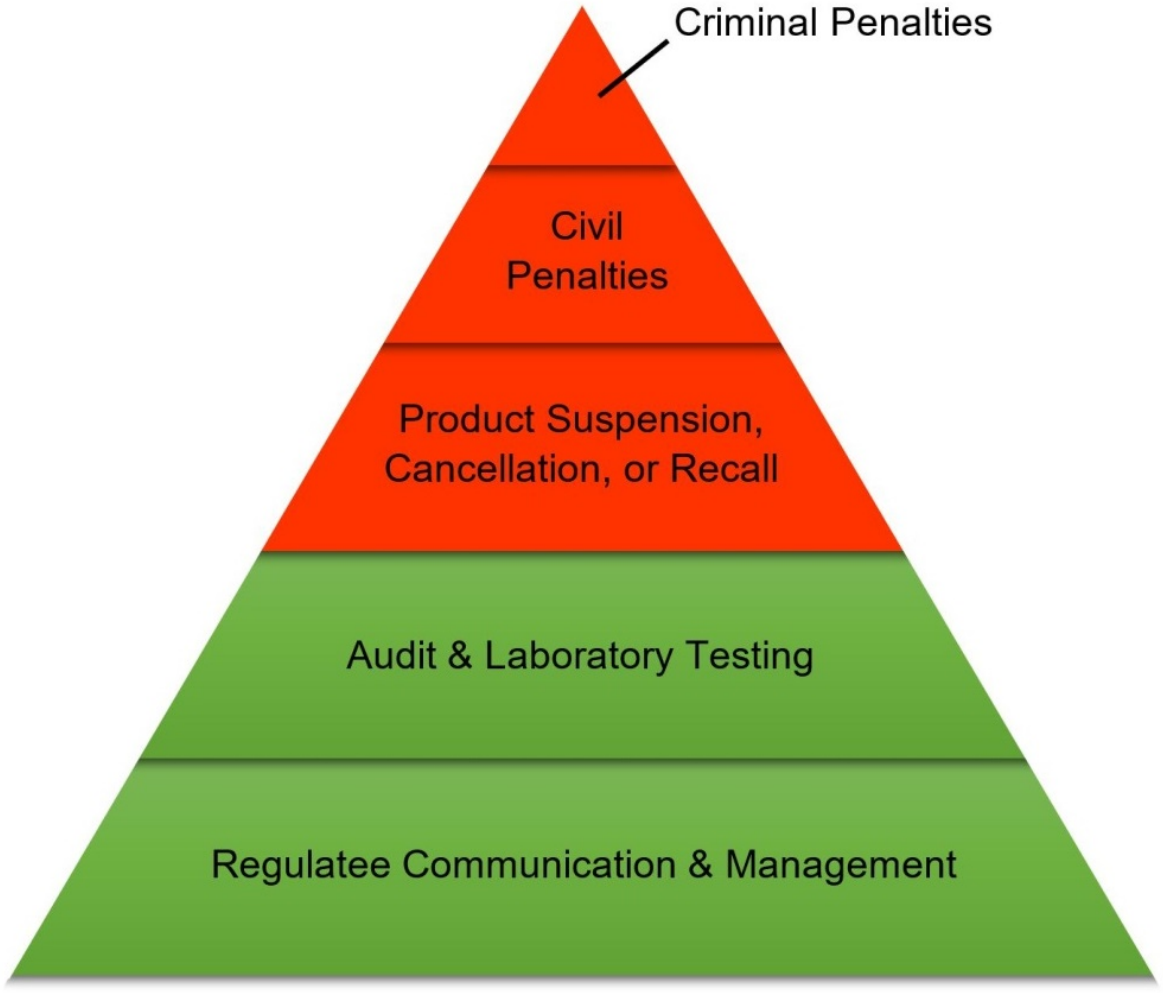
Closely adapted from TGA (2012h, p. 9).

5.2.2 RESPONSIVE APPROACH

The TGA also uses a suite of tools of increasing severity to compel compliance from regulatees. Since 'the majority of regulated entities intend to comply' (TGA 2012h, p. 8), the TGA first tries to encourage regulatees to comply voluntarily with regulatory requirements. When this encouragement fails, the TGA then resorts to more punitive measures, such as 'restrictions or warnings, suspensions

or sanctions and cancellations … [and] criminal or civil court action' (TGA 2017e, p. 59). This hierarchy of responses, or graduated technique of government, is depicted in the TGA's enforcement pyramid (see *Figure 5.3*). Unlike the original enforcement pyramid, the TGA enforcement pyramid lacks the uppermost, non-discretionary levels which are necessary for channelling regulatory action towards the pyramid's base.

Figure 5.3: The TGA Enforcement Pyramid.



Closely adapted from TGA (2012h, p. 8 [original colour]).

5.3 MEDICINE TYPES

In Australia, medicines are classed as either a *registered* or *listed* medicine. It is this classification, or risk rationality, which determines the degree of oversight a medicine receives throughout its life cycle.

5.3.1 REGISTERED MEDICINES

Medicines deemed high-risk and containing scheduled substances[28] are classed as registered medicines. Two different categories of registered medicines currently exist in Australia: low-risk registered medicines, or non-prescription medicines, which include over-the-counter analgesics, cough and cold preparations, and complementary medicines containing scheduled substances; and high-risk registered medicines, otherwise known as prescription medicines (Wong 2001, p. 6). Low-risk registered medicines are categorised as Schedule 2 and 3 substances under the *Poisons Standard 2013* (Cwlth)[28] and are obtainable from a supermarket or pharmacy. High-risk registered medicines contain ingredients that are classified as Schedule 4, 8, or 9 substances (see footnote 9) and can only be obtained by prescription.

5.3.2 LISTED MEDICINES

Medicines which are lower in risk compared with low and high-risk registered medicines are classified as listed medicines. The majority of listed medicines are complementary medicines, such as herbal medicines, traditional medicines, vitamins, nutritional supplements, and homeopathic and naturopathic medicines (Wong 2001, p. 6). Unlike registered medicines, listed medicines are used to treat non-serious and self-limiting conditions: they contain low dose, low-risk ingredients that are less likely to pose self-medication and safety risks to consumers. By law, listed medicines can only contain ingredients which have a long history of use and well-established quality and safety profiles; they cannot contain any of the scheduled substances specified in the *Poisons Standard* or substances which are otherwise restricted under Part 4 of Schedule 4 of the Therapeutic Goods Regulations 1990 (Cwlth) (Harvey 2012; TGA 2011d; Wong 2001). Listed medicines are also only able to contain low-risk indications to promote health maintenance or enhancement (TGA 2011d, p. 17).

5.4 PRE-MARKET REGULATION

Under the *Therapeutic Goods Act 1989* (Cwlth), all therapeutic products[29] prior to their import to, export from, manufacture, and/or supply in Australia must be placed on the Australian Register for Therapeutic Goods (also referred to as the Register or ARTG). The steps involved in the TGA's pre-

[28] These are substances identified under the Poisons Standard 2013 (Cwlth) as being one of the following: a pharmacy medicine (Schedule 2); a pharmacist-only medicine (Schedule 3); a prescription-only medicine or prescription animal remedy (Schedule 4); a cautionary substance (Schedule 5); a poison (Schedule 6); a dangerous poison (Schedule 7); a controlled drug (Schedule 8); or a prohibited substance (Schedule 9). The Schedule 1 label is currently not in use.
[29] Excluding exempt goods.

market scrutiny of medicines varies depending on whether a medicine is registered or listed (and therefore, the extent to which it poses a risk to consumers).

5.4.1 MEDICINE REGISTRATION

Prior to approval and registration on the ARTG, all registered medicines must undergo a pre-market evaluation by the TGA to assess evidence of the *quality* (i.e. formulation, composition, design, manufacture, and presentation of the medicine), *safety* (i.e. strength, toxicity, effects with prolonged use, adverse effects, self-medication risks, and seriousness of the medical condition(s) for which the drug is indicated), and *efficacy* (i.e. clinical and statistical significance of benefit) of the medicine (TGA 2011d; *Therapeutic Goods Act 1989* (Cwlth); Therapeutic Goods Regulations 1990 (Cwlth)). The type of evidence assessed by the TGA typically includes quality data (i.e. data on its chemical composition, consistency and reliability, sterility, and impurity), nonclinical data (i.e. its pharmacology and toxicology), and clinical data (i.e. from clinical studies or trials) which is supplied by the sponsor as part of the application (TGA 2011d, p. 15).[30] The data is evaluated by technical staff within the TGA and is compiled into three separate reports, each of which are examined by the TGA delegate[31] for final approval. The delegate can seek added advice and a review of the data supplied by the TGA from one of the TGA's independent statutory advisory committees. Prior to the regime's reform, advice specific to medicines could be obtained from the ACPM, ACNM, ACCM, or ACSOM. Copies of the evaluations are provided to the sponsor so that they can address any issues which arose during the review process and which might require the submission of additional data (TGA 2011d, p. 15). When the application is finally approved by the TGA delegate, sponsors receive a Certificate of Registration and an AUST R identification number which must be displayed on the product packaging.

The risks posed by the product may warrant certain conditions being imposed on the sponsor by the TGA at the time of approval. For example, the TGA may declare that the medicine can only be supplied under certain conditions (e.g. for hospital use or for specific indications only), or that it be manufactured in certain ways (e.g. by particular manufacturers only or under specific manufacturing conditions) (TGA 2011d, p. 16). The TGA can also prescribe that certain information, such as product safety warnings, be displayed on medicine labels (black-box warnings) and on Product Information (PI) or Consumer Medicines Information (CMI) so that the risks associated with the product are

[30] Sponsors of generic registered medicines need only provide evidence which establishes a medicine's therapeutic equivalence to an existing registered medicine (TGA 2011d).
[31] A representative appointed by the Secretary of the Department for Health to act on their behalf.

clearly communicated to consumers and healthcare practitioners. Sponsors of new registered prescription medicines (or new chemical entities) are also required to develop and adhere to a Risk Management Plan (RMP) as a means of monitoring, responding to, and minimising the risks posed by their product prior to marketing. This technology of performance often involves developing an overview of the safety profile of the medicine, a risk minimisation plan, and a pharmacovigilance (or adverse events response) plan (TGA 2011d, p. 16). The TGA may also stipulate that sponsors conduct additional post-marketing safety and efficacy studies and carry out educational programs to inform healthcare practitioners (TGA 2017c, p. 11). While all RMPs must be authorised by the TGA prior to approval, a sponsor's adherence to a RMP is not actively monitored by the TGA (2017c, pp. 9-11).

If the TGA rejects an application for registration, sponsors can appeal the decision. Appeals are first handled internally by the TGA—the TGA simply reconsiders the application and determines whether the original decision should be overturned. If the application is rejected a second time, the sponsor can then appeal the decision with the Secretary for the Department of Health or to the Administrative Appeals Tribunal (AAT)—an apparatus of the state which independently reviews the decisions made by Australian Government departments and agencies.

In the 2014 financial year, registering a new chemical entity cost sponsors a minimum of AU$221,400 as well as an annual fee—AU$6,585 for biological medicines and AU$3,955 for non-biologics (TGA 2014c, pp. 5-6). To register a non-prescription medicine in the same period required a AU$3,525 application and evaluation fee, and a AU$1,350 annual fee (TGA 2014c, p. 7).

5.4.2 MEDICINE LISTING

Unlike registered medicines, listed medicines are not subject to a pre-market evaluation by the TGA. Instead, sponsors are responsibilised; they are made to determine a medicine's degree of conformity with regulatory requirements autonomously. Sponsors self-assess the eligibility of a medicine for listing via the TGA's web-based electronic listing facility (ELF), a gatekeeping software, which, during the course of an application, determines electronically whether a product fits within the prescribed parameters for listing (Harvey 2012, p. 92). As part of the application, sponsors are required to provide details such as the product's name, manufacturer, and steps to be performed by the manufacturer, the product's route of administration, dosage, ingredients, indications, and warnings (TGA 2016a, pp. 57-8). Currently, the ELF allows sponsors to select from a list of ingredients which have been pre-approved by the TGA. The ELF also allows sponsors to select from either a list of standard indications or enter in their own unique indications using free text fields (TGA 2016a, p. 44). The TGA does not physically assess the efficacy of each indication proposed in the

application—that 'there is any evidence to show that the ingredient in the listed medicine is effective in the way claimed by the sponsor' (TGA 2013d, p. 2). However, the ELF does have the capacity to scan applications for restricted and prohibited terms.[32] Once a product's details are entered onto the ELF, and the software has scanned the application for restricted or prohibited statements, sponsors are directed to complete a Statutory Declaration. As part of the Statutory Declaration, sponsors are required to agree to several conditions, including that they *hold* evidence to support each indication listed in the application (TGA 2016a, p. 58).[33] While sponsors are legally bound to hold this evidence, 'the type and level of evidence required is not specified in the law' so 'a sponsor may base their certification on whatever evidence they believe appropriate' (Australian National Audit Office 2011, pp. 51-2), including evidence of a medicine's traditional use. Upon completion of the Statutory Declaration, the application is forwarded to the TGA's Business Management Unit and sponsors are required to pay an application fee (TGA 2016a, p. 56). When the payment has been finalised, a process which takes no longer than two days and is most often instant, the sponsor receives a Certificate of Listing and an AUST L number which must be displayed on product packaging (Australian National Audit Office 2011; TGA 2016a). The promptness of the listing process means that there is little opportunity for the TGA to delay the approval of an application to verify the information provided by the sponsor (Australian National Audit Office 2011, p. 71).

In the 2014 financial year, a medicine could be listed on the ARTG for AU$760 in application fees and AU$965 in annual fees (TGA 2014c). Failure to list *or* register a medicine can attract a maximum penalty of up to 4,000 penalty units[34] or 5 years imprisonment for criminal offences, and up to 50,000 penalty units for civil offences (under s. 19B(1) to (4) and 19D(1) of the Act).

5.4.3 LICENCING OF MANUFACTURERS

The product manufacturer nominated by the sponsor at the time of listing or registration must be licensed by the TGA prior to the product's listing or registration. Carrying out a step of manufacture without a licence—either because a licence is not current, or the licence does not authorise the

[32] While the ELF can scan for restricted and prohibited terms, the free text fields still allow sponsors to make claims which are often deemed inappropriate or extravagant for listed medicines. The TGA has indicated that some sponsors also 'game' the system intentionally by entering information into the ELF to identify which terms will prohibit applications from being accepted (Australian National Audit Office 2011, p. 80). The TGA is currently debating whether it would be feasible to have sponsors select from a list of permitted indications only, a scheme which remains the subject of ongoing public consultation (TGA 2016a, p. 45).

[33] Sponsors must also certify that the medicine is being manufactured by a licensed manufacturer in accordance with the Code of Good Manufacturing Practice, and, that the medicine only contains those ingredients (substances) that the TGA has already pre-approved and deemed to be low-risk (Australian National Audit Office 2011, p. 70).

[34] In 2014, a penalty unit was equivalent to AU$170.

carrying out of that step—is a violation of sections 35 and 35A of the Act and can attract a maximum criminal penalty of 4,000 penalty units or up to 5 years imprisonment, or civil penalty of 50,000 penalty units. As part of the licensing process, manufacturers are required to adhere to a Code of Good Manufacturing Practice (GMP). The Code of GMP used in Australia is modelled on the Guide to GMP operating under the international Pharmaceutical Inspection Convention and the Pharmaceutical Inspection Cooperation Scheme (known jointly as PIC/S). GMP applies to all aspects of the manufacturing process; to all personnel, premises, equipment, documentation, steps of manufacture, processes of quality management and control, contract manufacture and analysis, complaints handling, and product recall (Low, Hattingh & Forrester 2010).

Australian-based manufacturers usually undergo a TGA onsite audit to determine their compliance with the Code of GMP (TGA 2011d). Following the lodgement of the application, which requires the payment of an application (AU$940) and inspection fee (AU$615 per hour), the manufacturer will undergo a site inspection by an inspector or group of inspectors from the TGA (2013c & 2014c). The inspection leads to the production of an inspection report. If the inspection report identifies any practices which are inconsistent with the Code of GMP, corrective action by the manufacturer and a follow up inspection by the TGA must be undertaken before the manufacturer can be issued with a Certificate of compliance (TGA 2013b).

Overseas manufacturers must also obtain a licence to manufacture products for the Australian market. This licence is usually granted through clearance under a Mutual Recognition Agreement (MRA) or a compliance verification, or through a TGA onsite audit (TGA 2011d). A licence under a MRA is automatically granted to manufacturers based in countries recognised as having near-identical standards of GMP to those used in Australia (TGA 2011d). This currently includes all manufacturing facilities in Europe, members of the European Free Trade Association,[35] Canada, and Singapore (TGA 2011d). Under the MRA scheme, all post-licencing authorisations, inspections, and certifications are carried out by the national regulatory authority of the country in which the manufacturer is based (European Agency for the Evaluation of Medicinal Products 2003). A licence issued under a compliance verification requires the TGA to assess the GMP certificates and inspection reports supplied by the manufacturer as part of the initial application to determine whether they were issued in line with Australian standards (TGA 2011d). Put simply, a compliance verification involves a desk-top audit. This type of clearance is automatically extended to those manufacturers based in countries which endorse the Pharmaceutical Inspection Convention and the Pharmaceutical

[35] This includes Iceland, Lichtenstein, Norway, and Switzerland (European Free Trade Association 2018).

Inspection Cooperation Scheme (PIC/S),[36] as well as those manufacturers in New Zealand (TGA 2011d). The TGA conducts onsite audits for manufacturers in those countries that are not recognised by the TGA as having compatible GMP standards (TGA 2011d). These types of audits are usually only conducted as a last resort in circumstances where MRA or compliance verification cannot be granted (TGA 2011d).

5.5 POST-MARKET REGULATION

Following listing or registration, products are monitored on either a statutory, co-regulatory, or self-regulatory basis. The degree to which products are monitored is again determined on a risk basis.

5.5.1 PRODUCT TESTING AND MONITORING

Product quality, safety, and efficacy are typically monitored through adverse drug reaction (ADR) reports, quality control measures and manufacturer inspections, random and targeted laboratory testing, and random and targeted compliance reviews (TGA 2011d).

5.5.1.1 Adverse Reactions and Event Monitoring

ADR monitoring forms an integral part of post-market regulatory activities because it is used to affirm the safety profile of a medicine following its use within the general population. This monitoring is necessary for both registered and listed medicines. Registered medicines are approved based on the outcomes of phase III clinical trials, which are often of limited duration (i.e. they are not long enough to detect ADRs which occur with extended use), size (i.e. they do not contain enough patients to detect less common or rare ADRs), and diversity (i.e. do not contain a wide range of participants which is truly reflective of the makeup of the population), and on the basis that sponsors collect further data on the safety of the medicine post-registration. Listed medicines are approved without having to undergo a pre-market evaluation, and even though they are only able to contain pre-approved, low-risk ingredients, they can be prone to safety and quality risks because of poor manufacturing practice.[37]

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[36] This includes Argentina, Austria, Belgium, Canada, Cyprus, Czech Republic, Estonia, Finland, France, Greece, Hungry, Iceland, Ireland, Israel, Italy, Latvia, Liechtenstein, Lithuania, Malaysia, Malta, Netherlands, Norway, Poland, Portugal, Romania, Singapore, Slovak Republic, Slovenia, South Africa, Spain, Sweden, Switzerland, Ukraine, United Kingdom and USA (PIC/S 2014).

[37] For instance, listed medicines are often found to contain prescription-only ingredients and contaminants (Coghlan, Maker, Crighton, Haile, Murray, White, Byard, Bellgard, Mullaney, Trengove, Allcock, Nash, Hoban, Jarrett, Edwards, Musgrave & Bunce 2015). Listed medicine sponsors also have a reputation for having low levels of compliance with random and targeted laboratory testing (see s. 5.5.1.3).

ADRs can either be reported online via the TGA website or through the Adverse Medicine Events telephone hotline run by the independent, not-for-profit organisation the National Prescribing Service (NPS).[38] Reports received through the TGA website and Adverse Medicine Events hotline are entered into the Australian Adverse Drug Reaction Reporting System (ADRS), a database used by TGA staff to identify and flag safety concerns associated with all listed and registered medicines on the ARTG (TGA 2016f). If a reaction is common and matches an expected reaction to the product, no further action is taken by the TGA (Australian National Audit Office 2004, p. 103). However, when the reaction is uncommon or unexpected, the TGA will conduct an independent evaluation of the product to determine its role in causing the adverse reaction (TGA 2016f). From here, the TGA can direct sponsors to undertake further post-marketing studies, add warnings to product labelling or PI or CMI, place restrictions on the product's use within the population, cancel the product's listing or registration, or recall the product entirely (TGA 2016f).

Sponsors are legally required to report all serious ADRs to the TGA within 15 days of receiving information about an ADR (TGA 2017e, pp. 11-4). Significant safety issues are required to be reported in less than 72 hours (TGA 2017e, pp. 11-4). A sponsor's failure to comply with a condition of registration or listing (s. 21A(5) to (8) and 21B(2)) and notify the Secretary of an ADR (s. 29A(1) and 29AA(1)) can attract a maximum penalty of up to 4,000 penalty units and/or up to 5 years imprisonment for criminal offences, and up to 50,000 for civil offences under the *Therapeutic Goods Act*. There are currently no mandatory reporting requirements for other stakeholder groups under the Act.

Data indicates that sponsors are by far the largest reporters of ADRs. In 2015, up to 54% of all ADR reports received by the TGA came from sponsors (TGA 2016e, p. 5). Of the remaining ADR reports, 15% originated from State and Territory Health Departments, 14% from hospitals and hospital pharmacies, 6% from community pharmacies, 4% from general practitioners, and 4% from consumers (TGA 2016e, p. 5). Low rates of reporting among consumers and healthcare practitioners can be explained by the fact that ADR reporting procedures are highly complex, consumers and healthcare practitioners are more likely to make reports directly to sponsors rather than the TGA, and ADR reporting remains voluntary for healthcare practitioners (see *Chapter 7* for more of this type of discussion).

[38] The NPS is funded by the Department of Health and provides medicines information and resources to consumers and healthcare professionals (Low, Hattingh & Forrester 2010, p. 22).

5.5.1.2 Quality Control Measures and Manufacturer Inspections

In accordance with the Code and PIC/S Guide to GMP, manufacturers are required to document: all activities relating to GMP (i.e. a Site Master File); the requirements which products or materials must conform to during the course of manufacture (i.e. Specification Instructions); the materials, equipment, and computerised systems used during the course of manufacture and instructions for their use (i.e. Manufacturing Formulae, Processing, Packaging, and/or Testing Instructions); standard operating procedures (SOPs); the instructions on performing and recording certain operations (i.e. Protocols); evidence of the types of actions undertaken to comply with instructions, such as records of the history of each batch of product (e.g. Manufacturing Records); the results from product or material testing, along with an evaluation of their level of compliance with specifications (i.e. Certificates of Analysis); and the conduct of any exercises or investigations, together with their results, conclusions, and/or recommendations (i.e. Reports) (PIC/S 2017, pp. 17-8). Failing to document these activities constitutes a breach of a manufacturing licence and can attract a maximum penalty of up to 4,000 penalty units and/or 5 years imprisonment for criminal offences, and 50,000 penalty units for civil offences under s. 35B(1) to (4) and 35C of the *Therapeutic Goods Act*.

In addition to these internal review mechanisms, the TGA will perform regular onsite inspections of a manufacturer's facilities to ensure a manufacturer's ongoing adherence with GMP. Inspection frequency is determined not only by the degree of risk posed by the product, but also by the compliance rating of the manufacturer based on the compliance ratings the manufacturer has received on previous inspections. Those businesses with a low compliance rating and which produce products of a higher degree of risk, receive more frequent inspections than those businesses with more acceptable compliance ratings and which produce lower risk products. Inspection frequency can also be influenced by: changes in corporate structure; product changes approved by a national regulatory authority; warnings issued by a national regulatory authority; ADR reports; product recalls; random or targeted laboratory testing results; and tip-offs received from informants (TGA 2011d, pp. 32-3). This information is also used to determine whether an audit will be unannounced or announced (TGA 2011d, p. 34). A guide to the frequency of TGA audits is depicted in the inspection matrix in *Table 5.1*.

TGA licensed manufacturers based in Australia, along with all overseas manufacturers who were unable to obtain GMP clearance through a MRA or compliance verification, are subject to this auditing scheme.

Table 5.1: TGA Inspection Frequency Matrix for Medicines and Blood, Tissue and Cellular Therapies (in Months).

Risk Category	Re-Inspection Period (in Months)					
	Compliance Rating					
	Acceptable					Unacceptable
	3 x A1	2 x A1	A1	A2	A3	
Registered Medicines						
High	36+	36	24	18	12	Determined by Review Panel
Medium	36+	36	30	20	12	Determined by Review Panel
Low	36+	36	36	24	12	Determined by Review Panel
Listed Medicines						
Low	48+	48	42	30	18	Determined by Review Panel

Closely adapted from TGA (2013e) and (2016d).

Inspections can be carried out by an individual inspector or a group of inspectors and are most often announced; manufacturers are typically notified by phone and then by formal letter shortly before an inspection is due to commence (TGA 2013c, p. 15). At the time of inspection, manufacturers are required to supply: prior inspection and closeout reports; documents certifying the steps of manufacture (i.e. site authorisations); certificates outlining the conditions of licensing (or equivalent certificates and clearances for overseas manufacturers); records of products recalled or tested by the TGA's Office of Laboratories and Scientific Services (OLSS) between audits; records of products entered onto the ARTG between audits; and the Site Master File (TGA 2013c, p. 15). Inspections begin with a meeting between the TGA inspector(s) and the manufacturer's management team (TGA 2013c, p. 16). The inspector(s) then collate information on the manufacturing facility through interviews with the facility's personnel, by observing manufacturing processes and procedures, and by reviewing company files and computerised systems (TGA 2013c, pp. 16-7). Once the inspection is completed, the findings are presented in hard copy to the manufacturer at a closing meeting. The TGA inspector(s) outlines any conformity issues that were identified during the course of the inspection and the types of consequences the manufacturer can expect if these nonconformities are left unrectified—namely, the suspension or revocation of their licence, or civil or criminal penalties (TGA 2013c, pp. 17-8). The meeting also provides the manufacturer with the opportunity to discuss conformity issues directly with inspectors to resolve or clarify the issues identified (TGA 2013c, p. 18).

A formal Inspection Report is provided to the manufacturer by email following the inspection. The Inspection Report provides an overview of the data obtained from the inspection, a summary of the

types of activities conducted, a description of the findings and observations that were made, as well as a list of the nonconformities the manufacturer is required to rectify (TGA 2013c, p. 18). The report also provides the manufacturer with an overall compliance rating (i.e. an *acceptable* A1, A2, A3, or an *unacceptable* rating) which is used as a basis to determine the frequency of future onsite inspections.

Historically, conformity issues identified by the Inspection Report have been classified as either a *critical*, *major*, or *other* deficiency. Critical deficiencies are defined as those practices or processes which either produce or may potentially cause physical harm to the end user, or, constitute a form of fraud, such as the misrepresentation or falsification of quality control data (TGA 2013c, p. 19). A major deficiency is defined as those practices or processes which do not conform with marketing authorisation or conditions of licensing, and which constitute a major deviation from GMP standards. These deficiencies are noncritical in the sense that they are unlikely to cause physical harm to the end user or be deemed a criminal offence under law. Other deficiency classifications simply refer to those types of deficiencies which cannot be classified as either critical or major, but still demonstrate a departure from standards. Nonconformities can be grouped together and classified as a major deficiency even if each of the conformity issues identified do not constitute a major deficiency in their own right (TGA 2013c, p. 19). According to an Australian National Audit Office (ANAO) audit report, 60% of inspections conducted at prescription medicine manufacturing sites between 2008 and 2013 revealed at least one major deficiency (ANAO 2014, p. 69). Only 1.1% of inspections revealed critical deficiencies (see *Table 5.2* for further details) (ANAO 2014, p. 69). Audit data for other types of sites (i.e. for manufacturers of over-the-counter and complementary medicines) has been made available to the public since 2014 but is only expressed as a single figure for all manufacturers.

Table 5.2: Deficiencies identified by the TGA at sites manufacturing prescription medicines between 2008–2013.

Classification	No. of Deficiencies	% of Inspections with this deficiency	Total
Critical	More than 1	1.1%	1.1%
Major	More than 10	3.6%	
	6 to 10	8.4%	
	1 to 5	46.8%	58.8%
Other	More than 10	44.8%	
	1 to 10	51.3%	96.1%

Closely adapted from ANAO (2014, p. 69).

In 2015, 210 domestic and 121 overseas inspections were conducted by the TGA for manufacturers of medicines, blood, tissue, and cellular therapies (TGA 2016c). As of the 31st of December 2015, there was a total of 445 domestic and 440 overseas manufacturing sites for medicines, blood, tissue, and cellular products within the TGA's scope of inspection (TGA 2016c).

5.5.1.3 Targeted and Random Laboratory Testing

The TGA's OLSS conducts both targeted and routine laboratory testing on samples of listed and registered medicines to ensure their compliance with quality and safety standards (TGA 2015a). These tests are conducted in addition to the quality control measures employed by manufacturers as part of their GMP requirements. The frequency at which products are tested by the OLSS is determined on a product and compliance risk basis—registered medicines, and those medicines subject to an ADR report or complaint therefore tend to be prioritised over other types of medicines.

Prior to 2014, failure rates for prescription and non-prescription medicines during laboratory testing had not been published in the public domain with any real consistency. Since the Transparency Review, the TGA has attempted to increase its reporting of its regulatory activities as well as the enforcement of listed medicines quality and safety. As a result, not only have we seen greater reporting of laboratory test results, but we have also seen a higher proportion of complementary medicines (high compliance risk) tested than over-the-counter medicines (which have a higher product risk than complementary medicines) (see *Table 5.3*). Those medicines which are more likely to undergo laboratory testing, however, continue to demonstrate the lowest failure rates across all medicine types.

Table 5.3: Product Samples Which Failed OLSS Laboratory Testing in 2014.

Product Type	Total Tested	% Fail
Prescription Medicines	917	1%
Over-the-Counter Medicines	35	22.9%
Complementary Medicines	272	27.8%
Unregistered Products[39]	352	68.8%
Total:	**1,576**	

Closely adapted from TGA (2015a, p. 47).

[39] Unregistered products include all products which fit the definition of therapeutic good under the Therapeutic Goods Act but are not registered or listed on the ARTG. This includes medicines such as unregistered complementary medicines produced by authorised (legal) manufacturers as well as counterfeit medicines produced by unauthorised (illegal) manufacturers (TGA 2015a). The rate of failure for complementary medicines overall is therefore likely to be higher than what has been reported in this table.

5.5.1.4 Random and Targeted Compliance Reviews

To compensate for the lack of scrutiny listed medicines receive prior to approval, a proportion of listed medicines are selected to undergo a post-listing compliance review by the TGA. A compliance review involves a desk-top audit of those documents held by the sponsor which were not supplied at the time of listing. This list includes documentation in the form of the product's labelling, specifications, certificates of analysis, manufacturing formulae (particularly a list of the product's ingredients and their respective quantities), a summary of the evidence held by the sponsor to support the indications and claims of the product, and any supporting data (particularly in the form of Transmissible Spongiform Encephalopathy) (TGA 2016e).[40] Compliance reviews are either conducted at random (i.e. determined by computer at the time of listing) or are targeted (i.e. because of a complaint, a referral from within the TGA or by another regulatory authority, information published in the ARTG entry, or the prior compliance history of the sponsor) (TGA 2016e, p. 48). Sponsors of newly listed medicines receive automatic notification at the time of listing when their medicine is selected for a random review (ANAO 2011). The TGA aims to conduct reviews for 24% (or 688 out of 2,800) of all new ARTG listings each year (TGA 2011d, p. 34), although annual and half-yearly report data indicate that this number is much less.[41] In 2011, 10,000 complementary medicines were said to have active listings on the ARTG alone (ANAO 2011, p. 13).

Compliance reviews have revealed high rates of non-compliance among listed medicine sponsors over the past decade. In 2006, 75% (178 out of 237) of listed medicines which underwent a random compliance review were found non-compliant (ANAO 2011, p. 107). Similarly, over the 10-month period between July 2008 and April 2009, 70% of listed products which underwent compliance reviews were found non-compliant (ANAO 2011, p. 109). Approximately 90% (98 out of 110) of listed complementary medicines were found to be non-compliant[42] over the 9-month period between July 2009 and March 2010 (ANAO 2011, p. 109). These figures were consistent for both random and targeted products (see *Table 5.4* for a breakdown of these figures), and a substantial proportion of the

[40] Targeted reviews may require additional information to be supplied by the sponsor, including raw material specifications, certificates of analysis, the methodology and results of certain tests, importation permits or licences (particularly for the purposes for identifying prohibited substances), promotional and advertising material, and evidence of product efficacy (TGA 2016e).

[41] The TGA completed random and targeted reviews for 11% (or 222 out of 1,992) of all new listings in 2014 (TGA 2015a, pp. 17-9). Even if we were to include all reviews initiated by the TGA during this period (a total of 103 reviews) (TGA 2015a, pp. 17-9), this would still equate to just 16% (325 out of 1,992) of all new listings.

[42] According to the ANAO (2011, p. 109), 41.8% of non-compliant products were voluntarily removed from the ARTG by the sponsor. The remaining 58.2% were voluntarily rectified by the sponsor and continued to remain on the ARTG.

non-conformities were classed as *moderate* and *significant* breaches (ANAO 2011, p. 17). In 2014, a further 75% (123 out of 164) of listed medicines which underwent a random compliance review were found non-compliant (TGA 2015a, p. 19). *Table 5.5* reveals that a large portion of these conformity issues are a result of a failure to comply with labelling, advertising, and evidence requirements.

Table 5.4: Compliance Reviews of Listed Complementary Medicines Completed Between July 2009 and March 2010 (number of reviews, percentage).

Type of Review	Randomly Selected	Targeted	Total
No. of desktop compliance reviews completed.	31	79	**110**
No. of reviews **where full compliance** was found.	3 (9.6%)	9 (11.4%)	**12**
No. of reviews **where full compliance was not found**.	28 (90.3%)[43]	70 (88.6%)	**98**
a. Where the sponsor voluntarily corrected the deficiency.	25 (89.3%)	32 (45.7%)	**57**
b. Where the TGA cancelled the product at sponsor's request.	2 (7.1%)	35 (50.0%)	**27**
c. Where the TGA cancelled the product outright (without prior request).	1 (3.6%)	13 (18.6%)	**14**

Closely Adapted from ANAO (2011, p. 110).

Table 5.5: Compliance Issues Identified in Compliance Reviews of Listed Medicines Completed in 2014.

Compliance Issue:	No.	Fail Rate
Information provided in ARTG entry	7	3.7%
Manufacturing, quality and/or formation	14	7.4%
Labelling and/or advertising	83	43.9%
Evidence	39	20.6%
Safety	0	0%
Other	46	24.3%
Total:	**189**	**100%**

Closely Adapted from TGA (2015a, p. 21).

Conformity rates for those compliance reviews described exclude those medicines which had been cancelled by the sponsor upon the TGA's initial request for information and prior to the

[43] Of the products that were randomly selected and found to be non-compliant: 71% (20 out of 28) did not comply with basic labelling requirements or had labelling that may be misleading to consumers; 78% (22 out of 28) had manufacturing and quality issues; and 50% (14 out of 28) had made claims that could not be substantiated by evidence (ANAO 2011, p. 15).

commencement of the review.[44] When the sponsor voluntarily cancels a medicine, the TGA ceases their investigation into the product entirely (ANAO 2011, p. 110). Non-compliance rates could therefore be higher than those reported.

Of those reviews that were able to be completed and where non-compliance was found, the TGA most commonly issues the sponsor with a notice proposing to cancel the listing—a cooperative technique of government which aims to provide sponsors with an opportunity to address the conformity issue before the regulator escalates its response (TGA 2016e). Should the notice fail to generate compliance, the TGA can either suspend or cancel the product's listing on the ARTG or recall the product from the market entirely (TGA 2016e).[45] According to a recent TGA half-yearly report, 97.4% of all compliance actions against listed medicine sponsors following a post-market compliance review resulted in the issue of a proposal to cancel notice (TGA 2015a, p. 22). The remaining 2.63% of actions involved the direct cancellation of the medicine by the TGA without notice (TGA 2015a, p. 22). Of those products which received a proposal to cancel notice, 56.8% were rectified voluntarily by the sponsor, 27% were cancelled voluntarily by the sponsor, and 16.2% were cancelled by the TGA (TGA 2015a, p. 22). Although the TGA half-yearly performance report does not specify how long it takes sponsors to comply with a cancellation notice, data from the ANAO (2011, p. 106) indicates that it takes sponsors an average of 200 days to voluntarily cancel their listings.

5.5.2 PRODUCT ADVERTISING AND PROMOTION

Product quality, safety, and efficacy issues can also arise in the advertising and promotion of medicines—when advertising and promotional activities are conducted in ways that do not promote the quality and safe use of medicines, and when medicines fail to perform in the way they are claimed. *Figure 5.4* provides an overview of the various bodies involved in the regulation of medicines advertising and promotion. Direct-to-consumer advertising (DTCA) of prescription medicines in Australia is strictly prohibited by law (under s. 42DL(1)(f) of the *Therapeutic Goods Act*) because consumers are believed to 'lack adequate knowledge of [prescription] medicines and may be

[44] In 2014 alone, 62.1% of all compliance reviews initiated and subsequently abandoned by the TGA were terminated on the basis that the product was cancelled from ARTG by the sponsor prior to the commencement of the review (TGA 2015a, p. 15). The remaining 37.9% of reviews were abandoned on the basis that the medicine subject to the review had not yet been manufactured (TGA 2015a, p. 15).

[45] Listings can also be cancelled by the TGA without prior notice in those cases where the product could cause imminent death or harm, contains prohibited ingredients or substances, has been manufactured by an unlicensed person or company, and when a sponsor fails to respond to requests for information within 20 working days of the request (TGA 2016e).

negatively influenced by promotion' (Doran & Löfgren 2013, p. 20). Although DTCA of prescription medicines is strictly conceived as a statutory activity, DTCA complaints are usually handled by the industry association MA in the first instance. The DTCA of non-prescription medicines operates under a co- and self-regulatory arrangement, with the pre-approval and complaints-handling functions split across government (the Complaints Resolution Panel or CRP) and industry bodies (ASMI and CMA).

Figure 5.4: Authorities Responsible for the Regulation of Advertising of Prescription and Non-Prescription Medicines to Consumers and HCPs.

	Advertising to Consumers	**Advertising to HCPs**
Prescription	**Government Regulated** The TGA handles all complaints regarding DTCA of prescription medicines.	**Self-Regulated** MA handles complaints about MA members. All complaints regarding non-members are referred onto the TGA.
Non-Prescription Medicines	**Co-Regulated** The TGA's Complaints Resolution Panel handles complaints about DTCA in *specified media* (e.g. television, radio, newspapers, magazines, billboards, cinema or internet). ASMI and CMA handle complaints about DTCA in *other media* (e.g. leaflets, flyers, brochures, catalogues or letterbox drops) in relation to association members. Complaints about non-members in *other media* are referred onto the TGA.	**Self-Regulated** ASMI and CMA handle complaints about ASMI and CMA members respectively. All complaints regarding non-members are referred onto the TGA.

Closely adapted from ANAO (2011, p. 120).

Unlike DTCA, the promotion of prescription and non-prescription medicines to healthcare practitioners is permitted on the grounds that healthcare practitioners have the knowledge necessary to preclude any potential influence from industry and because 'the information asymmetry between drug manufacturers and doctors is less stark than that between suppliers and general consumers' (Doran & Löfgren 2013, p. 20). Prescription and non-prescription medicines promotion is an entirely self-regulated activity with little-to-no intervention by government *except* in those instances where a complaint concerns a non-association member (in which case, the complaint is forwarded to the

TGA).[46] Promotional materials must, however, conform to the requirements of the *Therapeutic Goods Act*,[47] the *Competition and Consumer Act 2010* (Cwlth),[48] and the applicable industry code of practice.

5.5.2.1 Types of Claims and Evidence Requirements

The claims used in product labelling, advertising, and promotion can be categorised as high-, medium-, or general-level claims. The strongest claims (high-level claims) can only be used by registered medicines and are used to assert that a product can treat, cure, manage, or prevent a disease or disorder, or treat a vitamin or mineral deficiency (Wong 2001, p. 6). Mid-strength claims (medium-level claims) can be used by both registered and listed medicines to assert that a product can promote health enhancement, reduce a disease or disorder, reduce the frequency of a discrete event, assist in the management of symptoms, and relieve the symptoms of a disease, disorder, or condition (TGA 2011a, p. 5). Low-strength claims (general-level claims) can likewise be used by both registered and listed products and are generally characterised as those claims which assert a product can assist with one's health maintenance, supplement one's vitamin or mineral intake, or relieve symptoms not specific to a named disease, disorder, or condition (TGA 2011a, p. 5).

Sponsors can use either scientific (i.e. quantifiable sources of support, such as clinical data, epidemiological data, and animal studies) and traditional evidence (i.e. sources which demonstrate the use of a substance for a health or medicinal purpose over three or more generations) in supporting these types of claims (Wong 2001, p. 21). While scientific evidence can be used to support all three types of claims, traditional evidence can only be used to support medium- and general-level claims. The reliance on traditional sources of evidence must be stated in product labelling and advertising (e.g. that a product has been *traditionally* used for this indication, or, that the stated claim is based on *traditional* use) (Wong 2001, p. 21).

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[46] When a complaint involving a non-member is received by an industry association, the association in receipt of the complaint will invite the non-member to have the complaint adjudicated by the association. If the non-member declines, the association can, if it so chooses, forward the complaint to the TGA for adjudication (TGA 2011b). The specific details as to how these complaints are handled and the sanctions (if any) that apply, have not been stated publicly.

[47] For prescription medicines, this means only advertising a medicine within the indications approved on the ARTG (s. 22(5)). For non-prescription medicines, this means advertisements which do not contain prohibited or restricted representations, or statements that suggest or imply the good has the recommended approval (endorsement) of the Australian Government (s. 42DL).

[48] Which includes the prohibition of advertisements containing false or misleading representations (s. 29 & 151).

5.5.2.2 Advertising Pre-Approval

Only certain types of DTCA require approval prior to publication. All DTCA of non-prescription medicines published in *specified media*, which includes broadcast media (e.g. television and radio), print media (e.g. newspapers, magazines, and academic journals), outdoor advertisements (e.g. billboards, bus shelters, taxi displays, and the sides and interiors of buses), or cinema advertisements, must receive pre-approval (TGA 2011b). The responsibility for approving advertisements in specified media has been delegated to the ASMI for over-the-counter (OTC) medicines and CMA for all complementary medicine advertisements. Under this arrangement, sponsors are required to submit all proposed broadcast media advertisements to the ASMI and all print, outdoor, and cinema advertisements to the CMA. All advertisements are reviewed against the *Therapeutic Goods Act*, Therapeutic Goods Regulations 1990 (Cwlth), and *Therapeutic Goods Advertising Code 2015* (Cwlth) and must not contain any of the prohibited[49] or restricted[50] representations specified under the TGAC. When approved, the advertisement receives an approval number which must be published on all print media (TGA 2011b). When an advertisement fails to receive approval, the sponsor can appeal the decision with the Minister for Health (TGA 2011b). Pre-approval fees are outlined in items 17 and 17A under Schedule 9 of the Therapeutic Goods Regulations and range from AU$120 to AU$1,115 depending on the medium. A further $205 per hour is charged by the ASMI and CMA for every additional hour of processing outside the allotted time.

At this stage, there is no formal requirement for non-prescription medicine DTCA appearing in *other media* (e.g. leaflets, flyers, brochures, catalogues, and letterbox drops) or in promotional materials directed to healthcare practitioners to obtain prior approval; sponsors are ultimately responsible for ensuring that all claims about a medicine conform with legislation and industry codes of conduct. However, under the ASMI Code of Practice, it is a condition of membership that all advertisements appearing in other media and directed to healthcare practitioners are reviewed by its Promotional

[49] A prohibited representation includes any reference to abortifacient action or the treatment, prevention, or cure of disease such as neoplastic, sexually transmitted disease (STD), HIV/AIDS or HCV, or mental illness (under s. 5(1) of the Therapeutic Goods Advertising Code 2015 (Cwlth)).

[50] A restricted representation includes any reference to any of the following: cardiovascular disease; dental and periodontal disease; diseases of the joint, bone, collagen, and rheumatic disease; diseases of the eye or ear which lead to blindness or deafness; diseases of the liver, biliary system, or pancreas; endocrine disease and conditions including diabetes and prostatic disease; gastrointestinal disease or disorder; haematological disease; infectious disease; immunological disease; mental disturbance; metabolic disorder; musculoskeletal disease; nervous system diseases; poisoning, venomous bites and stings; renal disease; respiratory diseases; skin diseases; substance dependence; or urogenital diseases and conditions (s. 5(2) of the Therapeutic Goods Advertising Code 2015 (Cwlth)). Unlike prohibited representations, which are outlawed entirely, a restricted representation can be made in an advertisement with the expressed approval of the Secretary of the Department of Health and with the endorsement of the Therapeutic Goods Advertising Code Council (TGACC) (the government body charged with maintaining the Therapeutic Goods Advertising Code).

Monitoring Panel (PMP) on an informal basis prior to publication. The PMP advises all ASMI members on how well an advertisement complies with the TGAC and how an advertisement can be improved prior to publication but does not provide a formal endorsement for an advertisement (ASMI 2016, para. 1). The cost of this evaluation is built into ASMI's annual membership fee, however industry association membership remains voluntary. Promotional materials for prescription medicines also does not require formal approval prior to publication (Wong 2001, p. 21).

5.5.2.3 DTCA Advertising Complaints (Non-Prescription Medicines)

The complaints process for the DTCA of non-prescription medicines contains facets of co-regulation and industry self-regulation.

The TGA's Complaints Resolution Panel (CRP) handles all DTCA complaints published in *specified media* (i.e. for all advertisements requiring prior approval). The panel consists of representatives from the CHOICE, ASMI, CMA, CHF, Pharmacy Guild of Australia (PGA), RACGP, and Medical Technology Association of Australia (MTAA), as well as a representative from the TGA. Complaints are submitted to the CRP in writing along with a copy of the advertisement (TGA 2011b). When a complaint is received, the CRP asks the advertiser—usually the sponsor of the product—to respond to the complaint in the form of a written submission (TGA 2011b). A copy of the response is sent to the complainant who can then challenge the response in a separate written submission (TGA 2011b). The CRP then presides over the investigation into the initial complaint and submissions by the sponsor and complainant to determine whether the complaint has merit (TGA 2011b). Should the CRP find for the complainant, the CRP can request that the sponsor withdraw the advertisement, publish a retraction, publish a correction, and/or withdraw the offending claim and provide the CRP with a written undertaking that they will not reuse the claim in future advertisements (s. 42ZCAI, Therapeutic Goods Regulations 1990 (Cwlth)).

The majority of complaints received by the CRP in the 2011-2012 financial year concerned complementary medicines (45.6%) and devices (42.6%) (TGACC 2011-2012, p. 12), and were often the result of a lack of evidence to support claims of efficacy (81.7%), misleading claims (43.3%), or the use of restricted or prohibited representations (10.2%) (TGACC 2011-2012, p. 14).[51] The highest

[51] Percentages have been calculated according to the total number of violations against certain aspects of the Therapeutic Goods Advertising Code in the 2011-2012 financial year. For lack of evidence to support efficacy, scores were calculated based on the number of s. 4(2)(a) violations. For misleading claims, scores have been calculated based on the total number of s. 4(1)(b), 4(2)(c), 4(4), and 4(5) violations combined. Prohibited and restricted representations have been calculated based on the total number of 5(1) and (2) violations.

proportion of complaints received concerned advertisements on the internet (73.5%), and in print (19.6%) and broadcast media (6.2%) (TGACC 2011-2012, p. 12). Although the CRP does not publish data on the proportion of complaints received for pre-approved advertisements (versus those which have not been pre-approved), O'Reilly (2016) claims that fewer than 0.05% of pre-approved advertisements are subject to a successful complaint. Most CRP determinations usually end with either a request to withdraw an advertisement (99.2%) or representation (93.6%) (TGACC 2011-2012, p. 12). Few determinations result in a retraction (26.3%) (TGACC 2011-2012, p. 12).

Should a sponsor fail to comply with the CRP's determination—which occurs in at least 20% of all determinations (TGA 2013a, p. 24)—the CRP can refer the complaint to the Monitoring and Compliance branch of the TGA. In these circumstances, the TGA can issue warning letters of various strengths or a Regulation 9 Order (i.e. a formal order to withdraw and/or publish a retraction, or rectify an advertisement) (ANAO 2011, p. 121). Should either of these cooperative techniques fail, the TGA can escalate their response by cancelling a product's listing or by referring the case on to the Commonwealth Director of Public Prosecutions (ANAO 2011, p. 127). The CRP can also go to the Secretary of the Department of Health directly to recover any advertisement in circulation and order its destruction (under s. 9(1), Therapeutic Goods Regulations 1990 (Cwlth)). Should a sponsor wish to appeal a CRP determination, they can make a written request to the Minister of Health within 90 days of the determination (under s. 48(2), Therapeutic Goods Regulations 1990 (Cwlth)). Sponsors can also make an application to the AAT should the Minster fail to overturn the decision (under s. 48(5) & (6), Therapeutic Goods Regulations 1990 (Cwlth)).

Data indicates that the CRP takes an average of 149 days, or five months, to issue a determination following the initial receipt of a complaint (ANAO 2011, p. 14). The TGA has also been criticised for its lack of timeliness in compelling compliance from sponsors following a sponsor's failure to comply with a CRP determination. Sponsors take an average of 183 days, or six months, to voluntarily rectify non-compliant and misleading advertising claims following the issue of a warning letter or multiple warning letters by the TGA (ANAO 2011, p. 127). It takes the TGA an average of eight and a half weeks to issue a sponsor with a Regulation 9 Order at the recommendation of the CRP (ANAO 2011, p. 130). The TGA also waits an additional three weeks to contact those sponsors who do not respond to the initial Regulation 9 Order (this allows sponsors time to cooperate with the TGA voluntarily) (ANAO 2011, p. 130). Prior to 2011, there were no records of the TGA ever having cancelled a product listing after a sponsor failed to comply with a Regulation 9 Order (ANAO 2011, p. 130). Legal action is also limited '[d]ue to the very low financial penalties currently available (a maximum of $6,600 for individuals and $33,000 for corporations) for advertising offences in the Act'

(ANAO 2011, p. 130). It is often believed that 'it is not cost-effective for the TGA to initiate a formal investigation of an advertising breach with a view of preparing a brief of evidence for consideration of prosecution by the Director of Prosecutions' (ANAO 2011, pp. 130-1). These issues have raised concerns about the deterrent impact of TGA and CRP sanctions (all of which are explored in *Chapter 6*).

The self-regulatory components of the non-prescription medicines DTCA regime comprise of voluntary codes of conduct and built-in complaint-handling mechanisms. ASMI and CMA handle complaints about DTCA published in *other media* (i.e. for all advertisements that do not require prior approval) for OTC and complementary medicines respectively, using separate industry codes of conduct (the ASMI Code of Practice and the CMA's Marketing & Supply Code of Practice), distinct complaints committees (ASMI's Marketing & Ethics Subcommittee and CMA's Complaints Resolution & Monitoring Committee),[52] and internal appeals processes.[53] ASMI and CMA also have mechanisms to pro-actively and randomly monitor those product advertisements not subject to pre-approval. Unlike the TGA and CRP, industry associations can issue monetary penalties in addition to demanding retractions, corrections, and enforceable undertakings to discontinue advertising. Prior to the reform of the regime, ASMI (2015, p. 45) and CMA (2015, p. 31) could issue fines of up to AU$50,000 for repeat breaches of the Code. Additional sanctions include the termination of industry association membership, and, for industry-generated complaints to ASMI's Marketing & Ethics Subcommittee, the reimbursement of out-of-pocket expenses to the successful party (ASMI 2015; CMA 2015). There is minimal reporting of complaints outcomes by the ASMI and CMA.[54] While

[52] The membership of ASMI's Marketing & Ethics Subcommittee comprises a lawyer with trade practices experience, a consumer, representatives from the RACGP and Pharmaceutical Society of Australia, up to three association members, and a TGA representative-observer (ASMI 2015, p. 38). The CMA's Complaints Resolution & Monitoring Committee comprises a complementary HCP, a consumer, up to six association members, the CMA's Chief Executive Officer, and a TGA representative-observer (CMA 2015).

[53] The membership of ASMI's Marketing & Ethics Subcommittee comprises of a lawyer with trade practices experience, a consumer, representatives from the RACGP and Pharmaceutical Society of Australia, up to three association members, and a TGA representative-observer (ASMI 2015, p. 38). The CMA's Complaints Resolution & Monitoring Committee comprises of a complementary HCP, a consumer, up to six association members, the CMA's Chief Executive Officer, and a TGA representative-observer (CMA 2015).

[54] The ASMI has an inconsistent history of publishing complaints outcomes in its Annual Reports. In the 2012-2013 Annual Report, 29.2% (82 out of 281) of the complaints received were found to have breached the ASMI Code of Practice and TGAC (ASMI 2012-13, p. 15). Of those products found in breach: 63% were due to the failure to include mandatory statements, that mandatory statements which were incorrect, or were not prominently displayed; 11% contained misleading information; 9% implied recommendation by a HCP; 6% did not include reference to an approved indication; 3% contained inappropriately presented scientific information; and 2% referred to a serious condition (ASMI 2012). The CMA only appears to publish data on key performance indicators (i.e. the number of complaints received, finalised, forwarded to the TGA, or referred on to the CRP). A large proportion of the complaints received by the CMA concern non-members (CMA 2013-14).

the ASMI and CMA will hear complaints regarding non-association members in *other media*, these complaints are more commonly dealt with and referred on to the TGA (ANAO 2011; TGA 2011b).

The TGA can investigate advertising breaches for non-prescription medicines directly irrespective of whether they were first subject to a complaint (ANAO 2011). The TGA currently accepts and investigates complaints regarding non-members of industry associations, retailers, distributors, and practitioners, as well as those complaints forwarded from the CRP, ASMI, or CMA (ANAO 2011). Most of the complaints dealt with by the TGA are those which have been referred from the CRP—approximately one third of all CRP determinations are referred onto the TGA due to the advertiser's failure to comply with a determination (TGA 2012a, p. 29). How these complaints are handled by the TGA remains relatively unclear due to the lack of transparency in this area. Much like the CRP, the TGA can take up to several months to complete a complaint investigation. Complaints made to the TGA directly between 2008 and 2010 took an average of 182 days, or six months, to resolve (ANAO 2011, p. 141).

5.5.2.4 DTCA Advertising Complaints (Prescription Medicines)

Complaints concerning the DTCA of prescription medicines are handled by MA. Although DTCA is prohibited under law, MA does allow DTCA in some forms. For example, un-named product advertisements (also known as de facto advertisements) are permissible under the MA Code of Conduct provided that the name or generic name of a product is not used in the advertisement (s. 9.4 and 9.5.2) and that the advertisement is primarily educational in nature (s. 9.5) (MA 2006). Under the *Therapeutic Goods Act*, DTCA of prescription medicines attracts up to 60 penalty units (AU$10,800). Under the MA Code of Conduct, DTCA attracts fines of up to AU$300,000.

5.5.2.5 Promotional Complaints

Promotional complaints are predominately handled by industry associations. Complaints concerning the promotion of non-prescription medicines are handled by the ASMI's Marketing & Ethics Subcommittee and CMA's Complaints Resolution & Monitoring Committee in the same way as DTCA advertising complaints. While the ASMI and CMA can hear complaints regarding non-association members, complaints can also be referred on to the TGA (ANAO 2011; TGA 2011b).

Like ASMI and CMA, MA is also charged with handling complaints for all promotional materials concerning prescription medicines. However, unlike sponsors of non-prescription medicines, all sponsors of prescription medicines are bound by the MA Code of Conduct as a condition of

registration on the ARTG (TGA 2011b). The MA Code of Conduct also has a much more extensive range of rules governing the interactions between industry and healthcare practitioners than the ASMI and CMA Codes—for example, the MA Code prohibits the giving of gifts and offers (MA 2015). MA sanctions include the withdrawal and/or cessation of promotional activity, the publication of correctional advertising, the distribution of corrective letters to healthcare practitioners, fines of up to AU$300,000, and the suspension or expulsion of MA membership (MA 2015). As with the ASMI and CMA, if a sponsor subject to a complaint is not a member of MA or refuses to abide by an MA determination, the complaint can be forwarded to the TGA for further action (ANAO 2011; TGA 2011b).

5.6 SUMMARY

The Australian pharmaceutical regulatory regime is comprised of a wide range of regulatory players: from the TGA and its expert advisory committees, to sponsors and their industry associations, consumers and public interest groups, and healthcare practitioners and practitioner associations. Sponsors are regulated using a combination of risk-based and responsive regulatory techniques of government. The TGA first regulates on a product and compliance risk rationality basis, based on the risks inherent to the product and the sponsor's risk of non-compliance. The TGA uses a graduated enforcement technique in responding to these risks; it begins by using low-level persuasive techniques before escalating to high-level punitive techniques when initial techniques fail to compel compliance. While the TGA is the principle regulator of this regime, regulatory functions are also carried out by the industry associations MA, ASMI, and CMA in the areas of DTCA advertising and promotion. In the advertising space, pre-approval occurs for all specified media by industry associations ASMI and CMA. Complaints handling is split across government (CRP) and industry bodies (ASMI and CMA) based on media type (specified or other) and industry association membership (non-member or member). DTCA of prescription medicines is usually considered the domain of the state; however, MA is usually the first point of call for the receipt of DTCA complaints. Promotion is regulated by MA, ASMI, and CMA, usually with little intervention by the state unless the complaint concerns a non-association member.

In addition to these technologies of agency, sponsors are also granted responsibilised autonomy to regulate not only their own conduct, but the conduct of others. Industry associations oversee sponsor self-regulation and use codes of conduct to establish further norms of industry conduct. Consumers, public interest groups, healthcare practitioners, and practitioner associations are tasked with ensuring

that both the regulator and industry carry out these functions in line with the greater public interest through technologies of agency and citizenship.

The following chapters, *Chapters 6* and *7*, investigates the extent to which this regime actually achieves compliance from sponsors and allows non-market non-governmental players, such as consumers, public interest groups, healthcare practitioners, and practitioner associations, to oversee the workings of the regime. Using a thematic analysis of public consultation submissions and interview transcripts, *Chapters 6* and *7* identifies stakeholders' perceptions towards the TGA and pharmaceutical regulatory regime, and those aspects of the regime which they perceive to be incapable of generating compliance from sponsors and participation from non-market non-governmental players.

6 REDUCED REGULATORY CAPACITY

Themes generated from the thematic analysis of consultation submissions and interview transcripts could generally be categorised under two over-arching themes: the limited capacity of the regulator, the Therapeutic Goods Administration (TGA), and by extension, the Australian pharmaceutical regulatory regime, to compel compliance from regulated entities (*Reduced Regulatory Capacity*); and, the limited capacity for democratic participation within the regime by non-market non-governmental players (*Reduced Capacity for Participatory Democracy*). This chapter, the first of two results chapters, begins by providing an overview of the themes derived from the consultation and interview data. It then explores the first of the two over-arching themes generated from the thematic analysis, *Reduced Regulatory Capacity*, and its implications for the operation of the pharmaceutical regulatory regime. The chapter finds that regulatory responses are often delayed and unlikely to occur, inconsistent, non-threatening, outweighed by the proceeds of non-compliance, and constrained due to the TGA's limited operational capacity. These features have decreased the deterrent impact of the risk-based and responsive regulatory techniques employed by the regime to the point where they are unlikely to achieve compliance from sponsors. This has rendered the regulator less able to intercede in the regime to address compliance issues, which, in turn, has allowed the regime to become shaped around the interests of the dominant hegemony in favour of capital accumulation.

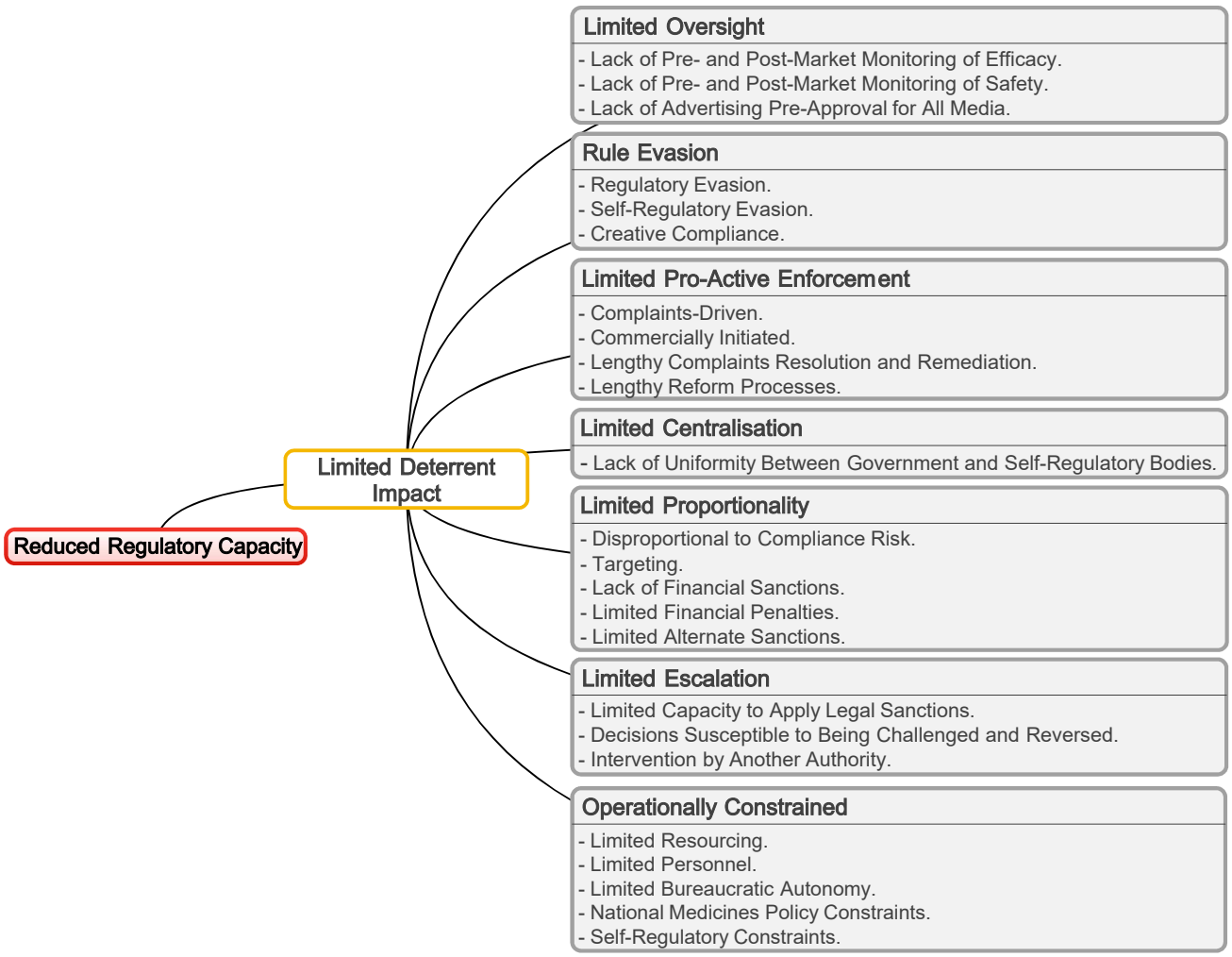
6.1 OVERVIEW OF RESULTS

Two principle themes were identified from the thematic analysis: the reduced capacity of the regulator and regime to compel compliance from sponsors (*Reduced Regulatory Capacity*); and, the reduced capacity for meaningful democratic participation within the regulatory regime by non-market non-governmental players (*Reduced Capacity for Participatory Democracy*). Each of these themes are explored separately in *Chapters 6* and *7*.

In those aspects of the regime where non-compliance is greatest, the capacity of the regulator and regime to achieve compliance from regulatees is severely reduced due to the low deterrent impact of the risk-based and responsive regulatory techniques employed *(Limited Deterrent Impact*). Stakeholders and interviewees perceived the deterrent impact of these regulatory techniques to be low due to: the low levels of oversight exercised by the TGA in these aspects of the regime (*Limited Oversight*); the capacity of regulatees to avoid being subject to the regime *(Rule Evasion*); the reactive nature of the regime *(Limited Pro-Active Enforcement*); the lack of uniformity between government and self-regulatory bodies *(Limited Centralisation*); the lack of proportionality (*Limited*

Proportionality); the TGA's inability to escalate enforcement beyond lower-level persuasive techniques (*Limited Escalation*); and the physical constraints placed on the TGA (*Operationally Constrained*). The relationship between these themes is depicted in *Figure 6.1*.

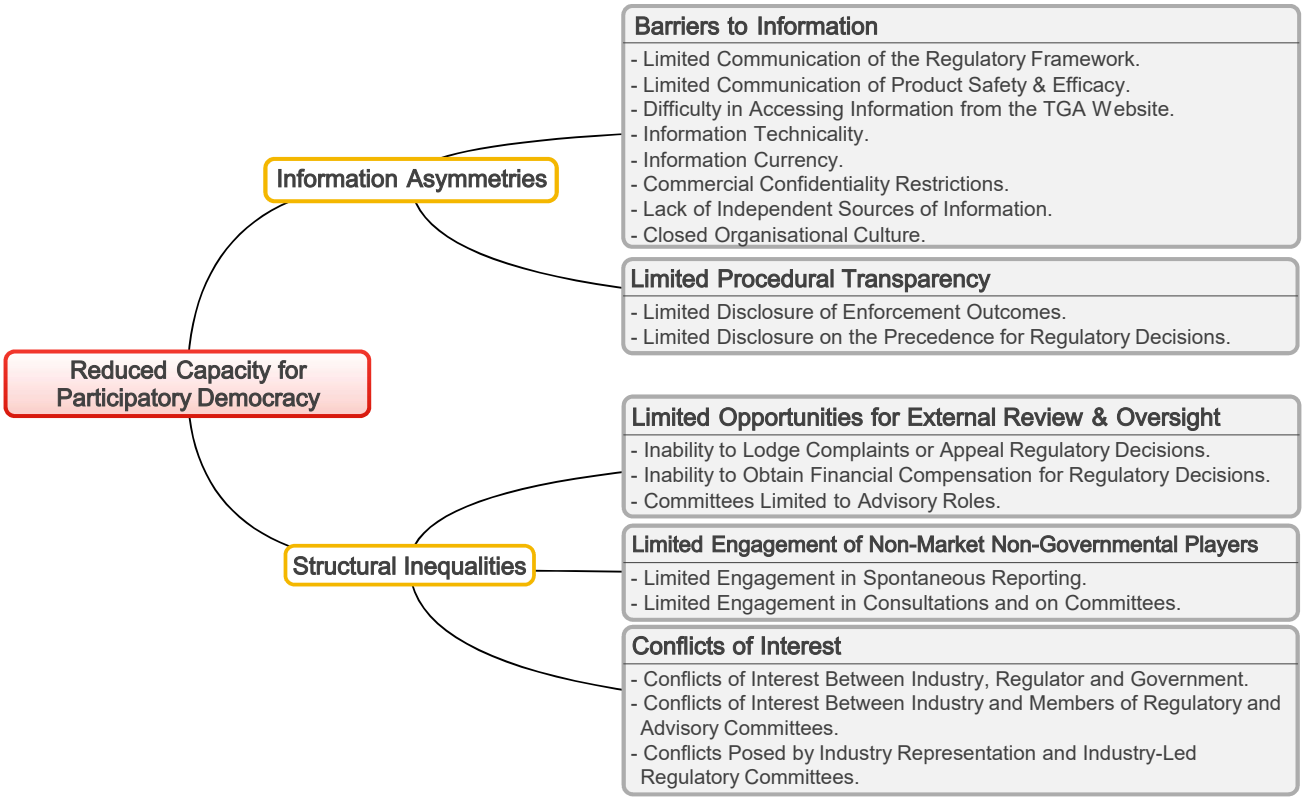
Figure 6.1: Themes Mapping the Reduced Regulatory Capacity of the Regulator and Regime.



The capacity for democratic participation within the regime is also reduced due to the presence of information asymmetries (*Information Asymmetries*) and structural inequalities (*Structural Inequalities*). Stakeholders and interviewees believed information asymmetries to be a direct consequence of informational barriers (*Barriers to Information*) and the lack of procedural transparency within the regime (*Limited Procedural Transparency*), which has rendered much of the information necessary for mobilising the individual and collective agency of non-market non-governmental players largely incomplete. Structural inequalities within the regime were perceived to be a direct result of the lack of external oversight the regime receives from non-market non-governmental players (*Limited Opportunities for External Review and Oversight*), the lack of engagement of non-market non-governmental players in the regime (*Limited Engagement of Non-Market Non-Governmental Players*), and apparent conflicts of interest between industry and other

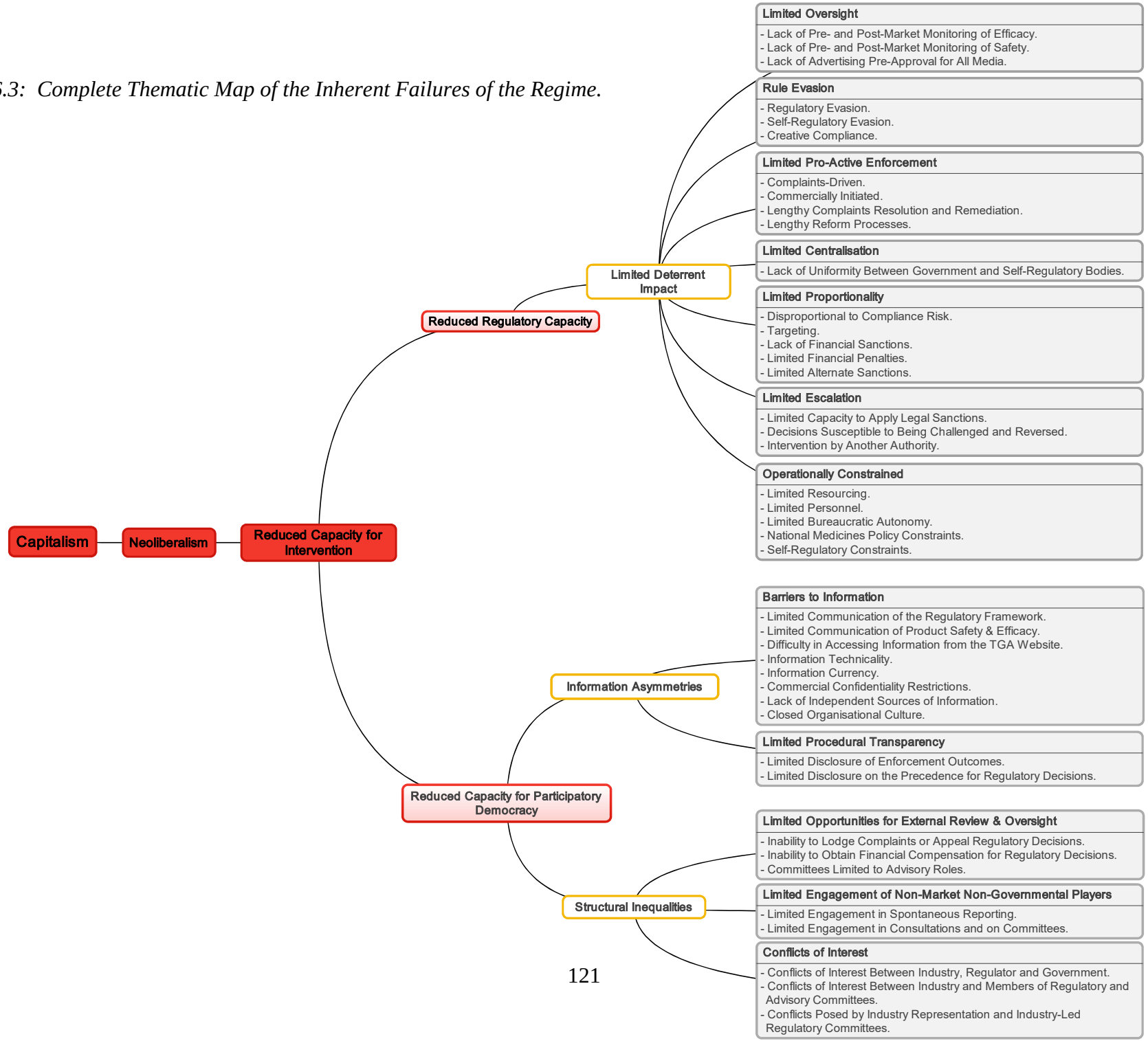
regulatory players (*Conflicts of Interest*). The relationship between these themes is depicted in *Figure 6.2*.

Figure 6.2: Themes Mapping the Reduced Capacity for Participatory Democracy Within the Regime.



The reduced capacity of the regime to generate compliance from regulated entities, along with the lack of opportunities for meaningful democratic participation, are a direct consequence of a combined risk-based and responsive regulatory technique of government. This technique of government does not adhere with the rationalities of risk-based and responsive regulation theory and more closely aligns with neoliberal rationalities of government that aim to limit forms of market intervention by non-market forces detrimental to the pursuit of capital (see *Figure 6.3*). This congruence with neoliberal governmentality has resulted in the production of a regime which limits forms of market intervention detrimental to the pursuit of capital, and therefore, a regime more supportive of hegemonic interests that favour capital accumulation.

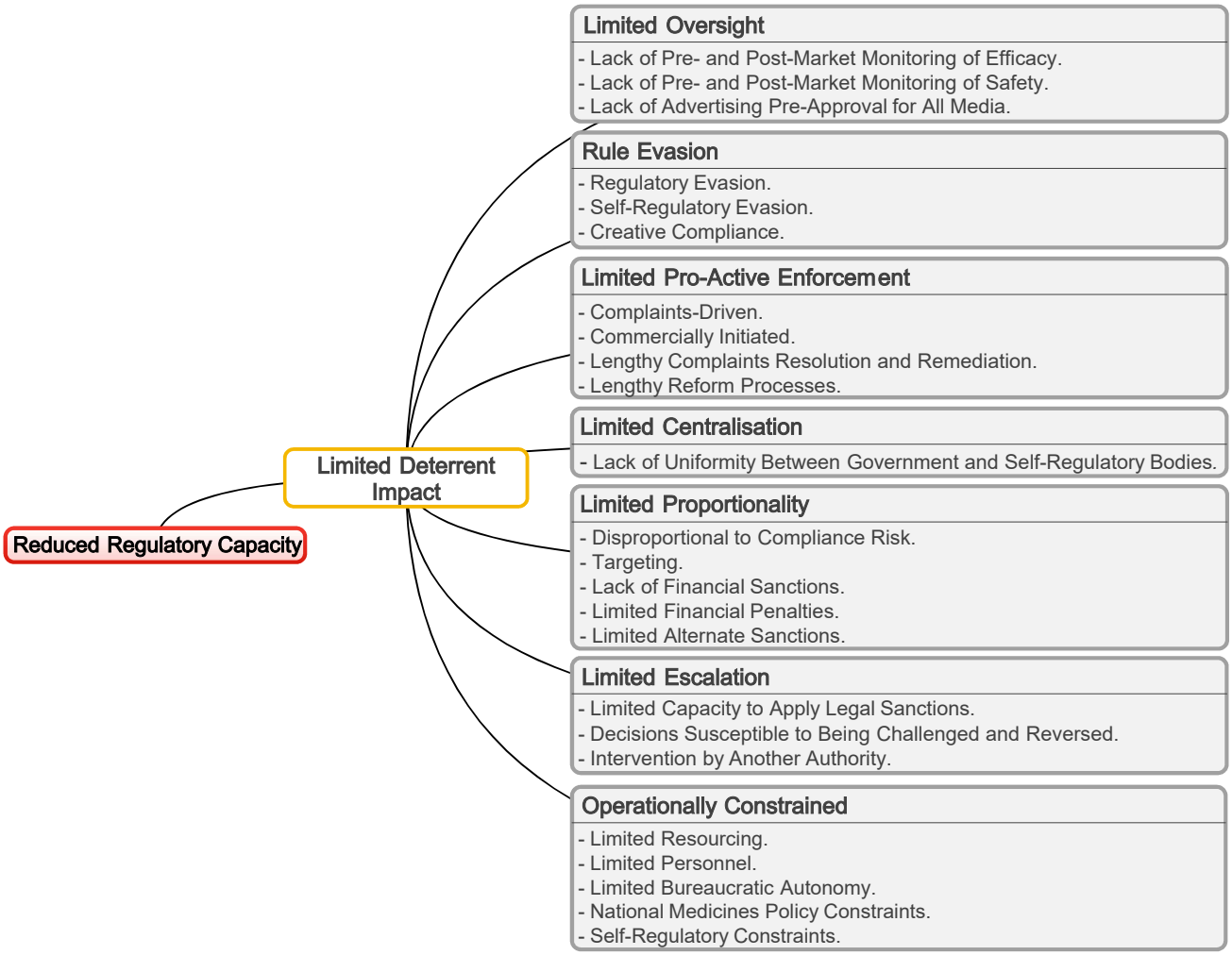
Figure 6.3: Complete Thematic Map of the Inherent Failures of the Regime.



6.2 LIMITED DETERRENT IMPACT

A lack of oversight, pro-activeness, centralisation, proportionality, and escalation within the Australian pharmaceutical regulatory regime, along with the capacity for rule evasion, and the presence of operational constraints, has decreased the deterrent impact of risk-based and responsive regulatory techniques and led to the production of a regime which is less able to compel compliance from regulatees (see *Figure 6.4*).

Figure 6.4: Themes Mapping the Reduced Deterrent Impact of the Regulator and Regime.



6.2.1 LIMITED OVERSIGHT

A lack of oversight in those aspects of the regime where non-compliance is greatest has reduced the certainty of capture, and therefore, the regime's capacity to detect and penalise non-compliance.

6.2.1.1 Lack of Pre- and Post-Market Monitoring of Efficacy (Listed and Registered Medicines)

The lack of pre- and post-listing efficacy evaluation provides listed medicine sponsors with fewer incentives to produce efficacious medicines and adhere with efficacy requirements. As listed medicines are automatically approved (sponsors self-assess their applications) and are not independently evaluated prior to listing (sponsors hold evidence but do not supply it), medicines are able to enter the market without independent scrutiny (Submissions 1030, 1053, 1073, 1090-91, 2012, 2017, 3016, 4015, 4023 & 7050). As listed medicines are statistically unlikely to undergo a post-market compliance review, listed medicines also have greater certainty of avoiding evaluation by the regulator post-listing (Submissions 1030, 1044, 1073, 2012, 2017, 3014, 3016, 3029, 4015 & 4023). In the absence of rigorous monitoring and the system's increasing reliance upon spontaneous reporting mechanisms (see 6.2.3.1), inefficacious medicines can remain on the market long before they are detected and the sponsors penalised under the current regime. Even if a listed medicine is subject to a rare compliance review, sponsors expose themselves to little financial risk for listing a medicine later found to be inefficacious: listed medicines can be cancelled to avoid review, and then re-named and re-listed without penalty (see 6.2.2.1); the financial cost of listing (and re-listing) a medicine is low (see 6.2.5.5); and sponsors are not financially penalised when found non-compliant by review (see 6.2.5.3). The low likelihood of detection and absence of an effective punishment payoff may explain why such a large proportion of listed products are found with insufficient efficacy during compliance reviews (Australian National Audit Office 2011, pp. 107-10) and the complaints determination processes (Therapeutic Goods Advertising Code Council 2011-2012, p. 14).

Although registered medicines are scrutinised for efficacy prior to being put on the market, they are not always evaluated and approved based on comparative efficacy (i.e. as having greater efficacy compared with pre-existing treatments on the market), as the extract below demonstrates:

> There's a condition called intermittent claudication which is a common condition—a lot of diabetics suffer from it and so on—associated with an inability to walk long distances without severe pain. [...] The endpoint that the regulators require for that condition is a six-minute walk test, which means they put people on the treadmill and they walk them for six minutes; with the drug and without the drug. They look at the increase that they walk on the treadmill in six minutes. So, a drug I recently saw, the incremental increase in distance walked within six minutes on a treadmill was 30 metres. So, the company says, "this drug works for intermittent claudication". Who says that it works? They walked 30 metres more in six minutes on a treadmill. How does that equate to value? [...] Does that equate to people being able to walk around to do their activities of daily living? The answer is no (Interviewee 2, p. 3).

> The regulator doesn't say "is this safe and efficacious compared to such and such", they simply say "is it safe and efficacious?" (Interviewee 2, p. 5).

Like most regulatory agencies, the TGA stipulates that sponsors need only establish that new chemical entities are more effective than a placebo.[55] This is because industry have been successful in arguing against the use of comparative efficacy studies as a baseline pre-market standard—industry have argued that demonstrating therapeutic advantage over existing treatments is costly, time consuming, and denies patients access to potentially useful treatments (Garattini & Bertele' 2007, p. 803). Pre-market comparative efficacy studies also entail a degree of uncertainty for sponsors; a drug can fail to achieve registration or attract fewer sales if greater, equal, or near therapeutic advantage over a less-expensive, pre-existing treatment cannot be established (Sorenson, Naci, Cylus & Mossialos 2011, p. 1). Although a medicine which lacks comparative efficacy does not constitute a compliance issue itself, the failure to evaluate comparative efficacy prior to approval raises two issues for risk-based regulation. First, as some products offer greater value (i.e. more benefits and fewer risks) over their comparators, the lack of comparative efficacy data places the regulator in less of a position to differentiate between the risks of comparable products (e.g. in the case of Vioxx, whether the risks posed by Vioxx and other COX-2 inhibitors were greater than those of less selective non-steroidal anti-inflammatory drugs and COX-1 inhibitors). This is problematic for risk-based regulators because they are denied access to information which can guide where their resources should be prioritised—essentially, all comparable products must be lumped into the same category of risk without the regulator being able to differentiate between them. Second, when a medicine is approved in the absence of comparative efficacy, there is less of an incentive for sponsors to carry out post-market studies to determine comparative effectiveness.[56] Once a product is approved, the TGA, as gatekeeper to the market, relinquishes much of the power it holds over sponsors by granting the sponsor approval (Carpenter 2010, p. 2). When the medicine is 'past the gate' (Carpenter 2010, p. 19), few sponsors are compelled to conduct post-market studies, even when these studies are

[55] Non-placebo (or active-controlled) trials are mandated in those circumstances where an existing treatment is available and has been shown to improve survival or reduce morbidity as the failure to provide treatment (by offering a placebo) would be unethical and likely to result in detrimental health outcomes for participants (Davis & Abraham 2013, p. 25). Even then, most treatments need only establish non-inferiority—a level of efficacy equivalent to a pre-specified, statistical fraction of the comparative treatment (Davis & Abraham 2013, p. 28).

[56] Although an argument can be made that those sponsors wishing to obtain a lucrative listing on the Pharmaceutical Benefit Scheme are required (and so motivated) to conduct post-market comparative efficacy studies, sponsors need only establish non-inferiority for the purposes of an application. This means '[a] drug that is less effective and/or more toxic than a drug already listed for the same indications might be considered for listing' provided that it can 'decrease the overall costs of therapy' or can be 'restricted to a subsequent line of therapy after the more effective or less toxic therapy' (Department of Health 2008, p. 6).

mandated by the regulator, because the medicine has already been approved—a fact best demonstrated in the historically low rates of post-market study completion overseas.[57] The lack of pre-market evaluation of comparative efficacy therefore increases the difficulty of determining the true risk of new treatments and compelling compliance from sponsors with post-market requirements.

6.2.1.2 Lack of Pre- and Post-Market Monitoring of Safety (Listed and Registered Medicines)

Although few of the consultations analysed here dealt with prescription and non-prescription drug safety, a small number of stakeholders and interviewees raised a variety of safety concerns in relation to these products (Submissions 1003, 1010, 1058, 1069, 1076, 1078, 2012 & 6005, Interviewees 1 & 7). One stakeholder referred to several listed medicines found on the Australian market containing contaminants and undeclared scheduled substances (Submission 2012). These claims are supported by recent studies which have documented the presence of substandard listed medicines on the Australian market (Coghlan, Maker, Crighton, Haile, Murray, White, Byard, Bellgard, Mullaney, Trengove, Allcock, Nash, Hoban, Jarrett, Edwards, Musgrave & Bunce 2015; Lim, Cranswick & South 2011). These safety issues arise as a direct result of the lack of quality and safety testing the listed medicines receive prior to marketing—a consequence of the safety profile of a listed medicine being assumed (not evaluated) on the grounds that it can only contain pre-approved low-risk ingredients. Listed medicines also experience low rates of post-market laboratory testing relative to the number of new product listings each year. This low level of oversight allows substandard listed medicines to avoid detection by the regulator until an adverse drug reaction (ADR) arises or a complaint is made.

Post-market studies for new chemical entities were also criticised by stakeholders and interviewee for being of a lower standard and quality compared with those studies conducted prior to market:

> post-marketing collection of information is very loose […] when you read those study proposals, they're absolutely shockingly bad. […] [Prior to market] in order to get the drug tested you go through very intensive protocols. Like, you know, for example, you'd have to write a grant application and you'd have to go through a committee member, you know lots of people, be peer reviewed and then you do the testing—phase one, phase two, phase three—and then the randomised control trials. It's a huge undertaking and every single adverse event is recorded, and it's a very rigorous protocol for trials

[57] Post-market studies are typically drawn out and fail to see completion; statistics from the US indicate that fewer than 34% (926 out of 2,701) of post-marketing commitments are honoured by sponsors (Garattini & Bertele' 2007, p. 804). Sponsors often cite a lack of time, money, and the fact that no doctor or patient wants to be randomised to the placebo or comparative drug sample as grounds for not proceeding with post-market studies (Garattini & Bertele' 2007; Sorensons et al. 2011).

> now. But once a drug has been approved, the system is hopeless. […] [T]hese studies that they were proposing were based on electronic databases in the US and Europe, and there's no way you're going to get any useful information out of that. They were trying to compare the instance of a particular side effect based on all these other drugs and it was totally unclear. That would be rejected by any grant committee, so it would not have passed at all. […] Why do we have these differences in standards post-marketing versus prior to the drug being approved? It's, it's…. For someone like, you know, who does all these grants and research, it was really shocking at the start. I just think that, yeah that's terrible. And that's, that's actually the most important part of the drug development because that's when you've got these untoward effects that may be captured (Interviewee 7, pp. 13-4).

The TGA does not engage in the end-to-end regulation of clinical trials; it only regulates clinical trials for products which are yet to be approved (i.e. Phase I, II, and III trials, not Phase IV trials). Because the TGA places greater weight on the pre-market rather than post-market regulation of medicines, few resources are dedicated to overseeing sponsor adherence with post-market study requirements. As a result, poor compliance (e.g. design errors, poor execution, and incompletion) with post-marketing study requirements is less likely to be detected by the regulator (Abraham 1995; Dukes, Braithwaite & Moloney 2014).

Another stakeholder also spoke of the TGA's lack of monitoring of sponsors' compliance with pharmacovigilance plans, particularly whether all ADR reports were being reported to the regulator and whether ADR records were being maintained by sponsors (Submission 6005). In the United States, where pharmacovigilance reporting is monitored and recorded, approximately 10% of companies fail to report serious ADRs within the 15-day mandated time frame (Ma, Marinovic & Karaca-Mandic 2015, pp. 1565-6). This study also found that the more severe an ADR, the less likely it was to be reported to authorities (Ma, Marinovic & Karaca-Mandic 2015, p. 1566). Other sources have also identified instances where companies have failed to report ADRs (Evans 2005; The Pharmaceutical Journal 2010) or have made incomplete reports (Institute for Safe Medication Practices 2015), rendering them meaningless for safety monitoring and evaluation purposes. According to the Institute for Safe Medication Practices (2015, p. 2), less than 50% of the ADRs reports submitted by pharmaceutical companies to the FDA between 2013 and 2014 contained complete information. This was in stark contrast to the proportion of complete reports made by consumers and healthcare practitioners (85%) (Institute for Safe Medication Practices 2015, p. 2). While these data are in no way indicative of the level of compliance by sponsors with Australian pharmacovigilance requirements, given the level of adherence in overseas jurisdictions, the lack of

independent monitoring and collection of pharmacovigilance data in Australia poses significant barriers for the TGA in monitoring sponsor compliance with pharmacovigilance requirements.[58]

6.2.1.3 Lack of Pre-Approval for All Advertisements and Promotional Materials (Listed and Registered Medicines)

The absence of pre-approval barriers for certain types of listed and registered medicine advertisements—including advertisements appearing in other media, on the internet and paid-TV—and promotional materials directed towards healthcare practitioners has increased the likelihood of consumers and healthcare practitioners being exposed to inappropriate advertising in certain advertising mediums (Submissions 2015, 2024, 2027, 2029, 4001, 7036, 7055-56, 7068 & 7092). Not only does the lack of prior approval render the regulatory regime wholly reliant upon compliance reviews and complaint processes to identify acts of non-compliance (see 6.2.3.1), and generated inconsistencies in the treatment of pre-approved and non-pre-approved advertisements (see 6.2.4.1), but it also provides less inducement for sponsors to comply with regulatory requirements because 'any breaches and penalties would be administered after the profits had been garnered' (Multiple Authors, Submission 7092, p. 9). The latter of these points is best demonstrated in the proportion of complaints received by the Complaints Resolution Panel (CRP) regarding advertisements which have not been pre-approved; Internet advertisements have consistently attracted a greater number of advertising complaints than those advertisements appearing in print and broadcast media (Therapeutic Goods Advertising Code Council 2011-2012 & 2012-2013).

6.2.2 RULE EVASION

The ability of sponsors to avoid being subject to regulatory requirements decreases the prospect of detection and punishment, and thus, the overall capacity of the regime to compel compliance from regulatees.

6.2.2.1 Regulatory Evasion (Listed Medicines)

Sponsors can avoid a post-market compliance review by cancelling, re-naming, and re-listing a product on the Australian Register for Therapeutic Goods (ARTG). As the compliance status of a product is unable to be determined prior to cancellation, penalties are unable to be applied in the event non-compliance occurs. Sponsors are alleged to have used this tactic to avoid compliance reviews

[58] For instance, by impacting upon the ability of the TGA to determine the frequency in which it must audit manufacturing sites to identify safety issues.

initiated by an advertising complaint (Interviewee 9, p. 5), to avoid taking remedial action when non-compliance is found by the regulator (Sponsor, Submission 2027, p. 14), and after a product has been cancelled by the regulator (Interviewee 9, p. 5). Notable examples include Swisse's Appetite Suppressant, which became Swisse Hunger Control when cancelled by the TGA,[59] and Undoit, which became Undoit Plus after a complaint to the CRP instigated a TGA compliance review.[60]

The voluntary withdrawal, correction, and re-listing of a formerly non-compliant product could be viewed as responsibilised behaviour by proponents of the compliance school. However, as the examples in the above paragraph demonstrate, sponsors appear to be exploiting these opportunities, and therefore, the cooperative posture of the regulator, as a means of *avoiding* penalty. When sponsors correct compliance issues or withdraw a non-compliant product entirely with little-to-no incitement by the regulator, cooperative rationalities of government assert that regulatees should experience little redress because this will reinforce the continued cooperation of the regulatee (see Yeung 2004; as cited in Morgan & Yeung 2007). Not only does this reward non-compliance, because detection and punishment can be avoided without penalty, but these rationalities of government also reinforce perceptions that sponsors are cooperative and law-abiding entities, because the detection of non-compliance fails to occur. The artificial perception, or reality, this generates of regulatee behaviour is a key feature of a neoliberal governmentality which 'endeavours to create a social reality that it suggests already exists' (Lemke 2001, p. 203). This neoliberal governmentality forms part of a larger macro-level hegemonic strategy which attempts to reinforce perceptions that regulatees are cooperative and law-abiding entities. This artificial reality therefore shapes and is shaped by a neoliberal governmentality which ultimately aims to limit state intervention.

[59] Swisse Appetite Suppressant was cancelled by the TGA on the grounds that it contained insufficient evidence to support claims that it suppressed appetite (Earl & Smith 2013). Swisse re-listed the product as Swisse Hunger Control and replaced claims that it suppressed appetite with the statement 'Traditionally used in India to help reduce hunger levels'. Swisse then sent a letter to its distributors shortly after (re)listing to assure purchasers that Swisse Hunger Control was 'not a new line of Swisse product, rather a new name for the same product' (Earl & Smith 2013).

[60] Undoit, a diet pill which claimed to prevent fat and carbohydrate absorption during digestion, was subject to an advertising complaint in 2012 (Hobday 2012). The inefficacious claims made by the product prompted a concurrent review by the TGA (Hobday 2012). Four months into the CRP investigation, the company cancelled the listing for Undoit and re-listed the product as Undoit Plus. Marketing manager Michael Romm claimed that the timing of the cancellation was 'not a coincidence', arguing that '[w]hen the TGA was looking into our advertising claims … they noticed at the same time that we'd changed the formulation but left the name the same and because they were looking at it at that time, they asked us at the time to change the name as well' (Hobday 2012, para. 14). The investigation was stopped by the TGA and CRP (TGA 2012d), despite the claimant maintaining that the claims remained identical to the original product (Hobday 2012).

6.2.2.2 Self-Regulatory Evasion (Listed and some Registered Medicines)

Unlike sponsors of prescription registered medicines, sponsors of non-prescription and generic listed and registered medicines are not compelled to become members of industry associations and can choose not to subscribe to an industry Code of Conduct. This has enabled sponsors to avoid the jurisdictional reach of self-regulatory bodies (Submissions 2009-10, 2012, 2017, 2025, 2027-28, 2037, 4010, 4019, 4027-29, 4032, 5006, 5008, 5010, 5018, 7034, 7054 & 7072, Interviewees 6 & 11). This avoidance is best demonstrated in the case of Ranbaxy Australia, a pharmaceutical company which in 2012 offered pharmacists AU$14,648 worth of free samples and a 90% discount on subsequent orders for the generic cholesterol-lowering drug Trovas (Academic, Submission 5010, p. 4). The offer violated both the Medicines Australia (MA) and the Generic Medicines Industry Association (GMiA) Codes of Conduct, but when a complaint was eventually lodged with GMiA, Ranbaxy declined to participate in the adjudication of the complaint on the grounds that it was not a member of either association (Academic, Submission 5010, p. 4). Although the Australian Self-Medication Industry (ASMI), Complementary Medicines Australia (CMA), and GMiA have mechanisms that allow listed medicine sponsors to voluntarily subscribe to a Code of Conduct without having to become a member of the association, few associations have reported an uptake of such offers:

> We have procedures in place to allow non-members to agree to be subject to our Code. But no one has taken us up on that offer as far as I can tell […] there is no means to compel non-members if they don't agree to be bound (Interviewee 6, p. 5).

The lack of application of industry codes to non-members has also generated a free-rider problem which, in turn, has increased perceptions of inequitable treatment among sponsors who are members of industry associations:

> non-members may presently lodge complaints against member organisations […] with the full knowledge that they, themselves are not held to the same standards of compliance. Industry members are also frequently at a disadvantage with respect to non-members. […] [M]ember companies are required to provide the data substantiating a claim being made to any consumer or competitor company that requests it. Often this data is commercial-in-confidence, yet it is still provided as it is a requirement of membership. In contrast, competitor companies that are non-members are under no obligation to provide data to substantiate any claims being made (Sponsor, Submission 2027, pp. 15-6).

This flexibility afforded by industry self-regulation has reduced the capacity of self-regulatory bodies to compel compliance from those sponsors who are not members. This leads to differences in the treatment of members and non-members which can generate perceptions of inequity, and thus, criticism and retaliation against the regime.

6.2.2.3 Creative Compliance (Registered Medicines)

Although not strictly a violation of administrative, civil, or criminal law, sponsors of prescription medicines have been accused of using de-facto advertising—the advertisement of a disease or condition which does not mention the name of a drug, but includes the publication of a company name and/or logo—as a means of advertising prescription medicines directly to the public (Submissions 2015, 2026, 4001, 4018 & 4029, Interviewee 5). Examples provided by stakeholders include the Pfizer campaign for the two-in-one combination heart pill Caduet[61] and the Bayer campaign for testosterone.[62] These types of advertisements encourage consumers to ask their doctor about treatment options for an advertised medical condition and often coincide with a separate promotional campaign where the product is marketed directly to healthcare practitioners. Pfizer's combined pill campaign, for instance, involved the publication of full-page Caduet advertisements in medical magazines and journals regularly accessed by healthcare practitioners. In addition to detailed information about the drug, the advertisements in medical magazines and journals allegedly contained the statement that 'patients will soon be asking about their suitability of combination heart medications' (Consumer Organisation, Submission 2015, p. 3). Although these types of advertisements aim to increase disease and treatment awareness, empirical evidence suggests that they only lead to an increase in sales for certain types of treatments (usually those manufactured by the campaign's advertiser) (W't Jong, Stricker & Sturkenboom 2004). According to MA, these types of advertisements do not constitute direct-to-consumer advertising (DTCA) as no specific medicine is being advertised and the information contained in the advertisement can be considered educational in nature (MA 2010, pp. 5-6). Although the provisions under the *Therapeutic Goods Act* 1989 (Cwlth) are not as specific as those under the MA Code of Conduct—which implies that space exists under law to challenge this interpretation of DTCA—stakeholders and interviewees have claimed that

[61] The advertisement prompted consumers taking multiple medications for blood pressure and cholesterol to talk to their doctors about combination treatments. The advertisement featured a bright red heart and a tear off slip which consumers could present to their doctor. A copy can be found at Pfizer (2010).

[62] The advertisement implied that age-related testosterone loss in males was a serious medical condition requiring treatment with testosterone therapy. This is despite the fact that age-related testosterone loss is a normal consequence of ageing and there is little evidence to support the use of testosterone therapies in reversing these age-related effects (Mintzes 2010, p. 3). MA eventually banned the advert for misleading marketing (see 6.2.5.4). A copy is available at Mintzes (2010, p. 5).

complaints regarding this practice made to the TGA directly have gone unanswered and un-actioned (Consumer Organisation, Submission 2015, p. 4). The state's relinquishing of responsibility for governing this space has afforded industry associations the degree of responsibilised autonomy that enables them to exploit current requirements and categorise a wider range of conduct within the scope of acceptable advertising.

6.2.3 LIMITED PRO-ACTIVE ENFORCEMENT

An emphasis on risk-based regulation has rendered regulatory enforcement largely reactive. The reactive nature of enforcement has delayed the detection and punishment of non-compliance to the point where it is perceived as less certain and threatening.

6.2.3.1 Complaints-Driven (Listed and Registered Medicines)

Regulatory activity is predominately driven by spontaneous reporting mechanisms. Aside from the select number of laboratory tests, compliance reviews, and manufacturer inspections conducted by the TGA each year, the TGA is predominately reliant upon adverse events reports, and advertising and promotional complaints, to identify acts of non-compliance (Submissions 1030, 1058, 1073, 1109, 2020, 2028, 4029, 7034 & 7036, Interviewees 5 & 7). The reactive nature of these risk-based regulatory techniques means that a non-compliant medicine could remain on the market until it is identified through spontaneous reporting.

The erroneous nature of spontaneous reporting mechanisms means that the capacity of the regulator to detect acts of non-compliance which arise from quality, safety, and efficacy issues is severely reduced. Not only is industry reporting unmonitored by the regulator (see 6.2.1.2 & 7.2.2.1), and vulnerable to self-interest (see 7.2.2.1), but consumers and healthcare practitioners are often unfamiliar with spontaneous reporting mechanisms (see 7.1.1.1) and claim to be discouraged from lodging ADR reports and complaints (see 7.2.2.1). An increased reliance on these less-than-reliable reporting mechanisms as a primary means of detecting industry non-compliance is likely to lead to fewer quality, safety, and efficacy (and therefore non-conformity) issues being identified.

6.2.3.2 Commercially Initiated (Listed and Registered Medicines)

A small number of stakeholders reported that regulatory action was mostly an outcome of commercially initiated activity rather than active enforcement on the part of the regulator (Submissions 1024, 1076, 1115 & 8023). Examples of the TGA's reliance on sponsors to act on quality, safety, and efficacy issues are provided below:

> When TGA was contacted to ask why some products were still listed [on the ARTG] as being TGA registered […] the response was that the TGA rely on the sponsoring drug company to notify them that the drug has been removed from the Australian market […] if the drug has been withdrawn from the Australian market due to safety concerns, it would seem sensible to remove the drug from the ARTG (for example, sibutramine[63] and sitaxentan[64] still have an active listing status) (Not-for-Profit NGO, Submission 1115, p. 3).

> [Our organisation] formally approached [name redacted] with details of inaccuracies in the CMI for allopurinol[65] […] The below was received from [name redacted] […] *the Clinical Evaluation Unit has written to all sponsors of allopurinol pointing out the inconsistencies in CMI and PI information* […] *The TGA does not approve the CMI information but is in a position to request that sponsors amend their PI documents as the Secretary approves PI's and there is also a requirement in our legislation that CMI is consistent with the approved PI. We have also raised with the innovator product a separate issue that the PI in MIMS is incorrect and doesn't reflect the approved PI* […] It is more than nine months since the fundamental errors in the CMI and MIMS were raised. Many thousands of patients and allied health professionals may have read the inaccurate information on dosing; […] patients may have had their healthcare adversely affected by this advice (Professional Association, Submission 1024, p. 1 [original emphasis]).

Proponents of the compliance school would argue that having regulatees identify and rectify regulatory issues voluntarily, irrespective of whether they are in fact the product of non-compliance, is essential to establishing a culture of compliance and reducing the resource burden on the regulator. However, the retrospective nature of commercially initiated enforcement means that consumers are primarily responsible for their own governance, and therefore, at greater risk of exposure to quality, safety, and efficacy risks which could have been averted with greater monitoring and/or more immediate intervention by the regulator. Since the regulator is reliant upon regulatees to bring quality,

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[63] Sibutramine (Reductil), a prescription drug for weight loss, was voluntarily withdrawn by Abbott Australasia over concerns of increased cardiovascular risk (TGA 2010a).

[64] Sitaxentan (Thelin), a prescription medicine for pulmonary hypertension, was voluntarily withdrawn by Pfizer because of the increased risk of acute liver failure (TGA 2010b).

[65] These inaccuracies relate to inappropriate dosing instructions supplied in Product Information (PI) and Consumer Medicine Information (CMI) documents. It is usually recommended that healthcare practitioners place patients on an ascending dosing schedule to minimise the risk of ADRs (Professional Association, Submission 1024, p. 3). At the time, the PI and CMI for allopurinol provided information which implied that the dosing schedule was discretionary and should be administered in accordance with the severity of the condition (i.e. 100-200 mg per day for mild conditions, 300-600 mg per day for moderately severe conditions, 700-900 mg per day for severe conditions). One case was reported by this stakeholder of an instance where a patient had selected their own dose and suffered from an ADR (Professional Association, Submission 1024, p. 3).

safety, and efficacy issues to their attention, and to rectify them voluntarily, commercially initiated enforcement decreases the capacity of the regulator to identify acts of non-compliance when they occur because sponsor adherence is not actively monitored by the regulator (see 6.2.1). The voluntary rectification of compliance issues is also difficult to penalise since cooperative rationalities of government assert that regulatees should not be reprimanded for acting cooperatively (see Yeung 2004; as cited in Morgan & Yeung 2007). This rationality was affirmed by one TGA employee who indicated that the TGA was more inclined to take action against those sponsors who intentionally concealed substandard products (i.e. products with quality, safety or efficacy defects) than those sponsors who reported a substandard product to the TGA 'as the company have done the right thing by reporting it' (TGA 1, pp. 5-6).[66] Again, this has the unintentional effect of rewarding non-compliance, because non-compliance can occur without penalty, and contributing to the artificial reality that regulatees are largely cooperative and compliant entities.

6.2.3.3 Lengthy Complaints Resolution and Remediation (Listed Medicines)

The timeliness of enforcement action, especially in the remediation of DTCA for listed medicines, has also rendered certain aspects of the regulatory regime wholly reactive. Stakeholders and interviewees have attributed delays in DTCA remediation to three principle causes. Most attribute delays to the direct failure of the TGA to evaluate product efficacy prior to marketing (Submissions 1031, 2009-12, 2016-17, 2020-22, 2036-37, 3026, 4015, 7034, 7047 & 7090). This delay has led to a reliance on spontaneous reporting mechanisms and a 'down-stream' complaints system to identify efficacy issues (Academic, Submission 2017, p. 4), which has increased the volume of complaints, and therefore, the constraints placed on these apparatuses of the state to remediate complaints in a timely manner. As one stakeholder argued:

> the current volume of complaints is a sign of issues elsewhere in the system—in an optimally functioning regulatory environment, there quite simply wouldn't be so many questionable advertisements in the marketplace to prompt complaints (Complaints Body, Submission 7047, p. 4).

Stakeholders also attributed delays to the TGA's lack of timeliness in responding to complaints forwarded to it from the CRP (Submissions 7034, 7046, 7054, 7070 & 7086); one stakeholder referred to four recent cases where the TGA had taken over 15 months following a CRP referral to issue the sponsor with an Order (Industry Association, Submission 7034, pp. 4-5). The CRP itself was also criticised over perceptions that its members lacked the expertise necessary to evaluate claims of

[66] See Footnote 14 in Chapter 3.

efficacy (Submissions 1101, 2014, 2029, 2034, 7009, 7043, 7075 & 7086). This prompted some industry stakeholders to advocate for greater industry representation—and complementary medicines expertise in particular—on the CRP (Submissions 1095, 2014, 7006-07, 7009, 7012-16, 7040, 7048, 7061 & 7075). However, one stakeholder refuted the claim that the CRP lacks expertise, arguing that 'if poor assessments of evidence were being made with any frequency, there would be a large record of CRP decisions overturned by the delegate', and at this time, '[t]here is no such record' (Complaints Body, Submission 7047, p. 3). The argument can also be made that, if the TGA dedicated more time to evaluating efficacy claims prior to market, the CRP would not be required to adjudicate on such a large volume of efficacy-related complaints in the first place (see *Chapter 8*).

Delays in the remediation of DTCA complaints effectively decrease the deterrent impact of sanctions. Because CRP determinations and TGA warnings and Orders have low celerity, they are more likely to occur in isolation to, and have less of a connection with, the initial breach. As sponsors continue to profit from illicit claims prior to them being rectified (see 6.2.5.5), and few financial incentives exist to motivate sponsors to conform with the regulatory requirements (see 6.2.5.3 & 6.2.5.4), an eventual request to withdraw, retract, and correct an advertisement becomes 'a reflective measure' which 'occurs after an offending advertisement has been exposed to the public and [has] most likely made some impact on consumers' (Professional Association, Submission 2030, p. 1). Delays in DTCA remediation can also be exploited by sponsors to increase the immediacy of rewards (i.e. profits made from the illicit claim) and delay the imminence of costs (i.e. the CRP determination, or TGA warning or Order). Interviewee 9 (p. 9) believed this to be the case with Reckitt Benckiser and the advertising of pain-specific Nurofen, arguing that Reckitt Benckiser relied on 'continued appeals' and 'delays in the system to just keep on promoting'. In the case of Sensaslim, the sponsor went so far as to take the complainant to court as legislation currently prohibits the CRP from investigating a complaint when the product is subject to court action (Dowden 2012, p. 38).[67]

6.2.3.4 Lengthy Reform Processes (Listed and Registered Medicines)

The drawn-out process of regulatory reform has also decreased the capacity of the regulator to act on industry non-compliance. Numerous examples were provided by stakeholders and interviewees of consultations, reviews, and enquiries which had been initiated by the regulator, but never saw completion:

[67] Threats of defamation, though rare, would also have the dual benefit of potentially forcing the complainant to withdraw the complaint.

> In July 2005 the TGA established the Complementary Medicines Implementation Reference Group (CMIRG) to oversee the implementation of these recommendations. I am a consumer representative on CMIRG. The last meeting of CMIRG was November 2008 […] There has been no official feedback since that meeting, to any CMIRG members (that I know of, certainly none to me), of any progress with implementation of these remaining recommendations. Nor has there been any reason given for [why] CMIRG became inactive (Unknown, Submission 1103, p. 1).[68]

> In April 2010 the TGACC reviewed a revised Therapeutic Goods Advertising Code (with an accompanying Explanatory Statement) and recommended that the TGA adopt the revised Code. More than three years later, the revised Code is still not in place. In December 2011, […] [t]he TGACC recommended that the TGA deal with the issue "quickly and expeditiously" […]. To date, there has been no action by the TGA (Industry Association, Submission 7034, p. 13).[69]

Stakeholders and interviewees have largely attributed the inertia on regulatory reform to a lack of political will and the increasing influence of private interests in policy processes (Submissions 1076, 2010, 2012, 2017-2018, 2020-22, 2037, 4015, 7046, 7054, 7070 & 7079, Interviewee 5 & 9). Evidence of industry attempts to delay potential reforms to the regime were evident in some of the consultations analysed as part of this study. Many industry stakeholders criticised the TGA for the lack of time provided to respond to consultation documents (Submissions 1023, 1025, 3001-02, 3007, 3009-10, 3017-19, 3024, 3031, 3033, 3036-37, 3039, 3103, 3110-12 & 3124), which many believed required the production of a regulatory impact statement (Submission 2009, 3001, 3002, 3018, 3021 & 3039), and further consultation (Submissions 3013 & 3112). Concerns about the increased costs, stigma (criminalisation), and duplication the proposed reforms would generate were also raised on several occasions (explored in detail in *Chapter 8*). Since the state is the 'political organiser' (Mahon 1979, p. 166) of the various relations, and therefore, interests, inside the state, state power is essentially an expression of the (unequal) structure of these relations. The lack of political will on these issues can therefore be attributed to this structure of representation which is generally more representative of industry. The pervasiveness of these interests has delayed the implementation of regulatory mechanisms which would otherwise enhance the capacity of the regulator to detect and punish non-compliance. Hence non-compliance and its ensuing harms have been allowed to continue with little restraint.

[68] This submission was made to the Transparency Review in February 2011. According to the Australian National Audit Office (2011, p. 56) the CMIRG ceased operation after this meeting in November 2008.
[69] This submission was made to the 2013 consultation Regulation Impact Statement: Regulating the Advertising of Therapeutic Goods to the General Public.

6.2.4 LIMITED CENTRALISATION

The decentralisation of the pre-approval and adjudication process for DTCA complaints for listed medicines has generated inconsistencies in the use of risk-based and responsive regulatory techniques between government and self-regulatory bodies, which, in turn, has generated perceptions of inequitable treatment among regulatees.

6.2.4.1 Lack of Uniformity Between Government and Self-Regulatory Bodies (Listed Medicines)

As pre-approval and complaints handling functions are shared between industry associations and the CRP, discrepancies immediately arise in the application of penalties across each of these adjudicating bodies. Penalties are not only inconsistent due to the differences in the type and severity of sanctions issued across bodies (e.g. not all bodies issue sponsors with financial penalties, or fines above AU$50,000 per offence), but also because advertisements featured in less prominent mediums (*other media*) and adjudicated by industry bodies will receive greater penalties than those advertisements which appear in more prominent mediums (*specified media*) and are adjudicated by the CRP (more in 6.2.5).

On a practical level, the decentralisation of the pre-approval and complaint processes has the potential to produce inconsistent decision-making between the various bodies (Submissions 1101, 2011, 2014-15, 7004, 7042, 7048, 7050, 7061, 7066, 7077, 7086 & 9205). For instance, an (inaccurate) advertisement appearing in two different mediums can be adjudicated by two separate bodies, and therefore, result in two different outcomes:

> The split delegation [for pre-approval] means that the ASMI delegate will review a therapeutic claim for a complementary medicine in television or radio while a CHC delegate will review the same claim in print. […] The notion that the same claim may be acceptable in a print advertisement but not a television advertisement is unacceptable (Sponsor, Submission 7086, p. 3).

> Complaints about print media, radio, television and internet advertisements for non-prescription medicines and medical devices may be made to the TGA's Complaints Resolution Panel (CRP), but complaints about other advertisements (for example, in-store promotions) must be made to either the CHC (for complementary medicines) or to ASMI (for non-complementary over the counter medicines) […] a complaint about the same advertisement in two different media (for example, in a newspaper and an in-store brochure) must be made to two different complaints bodies, 'even if the substance of the advertisement and the complaint is the same'. The separation of these functions creates confusion and inconsistency (Consumer Organisation, Submission 2015, p. 3).

Inconsistencies also arise by virtue of a product being subject to a successful complaint or TGA enforcement after it has received advertising pre-approval on the grounds that the product was later found to contain insufficient efficacy:

> pre-approvals officers do not review the evidence to support therapeutic indications that are listed on the Australian Register of Therapeutic Goods (ARTG) (such as "temporary relief of pain"). They will only assess whether such claims are in fact listed on the ARTG, and also review extrapolations on these claims (such as "clinically tested to provide temporary relief of pain in 15 minutes"). The complaints process, on the other hand, will review the evidence to support claims. As such, the two systems review the same advertisements based on different parameters and different outcomes may occur (Sponsor, Submission 7086, p. 2).

> There have been instances where a TGA Delegate exercising a different power under the Act to that which CHC has used to approve an advertisement, (i.e. Paragraph 30(2)(ba)), has decided to propose the cancellation of the product from the Register partly because the advertising approved by the CHC does not comply with the Advertising Code. This raises serious issues for the industry […] [as] a company will often in good faith embark on a costly advertising campaign in reliance on the CHC approval processes (Industry Consultant, Submission 1101, pp. 7-8).

These discrepancies, which are a direct consequence of the TGA's failure to evaluate efficacy prior to listing (see 6.2.1.1), have not only led to different standards of enforcement, but have also generated perceptions of inequitable treatment among industry stakeholders.[70] This perception of inequity may explain, in part, why some sponsors may be reluctant to comply with an initial complaint determination or an administrative request following a compliance review.

[70] For instance, sponsors and industry stakeholders often labelled the pre-approval and complaints processes as highly subjective (Submissions 2011, 4008, 7006-07, 7042-43, 7048, 7053, 7060-61, 7066 & 9208). Many have refused to support changes to these processes—including an increase in penalties for the CRP—while these discrepancies in decision-making continue to occur. For example, one sponsor argued that:

> we are opposed to the proposal to increase penalties for advertising breaches because the TGA regulations are interpretative, not definitive, and are subject to a large degree of interpretation. As currently happens and is likely to continue, sponsors and the TGA (and even different reviewers within the TGA) may interpret these regulations differently and it is unreasonable to subject sponsors to large financial and civil penalties unless there is absolute clarity on what is allowable and what is not (Sponsor, Submission 7061, p. 3).

6.2.5 LIMITED PROPORTIONALITY

The lack of proportionality generated by risk-based and responsive regulatory techniques has not only reduced the deterrent effect of the regime, but also produced perceptions of inequitable treatment among regulatees.

6.2.5.1 Disproportional to Compliance Risk

The regime is predominately oriented towards mitigating product risks (those products with a high product risk profile) rather than compliance risks (those risks posed by sponsors at greatest risk of non-compliance). This emphasis on product risk is most evident in the comments made by TGA staff; the written statement below was provided in response to a set of follow up questions to the group interviewees:

> TGA adopts a risk-based approach to *product regulation*. This risk-based approach identifies the *risks posed by therapeutic goods* and regulates *products* based on this degree of risk. This system of risk management ensures that a *high risk product* (such as a new chemical substance) receives more in-depth analysis than a *lower risk product* with extensive safety data. […] the TGA applies a system of oversight for identifying, analysing and evaluating the risks associated with *the product itself*, as well as the manufacturing process to ensure *products* available in Australia meet community expectations (TGA 7, p. 5 [added emphasis]).

The Department of Health has also echoed these sentiments. In 2011, the then Secretary for Health, Catherine King, stated that the TGA's role was to act as:

> the regulator of safe, effective and quality products […] not the regulator of industry in essence. […] [Y]ou hope that industry in ensuring that they comply with the regulatory requirements […] that they actually do that (Lauder 2011, para. 26).

The prioritisation of product risk over compliance risk has made the regulator and regime less responsive to non-compliance.[71] Products with low product risk receive less external regulation, and therefore, less certain, swift, or severe punishment for non-compliance, than products with a high product risk. Because of this prioritisation, products with low product risk have generally exhibited 'high[er] rates of non-compliance, and therefore, … [a] higher compliance risk, than those products

[71] This is not to say that regulation should not be proportional to product risk, but that the regulation of product risk should not be at the expense of all other forms of risk, especially the risk of non-compliance.

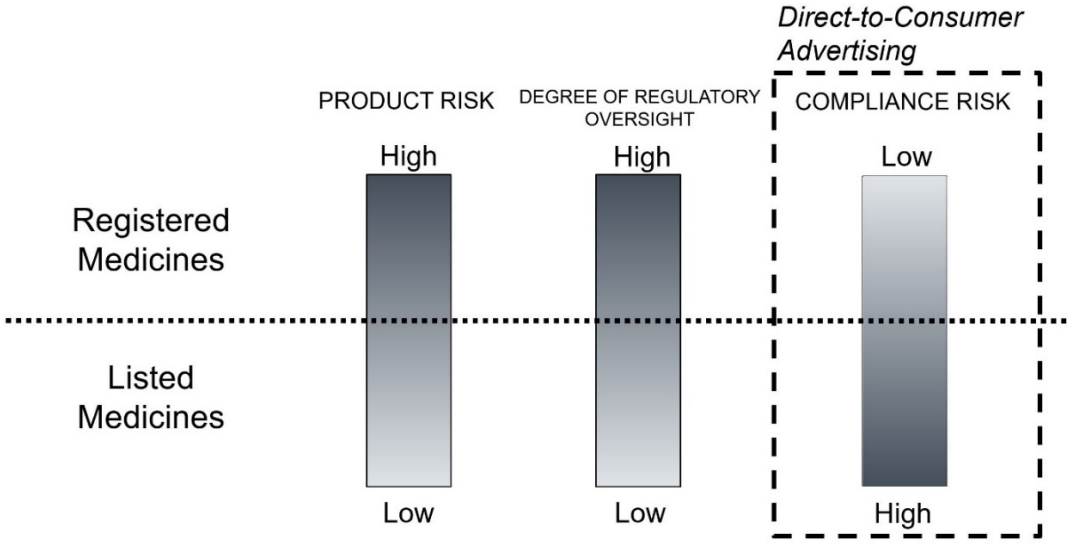
with higher product risk' and subject to greater amounts of external regulation (see *Figure 6.5*) (Bandiera 2015, p. 10). This relationship between product risk and rates of non-compliance was observed by some stakeholders and interviewees (Submissions 1103, 2010, 2017, 2021-22, 2025, 4001 & 4015, Interviewee 9 & 11). For example, Interviewee 11 stated that the deterrents available for high-risk products, particularly in the areas of product quality, safety, and efficacy, were a major reason why sponsors of high-risk products were more likely to comply with these types of requirements. Interviewee 11 stated that:

> The risks of being non-compliant are much greater for your business in those high-risk products […] part of the reason why there is an emphasis on [reforming] complementary medicines and on devices is because the prescription medicines sector is so highly regulated that it doesn't have a record of high non-compliance […] therefore it wasn't the focus (Interviewee 11, p. 9).

> [I]n prescription medicines, the sanctions are higher, … the reputation is, is … the risks are higher, … so… you know, it's easy, it's easy to see why sanctions create compliance in those high-risk areas (Interviewee 11, p. 15).

The prioritisation of product risk over compliance risk is part-and-parcel of the neoliberal program. It provides justification for rationalising state intervention on the basis that intervention should only occur for high-risk, rather than low-risk, products. Product risk prioritisation also provides justification for rationalising state intervention on the basis that only product risks, and not compliance risks, should be subject to intervention, especially in low-risk product areas (more on this point in *Chapter 8*).

Figure 6.5: Degree of Regulatory Oversight Compared with the Level of Compliance Risk.



Closely adapted from Bandiera (2015, p. 10).

6.2.5.2 Targeting

A small number of stakeholders and interviewees held perceptions that the TGA explicitly targeted certain sponsors over others. Interviewee 8 provided two explicit examples of targeting behaviour.

In the first example, a company sold several products on the Australian market which had not been listed on the ARTG. According to Interviewee 8 (p. 8), this company had been aware of the legal requirements for listing, having previously listed several products, but had acted on incorrect advice provided to them by a regulatory consultant—that these new products did not need to be listed because of the operation of a particular Act and due to the fact that the company was bringing the products through New Zealand. Interviewee 8 (p. 8) therefore believed that the company was 'not a recidivist organisation' but 'an organisation that thought they're doing the right thing'. According to Interviewee 8, the TGA proceeded to quarantine and seize all the non-compliant stock, and then prosecuted the company under the Act in the range of millions of dollars. The company had been aware of other companies selling identical products on the Australian market which were not listed, so the company wrote to the TGA and provided them with these examples, but no response was received from the TGA (Interviewee 8, p. 8). It was alleged that the company had written several letters, to the Minister and to the Head of the TGA, about the lack of action on similar products, but again there was no response and the identical products continued to remain on the market. This had led Interview 8 (p. 8) to believe that the TGA had simply 'knocked off the biggest player in the field because they were the largest distributor in Australia, [and] made an example of them'. The Interviewee went on to state that:

> No one cared. It hasn't changed the industry. It hasn't, it hasn't been effective regulation because the thing they complained about […] is still being done by everyone else.

The second example provided by Interviewee 8 concerned Pan Pharmaceuticals (see 4.3.1). Interviewee 8 (pp. 5-6) claimed that the TGA had conducted two separate audits prior suspending Pan's licence and instigating a worldwide product recall—the two-day audit on the 24th and 25th of February (the February Audit) and the five-to-six-day audit in April (the April Audit). The February Audit had identified five critical deficiencies at Pan's manufacturing facilities; the April Audit identified a further four (a total of nine critical deficiencies overall). According to the Interviewee, the TGA did not provide Pan with an Audit Report or conduct a closing meeting following the February Audit and prior to the commencement of the April Audit (Interviewee 8, p. 6). The TGA later claimed (in court) that the February and April Audits had not been two separate audits, but part

of the same audit which had been conducted in two distinct parts (Interviewee 8, p. 6).[72] The Interviewee argued that if the TGA had determined, in February, that Australia's largest supplier of therapeutic goods had been operating on a basis of five critical deficiencies, the TGA should have dealt with these deficiencies immediately because of the public health ramifications posed by deficiencies with a critical rating (Interviewee 8, p. 6). However, Interviewee 8 (pp. 5-6) alleged that the TGA chose not to act on these deficiencies, or alert the company, and instead chose to conduct a further investigation (the April Audit) with the intent of building a stronger case against the company. The Interviewee questioned the TGA's approach in this situation:

> what should a regulator do? "Oh my God! This is a disaster. Quick! We'd better tell the company, they need to do something straight away because the health and safety of the nation is at risk." That's what they should do. But they didn't. They didn't say a word. They didn't give the usual post-audit meeting that they're supposed to have, that their policies say they have. […] [T]hey didn't deliver an audit report (Interviewee 8, p. 6).

> the regulator should immediately tell the company and help the company fix it. Shut them down straight away or help them fix it straight away. But what does a policeman do? The policeman says "oh this is good. […] let's see if we can get some more and really put them in jail for life but don't tell them [be]cause they might fix it up. If they fix it up, we might not be able to get them". And that's what happened. That is exactly what's happened. Enforcement thinking overtook regulatory thinking, completely suborned it to the mission objective of putting Pan in jail for life. They went out there in April to get more evidence to kill them dead and in the meantime, you can do the mathematics, hundreds of millions of tablets and capsules produced under a regime of five critical deficiencies were out there being consumed (Interviewee 8, pp. 5-6).

The Interviewee went on to claim that one of the nine critical deficiencies listed in the April Audit Report, and which had been one of the original five critical deficiencies identified in the February Audit, had been rectified by the company in the period between the February and April Audits, and prior to the production of the April Audit Report. Despite this deficiency allegedly being rectified, it remained listed as a deficiency in the April Audit Report (Interviewee 8, p. 5). Again, the Interviewee questioned:

> How can that be right? How can that be responsible? How can you include in a report that you are using to shut down a public listed company a critical deficiency that you know has been rectified? And

[72] The Interviewee disagreed with this assertion, claiming to have seen a draft audit report for the February Audit produced by one of the inspectors which had never been supplied to the company (Interviewee 8, p. 6).

> I know that they knew because an email from one of the auditors to the lead auditor said it's been fixed (Interviewee 8, p. 5).

These perceptions of targeting arise as a direct result of risk-based regulatory techniques which prioritise the regulator's resources towards those non-compliant companies who they consider to be the greatest risk and regulatory priority. Because of this prioritisation, not all compliance risks are able to be attended to, which leads to different standards of enforcement. Not only is this risk rationality at odds with the rationalities of responsive regulation theory, which 'appeals to the better nature of the regulatee' (Gunningham 2011, p. 194) and represents a central limitation of a combined risk-based and responsive regulatory approach, but it also gives rise to perceptions of inequitable treatment among stakeholders and interviewees (Submissions 1101 & 1111, Interviewee 8 & 9). One stakeholder expressed concerns about a genuine fear of reprisal among industry against those who choose to challenge a TGA decision:

> industry has generally been fearful of offending the TGA in case this prejudices their relationship with the regulator and adversely impacts on new products coming down the research and development stream. This fear is genuine as it is based on specific experiences. […] [I]n many cases, particularly where procedural fairness has been lacking, companies will seriously weigh up whether it is best to challenge the adverse decision or risk the TGA behaving negatively towards future applications (Regulatory Consultant, Submission 1101, p. 6).

Perceptions of targeting and reprisal from the TGA are likely to lessen the perceived legitimacy of the regime, and therefore, impact on the cooperativeness of regulatees.

6.2.5.3 Lack of Financial Penalties (Listed and Registered Medicines)

In certain cases, the TGA is unable to issue financial penalties for violations of the regulatory regime. For example, under current DTCA arrangements, the CRP is only empowered to request that sponsors withdraw an advertisement, issue a retraction or correction, or commit to an enforceable undertaking (i.e. not to reproduce the offending claim for a defined period). Due to these limited powers, the CRP is unable to apply further sanctions, and thus, operate beyond the bottom most levels of the enforcement pyramid when sponsors fail to comply with determinations (see *Figure 6.6* in 6.2.6.1). Stakeholders and interviewees were able to provide multiple examples where sponsors had simply ignored CRP determinations and continued to advertise false and misleading claims; these examples included Bayer's Berocca Performance, Reckitt Benckiser's Nurofen, and Homeopathy Plus! (Submissions 7024, 7046, 7079 & Interviewee 9). While the CRP has the capacity to refer these cases

to the TGA or the Secretary, both of whom are able to issue a warning letter or an Order when determinations fail to compel compliance, few graduated responses exist beyond these warnings and Orders when administrative requests fail (see 6.2.6.1). As sponsors are required to do no more than rectify the initial advertisement and issue a correctional notice, all of which comes at an additional cost to the sponsor, sponsors have little incentive to comply with CRP determinations and TGA administrative requests, especially when a non-compliant advertisement is likely to maximise profit. The absence of penalties generates a market environment which encourages sponsors—amoral calculators and political citizens alike—to disobey regulatory requirements (Submissions 3030, 7046, 7070 & 7079, Interviewees 6 & 9), because:

> marketing focused organisations overrule what is delivered to them from their reg[ulatory] affairs departments […] on the basis that they argue, our competitors are saying x so we muct (sic) say x or stronger to remain commercially viable with new product launches […] The only think (sic) that will pull in this approach is for them to see that the TGA has teeth (Sponsor, Submission 3030, p. 3).

The absence of financial penalties is not exclusive to the DTCA aspects of the regulatory regime. As prescription and non-prescription medicines promotion is not underpinned by the Therapeutic Goods Act, civil and criminal penalties for violations of therapeutic goods promotion are not available to the TGA.[73] Non-prescription medicines found non-compliant by a random or targeted compliance review also avoid civil and criminal penalties—these medicines are only met with a cancellation notice, a suspension or cancellation, or in rare (and untried) circumstances, a product recall. As few financial incentives exist to compel compliance from profit-motivated sponsors, compliance continues to appear to be the less rational response.

6.2.5.4 Limited Financial Penalties (Listed and Registered Medicines)

Industry associations can apply financial penalties between AU$10,000 to $300,000 for Code breaches. However, stakeholders and interviewees believed these fines had little financial impact on sponsors, especially relative to the number of sales (and amount of profits) therapeutics goods advertising and promotion appears to generate:

> if the fines are not high enough they'll continue to do things. That's still much less than all the profits [they will receive] […] they will do whatever they can to maximise their profits (Interviewee 5, p. 11).

[73] The only exclusion is those instances where a registered medicine is promoted for indications outside those approved by the TGA, which is punishable under s. 22(5) of the Therapeutic Goods Act.

> They just write this shit off. They don't care […] sanctions have to matter and it doesn't feel to me as though they have sufficient effect (Interviewee 3, p. 11).
>
> $50,000 is not going to actually stop the activity. That's a big part of the problem (Interviewee 4, p. 2).
>
> the maximum fines imposed by MA for Code breaches ($300,000) are relatively modest and unlikely to be a significant deterrent (Academic, Submission 2017, p. 2).

Bayer's testosterone (see 6.2.2.3), for example, attracted a AU$10,000 fine from MA for misleading marketing—less than half the cost of placing the initial advertisement (Mackee 2012, para. 14).

Fines issued in Australia appear to be lower than those issued in some overseas jurisdictions. For example, in 2009, the US Justice Department fined Pfizer (the equivalent of) AU$2.7 billion for off-label prescribing (Academic, Submission 2017, p. 2). The same type of offence attracts a AU$300,000 fine under the MA Code (and just AU$10,2000 per offence under s. 22(5) of the Act). Although MA did not receive any complaints against Pfizer concerning off-label prescribing at this time, Pfizer had received a total of 16 convictions under the MA Code for unethical promotional activities between 2005 and 2009; these fines averaged AU$55,000 (Academic, Submission 2017, p. 2). Other companies which had advertised products for off-label uses in the 2009 calendar year received fines no greater than AU$100,000 (MA 2009, pp. 27-34).

Because these penalties are disproportionate to the profit generated from non-compliance, penalties issued by industry associations are less likely to have the deterrent impact necessary to compel compliance from sponsors.

6.2.5.5 Limited Alternative Sanctions (Listed Medicines)

The alternative sanctions available to the regulator are unlikely to have a deterrent impact on businesses. The ease and low cost of listing a medicine on the ARTG, especially when compared with registering a medicine, means that threats to suspend or cancel a listing provide less of an incentive for listed medicine sponsors (Interviewee 6). On the rare occasion sponsors are directed to publish a correctional notice, notices are likely to be published in a medium different from the original advertisement, such as the sponsor's website (Submission 2013 & Interviewee 9). While this is often a direct result of the original advertisement no longer being in circulation, as advertising remediation is a drawn-out process (see 6.2.3.3), the retraction ultimately has a lower reputational impact than one

appearing in the same medium as the original advertisement, because it does not reach the same audience and must be actively sought by the consumer.

The issue of a determination by CRP in of itself is unlikely to have a material and reputational impact on sponsors. Sponsors can continue to sell a product while it is subject to a CRP investigation (Submissions 2018 & Interviewee 4). The CRP also allows sponsors to sell all remaining products containing false and misleading claims after a determination has been issued (Submissions 1077 & Interviewee 9). These problems were conveyed by one interviewee following a successful complaint against a falsely advertised product:

> Interviewee 9: eventually the TGA delisted it. I was still upset that it was continued to be sold, often of course with the TGA they are likely to be sold off—
>
> Researcher:—Until the stock runs out?
>
> Interviewee 9: —Until the stock's run out without any sort of warning label or whether that this product has been delisted for lack of efficacy. […] [W]hat's the point of delisting if it's still in the pharmacies without any warning label? […] I've been trying to convince pharmacists that they should ethically sort of, you know, if something's delisted then they should ask the Sponsor to remove it and reimburse them. But [claps hand on table] easier to sell it (p. 15).

Alternative sanctions, in their current form, are unlikely to have a deterrent impact on corporate conduct. The ease and low cost with which listed products can be re-listed on the ARTG means that threats to suspend or cancel a listing are less likely to have a reputational and material impact on sponsors of listed medicines. CRP complaint investigations and determinations also permit sponsors of listed and low-risk registered medicines to sell non-compliant products unimpeded, even when the CRP finds in favour of the complainant. CRP determinations therefore have little effect on the way in which sponsors conduct themselves in their day-to-day activities—sponsors can continue to profit from non-compliant products in the absence of stigma and bureaucratic impediment.

6.2.6 LIMITED ESCALATION

The inability of the TGA to escalate enforcement prohibits the TGA from applying high-level punitive techniques, and therefore, from moving beyond low-level persuasive techniques.

6.2.6.1 Limited Capacity to Apply Legal Sanctions

Although a range of legal sanctions are available for advertising offences, such as, for advertising a product for unapproved uses, publishing an advertisement which requires prior approval, and false and misleading advertisements, civil and criminal penalties have yet to be applied to advertising breaches with any success. Some stakeholders have attributed the absence of prosecution to cost considerations, specifically the cost required to take a case to court relative to the size of the fine imposed, which has made the prospect of pursuing legal action financially infeasible (Submission 7050, Interviewees 2 & 10). Difficulties in establishing criminal liability for advertising offences is also said to have to discouraged prosecution (Submissions 2010, 2021, 2022, 2028, 2035, 4015 & 9202)—proving the intended purpose of an advertisement can be difficult without access to a sponsor's marketing plans and when an advertisement can be construed as a form of consumer education (Academic, Submission 4029, p. 2).

In some aspects of the regulatory regime, the absence of legal sanctions inhibits the ability of the TGA to escalate enforcement altogether. The TGA (and Secretary) are unable to apply legal sanctions in circumstances where sponsors fail to comply with administrative requests and Orders because these powers do not exist under the Act. Similarly, in prescription and non-prescription medicines promotion, the absence of legal powers has limited the ability of the TGA to intervene on issues concerning therapeutic goods promotion and to apply sanctions in those cases referred to it by industry bodies. Some stakeholders—including members of the TGA—have attributed these failures to the Australian Government, which has constrained the degree to which the TGA can exercise authority within the regime:

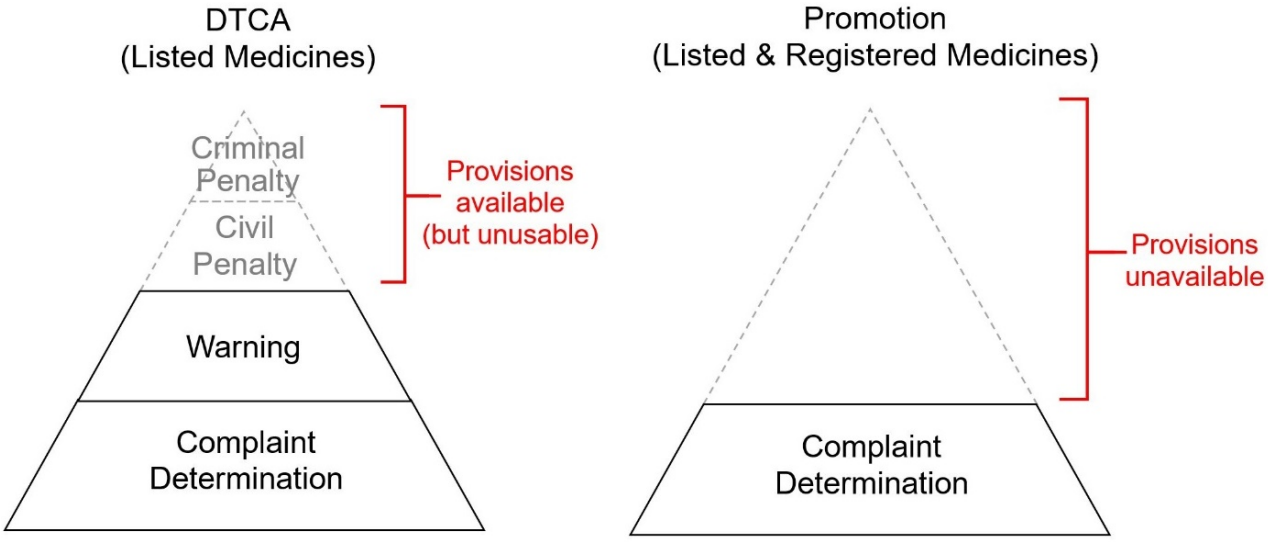
> the current legislative framework is both unenforced and unenforceable […] fault rests not with the TGA but the parliament which has failed to provide the necessary statutory authority for the TGA to be effective in this area (Professional Association, Submission 9202, p. 5).
>
> We work within the Act and if our power is broadened, that's up to the Government (TGA 2, p. 3).[74]

The inability to escalate regulatory enforcement in DTCA and promotion substantially reduces the TGA's capacity to compel compliance from regulated entities. Ayres and Braithwaite (1992, p. 26) argued that it is only by 'maximizing the difference between the punishment payoff and the cooperation pay off' that 'cooperation [appears] the most economically rational response'. However,

[74] See Footnote 14 in Chapter 3.

in many aspects of the regulatory regime, regulation continues to operate at the lower levels of the enforcement pyramid because the absence of and/or inability to apply sanctions, prohibits the TGA from escalating enforcement beyond lower-level persuasive techniques (see *Figure 6.6*). These limitations not only constrain the TGA to using cooperative techniques of government, but also makes the TGA, and ensuing enforcement action, appear less formidable to the uncooperative sponsor. The absence of punishment in these circumstances means that the highest-level penalties available to the regulator are unlikely to produce the punishment payoff necessary to usher in a culture of compliance.

Figure 6.6: A Representation of the Enforcement Pyramids for DTCA and Promotion (How the Pyramids Operate in Practice).



6.2.6.2 Enforcement is Susceptible to Challenge and Reversal

Stakeholders and interviewees indicated that TGA enforcement, for non-compliance and for quality, safety, and efficacy concerns more generally, are prone to appeal and being overturned (Submission 1101, Interviewees 3, 10 & 11, TGA 1 & 4). This issue was confirmed by members of the TGA personally:

> [It's] [f]rustrating that TGA decisions are overturned (Aspen for example). If [a] product is not approved or is removed from the ARTG, sponsors have the ability to appeal the decision internally and externally (not just at the AAT) (TGA 4, p. 2).[75]

Evidence of these types of decisions are available in a small number of court judgements (see *Aspen Pharmacare Australia Pty Ltd and Minister for Health and Ageing* (2012) AATA 362 & 376; *Ego*

[75] See Footnote 14 in Chapter 3.

Pharmaceuticals Pty Ltd and Minister for Health and Ageing (2012) AATA 210; *Health World Limited and Minister for Health and Ageing* (2013) AATA 388).

There are several reasons why TGA decisions may be prone to appeal and reversal. Since enforcement is unstandardised (a limitation of responsive regulation) and is sometimes motivated by risk considerations rather than the better nature of the regulatee (a limitation of a combined risk-based and responsive regulation approach), TGA decisions are not always going to be perceived as judicious by sponsors, which is likely to lead sponsors to retaliate and appeal TGA decisions. Since enforcement is less formal and concrete, TGA decisions are less likely to receive the backing of the judicial and political stratum. TGA decisions are also prone to being reversed because courts and administrative tribunals attempt to review the scientific evidence which led to a decision when they neither possess the expertise nor evaluate evidence with the same degree of depth as the TGA.[76] As Interviewee 10 explains:

> if you consider that when a drug goes through—certainly when a prescription medicine goes through TGA—it goes through several months of scrutiny by a number of experts. […] [I]t goes through a pharmaceutical subcommittee of experts. Then it goes to ADEC [now ADRAC]. So, you have about ten people at each level—experts—discussing this, knocking it around… and if the company doesn't like the decision, it can go to the AAT with one judge and two experts. […] The AAT doesn't listen to… it doesn't consider whether TGA… applied the right procedures. They rehear the evidence. I mean, that's absolutely nonsensical. You've got two people [experts], who by definition cannot be qualified in all in the areas the TGA have looked at [i.e. quality, safety and efficacy] […] you can't have two people who are qualified in all of those (Interviewee 10, pp. 12-3).

The appeal and reversal of TGA decisions has two main implications for the TGA and regulatory regime. First, it undermines the authority and expertise of the TGA to the point where the regime appears less formidable. For example, in the case of Urinary Tract Support, the CRP's initial decision to require Health World Limited to publish a retraction was overturned by the AAT on the grounds that the advertisement and labelling containing the misleading claims were no longer in circulation and had since been replaced by an alternate advertisement containing an alternative statement (*Health World Limited and Minister for Health and Ageing* (2013) AATA 388, para. 84). Second, the challenge and successful appeal of TGA decisions could deter the TGA from making risk-averse decisions in future in ways reminiscent of a compliance trap, because risk-averse decisions are more

[76] This is not to say that the TGA and regulatory regime should not be subject to external accountability, but that in their current form these external bodies appear ill-suited to evaluating the science behind pharmaceutical products.

likely to be challenged by sponsors and are less likely to receive judicial and political backing. These sentiments were evident in some of the comments made by a former employee:

> People often used to talk about the *Canberra Times* Test, "if we do this and it goes wrong, what's it going to look like in the *Canberra Times*?" […] "if we make this decision and it goes to appeal, how are the courts going to look at it?" You're trying to sort of pre-empt the courts without really making your own decisions (Interviewee 10, p. 12).

> TGA actually bringing legal action is very difficult to do. That was something we used to say: if you want to get a product off the market, you have to stop it before it gets there. Once it's on the market it's much more difficult to get it off. If there is a serious problem with a product, then you have to stop it from getting to the market in the first place… because, once it's on there, the company then gets… the law bends over backwards to be fair to the company (Interviewee 10, p. 13).

One interviewee, however, argued that the TGA may be motivated to make decisions knowing that they will be overturned because this insulates them from potential liability and negative publicity:

> my understanding of it from how I read it, is that in some ways, it protects the decision-maker from their decision… because then they can always claim they didn't make the decision, it was overturned. […] [W]hen that decision is overturned by the AAT the original decision-maker feels no guilt […] because their original decision was the cautious, risk aversion decision. […] [P]roducts receive… negative decisions, for example, … not because they're necessarily […] going to be a problem when used in the community, [or] because there is [in]sufficient data to support them being used in the community under the supervision of the prescriber… but because the decision-maker is risk averse and they don't want to make a decision where there is a potential for an adverse effect […] If it's overturned by the AAT then they are defended because if they [the Australian Government] ask into that product into the future, they can say "well I made a risk-averse decision […] it was the AAT that said it was okay, not me" (Interviewee 11, pp. 12-3).

Evidence of these types of sentiments were present in some of the comments made by current TGA employees. For instance, in response to a question on the number of TGA decisions overturned on appeal, one employee stated that:

> We can't determine how courts will react to a recall. [The] Federal Magistrates court in Brisbane overturned [a] recalled drug […] to note, the TGA said not to (TGA 1, p. 5).[77]

[77] See Footnote 14 in Chapter 3.

If the regulator feels trapped because its decisions are likely to come under scrutiny and their deterrent impact is likely to be lessened, it is possible that the regulator may be adopting a precautionary approach to decision-making and making decisions on the basis of avoiding all potential risk, even when clear evidence of risk is lacking. This may be the regulator's way of retaining some level of legitimacy and coping with compliance trap when political and judicial support is less than forthcoming.

The trap generated by the appeal and reversal of TGA decisions has prohibited the TGA from carrying out the types of enforcement typical of the mid-to-high pyramidal levels of the enforcement pyramid (*Figure 2.1*). This trap has ultimately confined the regulator to lower-level pyramidal techniques and reduced its legitimacy when it has attempted to pursue mid-to-high-level pyramidal techniques.

6.2.6.3 Intervention by Another Authority

The Australian Competition and Consumer Commission (ACCC) has intervened on several matters concerning therapeutic goods in those instances where the TGA has been unable to respond or escalate its response further. The ACCC has taken up several DTCA complaints (Submission 1109, Interviewees 6 & 9), including the notable cases of Nurofen and Sensaslim. The ACCC has also stepped in on issues concerning therapeutic goods promotion, and pushed industry associations, like MA, to develop more robust codes of conduct (Submissions 5001-02, 5005, 5010, 5016-17, 5019, 5022 & 7087, Interviewees 9 & 11). For example, the 18th edition of the MA Code of Conduct, effective as of the 16th of May 2015, now includes revisions to publicly disclose all transfers of value, such as speaking fees, advisory board fees, and sponsorship, made to healthcare practitioners (ACCC 2015, para. 2). These inclusions only came about through pressure applied on MA by the ACCC—the ACCC would only authorise the MA Code of Conduct, and thereby grant the Code statutory protection from legal action which may arise from conflicts with the *Competition and Consumer Act 2010* (Cwlth),[78] when the Code adequately met ACCC requirements.

The ACCC's intervention on these matters has effectively diminished the authority of the TGA by highlighting the agency's incapacity to undertake these types of actions independently. In fact, the perceived ineffectiveness of the TGA on advertising and promotional matters has led some stakeholders to advocate that the TGA should no longer be charged with advertising and promotional

[78] Authorisation is only granted in those situations where 'the public benefit from the conduct outweighs any public detriment' (ACCC 2015, para. 13).

regulation, and that the CRP should be disbanded in favour of the ACCC handling all advertising and promotional complaints under consumer law (Submissions 1087, 2029, 7086 & 9203). Direct intervention by the ACCC on these matters also has implications for enforcement. In its current capacity, the ACCC is unable to act on every TGA administrative request failure. This is because the ACCC already has a considerable regulatory remit and it neither has the time nor resources to act on each request failure (Submission 9203 & Interviewee 9). The irregularity and rarity of this ACCC intervention means that advertising and promotional infringements do not always result in high-order punitive sanctions, and therefore, equitable treatment of all regulatees. Although the ACCC provides a valid fail-safe option in those situations where TGA administrative requests fail to generate compliance, in its current form, intervention by the ACCC is unable to generate more equitable or hierarchical levels of enforcement.

6.2.7 OPERATIONALLY CONSTRAINED

A lack of resourcing, personnel, and bureaucratic autonomy, along with the constraints of the *National Medicines Policy* (NMP) and self-regulation, has limited the capacity of the TGA to act on non-compliance.

6.2.7.1 Limited Resourcing

A lack of resources has reduced the capacity of the TGA to respond to industry non-compliance (Submissions 1044, 1051, 1068, 1074, 1081, 1108-09, 1119, 2009-10, 2015-16, 2028, 2034, 3001, 3005, 3016, 3025, 3033-34, 3103, 5009, 5017, 5019, 5022-23, 7006, 7021, 7024, 7046-48, 7050, 7053, 7061, 7070, 7079, 7090-92 & 8004, Interviewees 2, 4-7, 10 & 11). Resource constraints can be directly attributed to the Australian Government's cost-recovery policy, which, stakeholders and interviewees argue, has restricted the TGA to those activities where costs are directly recoverable (Submissions 1002, 3016 & 7086, Interviewee 4, 9 & 11). This restriction has meant that those activities which are not or cannot be cost-recovered, are unlikely to be carried out due to the absence of alternative sources of funding. These issues are exemplified by the quotes below:

> they had the Review of the complementary medicines industry. There were quite a number of recommendations in that, but they still haven't been fulfilled. And you've got to ask, well why? [...] at the end of the day, it seems to get back to costs [...] The whole system's run through cost recovery. So, it's easy to be critical of that set up… because everything has to fit in within a budget (Interviewee 4, p. 6).

> it constrains the TGA from doing some of the public health activities that it should be doing… that can't come from direct cost-recovery. By being directly cost-recovered, you have to be… paying for the services [...] and there are some public health messages around education, awareness… and information and safety that [...] can't be cost-recovered (Interviewee 11, p. 10).

Cost considerations also prohibit the TGA from undertaking any new activities or implementing new mechanisms that would otherwise enhance its capacity to regulate industry and provide the levels of information necessary to aid health literacy, as the quotes below demonstrate:

> If we accept the proposal, at face value that every API [active pharmaceutical ingredient] of every CM is subject to thorough review, how does the TGA propose to police the implementation? […] [D]o they have the resources to ensure that papers are not improperly included or excluded from reviews? […] the TGA does not (and could not be foreseen to) have the resources to police such a system (Industry Consultant, Submission 3001, p. 20).

> This approach may yield consistency in decision-making […] However, [our organisation] notes the TGA's resources may already be at capacity with its current responsibilities, […] this may affect its other work (Consumer Organisation, Submission 7050, pp. 13-4).

> The reduced capacity of the TGA to undertake additional activities to protect public health such as supporting independent pharmacovigilance studies and supporting communication and transparency is a serious concern. "Too costly" was the reason given when the TGA refused to provide CMIs and PIs on its website following a review that concluded that it was the best option for consumers and health professionals alike [...] I am concerned that the recommendations of this panel review could be downgraded as "too costly" (Academic, Submission 1119, p. 7).

These cost considerations ultimately prohibit the TGA from responding to non-compliance by restricting the TGA to those activities which are cost-efficient for it to administer.

6.2.7.2 Limited Personnel

The TGA is also said to have inadequate levels of staffing relative to its current workload (Submissions 1044 & 1081, Interviewees 3-4 & 11). As a point of comparison, a small number of stakeholders and interviewees contrasted the differences between the staff-to-workload ratios of the TGA and the United States Food and Drug Administration (FDA):

> If you're talking about comparing the TGA and FDA; FDA has an enormous budget, an enormous number of personnel and in some ways, they are functionally doing the same work (Interviewee 3, p. 18).

> bodies like the FDA have significantly more resources to run a therapeutic goods list comparable to Australia's ARTG with 17,000 staff to TGA's 500 (Consumer Organisation, Submission 1044, p. 5).

Although low levels of staffing can be attributed to cost-recovery limitations, stakeholders and interviewees claimed that staffing has also been affected by the availability of applicants with the requisite skills, as Interviewee 11 (p. 10) explains:

> If you look at the number of qualified graduates that come out of universities, there are plenty of them around, but where do they go? They don't necessarily choose the government as a place to use their skills.

With fewer personnel at their disposal, the TGA is placed in less of a position to act on non-compliance.

6.2.7.3 Limited Bureaucratic Autonomy

The TGA is not an independent statutory authority in its own right; it is a divisional unit which falls under the Department of Health and broader Australian Government. This arrangement places direct constraints on the day-to-day operation of the TGA. The TGA is confined to the policy (see 6.2.7.4 & 6.2.7.5) and funding arrangements (see 6.2.7.1) imposed on it by the Australian Government. The TGA is also subject to departmental administrative constraints. The Department of Health has direct control over the TGA's media and public messaging:

> all media and public affairs inquires go to the Department of Health spokesperson, they then get filtered to the TGA who may respond. It goes then back to… the Department of Health media person who then determines whether the response will be made public or not […] the TGA doesn't have control over its own messaging (Interviewee 11, p. 12).

> they sit under DoHA. They may give the appearances of being independent, but they are actually sitting under DoHA […] the way they communicate with the world and how the TGA presents itself is filtered through DoHA (Interviewee 3, p. 17).

> they can't talk to anyone by themselves […] they can't put out a press release without it going through [the DoH] (Interviewee 3, p. 18).

And while product testing and assessments are conducted independently of the Department, the Department is also able to intervene on decisions concerning the regulation of prescription and non-prescription medicines. For example, one interviewee spoke of an instance where the Department, and Minister for Health in particular, was able to exert influence over the TGA and a TGA expert advisory committee in a decision concerning the registration of a medicine:

> recently, just in the last meeting, we were asked to comment on it [the drug] again and I thought why are we commenting on this again? Because [...] there wasn't much more to comment, but there were slight[ly] differently worded questions. [...] [It] actually originated in the Health Minister's Office. She actually specifically contacted the TGA and said "what's this? What's the deal with this?" And so that came up for discussion (Interviewee 7, p. 13).

Although the lack of statutory authority provides the TGA with greater accountability to Government and insulates the TGA from direct influence by industry, it also reduces its public accountability, a limitation of many public-sector agencies, and exposes the agency to indirect forms of industry influence which occur at higher levels of government (more on this at 7.2.3.1.). Because of this array of issues, the capacity of the TGA to respond to compliance issues is severely reduced.

6.2.7.4 National Medicines Policy Constraints

The principle objectives of Australia's NMP places the general public health interest in direct competition with private interests. The capacity of the TGA to act on regulatory issues is therefore inhibited when policy objectives aimed at protecting consumers directly conflict with the objective of maintaining a responsible and viable medicines industry. An example of this type of conflict concerns evidence requirements for listed medicines; consumers and public interest groups want all listed medicines to be evaluated for efficacy prior to marketing, but sponsors have successfully argued that such requirements would be cost and time-prohibitive, especially given the low-risk nature of listed products. The following quote clearly captures this tension:

> [This organisation] understands that Listed medicines are considered lower risk and that the Listed process provides consumers with expedited access to these medicines. However, there must be a balance between providing expedited access to therapeutic goods and ensuring Sponsors are meeting their requirements and hold robust evidence to support the claims made on their products [...] the original version of the draft document appeared to be targeted at addressing consumer needs, while

> Version 2 appears to be aimed at reducing the "burden" on industry. [Our organisation] finds this shift disappointing (Consumer Organisation, Submission 3115, pp. 1-2).

These conflicts delay the regulator from acting on non-compliance and implementing mechanisms which would otherwise enhance its capacity to act.

6.2.7.5 Self-Regulatory Constraints

The Australian Government's preference and public endorsement of industry self-regulation (Department of Health 2011, pp. 1-2) has effectively restricted the degree to which the TGA can exercise authority within the regulatory regime. The TGA's attempts to respond to non-compliance or introduce measures that would otherwise enhance its capacity to respond to non-compliance are often met with resistance from industry because these actions act counter to the notion of responsibilised autonomy (see *Chapter 8*). In fact, some industry stakeholders have used the Australian Government's official endorsement of self-regulation as a primary reason against the implementation of additional regulation, as the quote below demonstrates:

> Self-regulation in advertising is broadly recognized and supported by government as an effective mechanism for achieving health policy outcomes and one that should be considered before legislated regulation is introduced (Industry Association, Submission 2003, pp. 1-2).

These interests have delayed the regulator from acting on non-compliance and implementing mechanisms which would enhance its capacity to achieve compliance.

6.3 SUMMARY

In those aspects of the pharmaceutical regulatory regime where non-compliance is greatest, the regime's capacity to identify and act on non-compliance has been reduced due to: the low levels of oversight exercised in these aspects of the regime; the capacity of regulatees to evade being subject to the regime; the reactive nature of the regime; the regime's lack of centralisation and proportionality; the regime's inability to escalate beyond lower-level persuasive techniques; and the operational constraints placed on the TGA. These techniques of government have decreased the overall deterrent impact of the regime, and therefore, its general capacity to achieve compliance from sponsors.

These techniques of government are at odds with the rationalities of risk-based and responsive regulation theory, which advocate for 'escalating (and increasingly undelegated) forms of government intervention' (Ayres & Braithwaite 1992, p. 158). Instead, these techniques are more closely aligned with neoliberal rationalities of government which aim to limit forms of market intervention by the state detrimental to the pursuit of capital. The disconnect between the techniques employed by the regime and the rationalities of risk-based and responsive regulation indicates that these techniques have been severed from the ideological foundations of the original theories so that the regime is more closely aligned with a neoliberal governmentality.

This governmentality has formed part of a hegemonic project which attempts to secure general support for governmental techniques which have the least amount of impact on the capacity of industry to accumulate capital. Support for this governmentality was originally secured by framing private interest issues as the general public health interest (see *Chapter 4*). This support has been maintained because this governmentality has essentially functioned as a 'politics' or 'regime of truth' (Foucault 1991; as cited in Lemke 2002, p. 55). For example, the regulator's incapacity to achieve compliance from sponsors reinforces the mentality that state intervention should be minimal and that regulated entities should be responsible for their self-regulation. Claims that regulatees are cooperative and capable of self-regulation are reinforced by the regulator's inability to detect and act on non-compliance, and to predict and mitigate risk. Similarly, responsibilisation portrays sponsors and industry associations as cooperative entities capable of self-regulation while at the same time granting them the autonomy to define and work within their own set of rules. By creating a reality which it says already exists, this governmentality 'create[s] a discursive field' or 'knowledge' where the exercise of this particular type of government is deemed rational (Lemke 2002, p. 55). It therefore constructs and shapes subjects in line with a neoliberal rationality that effectively serves the long-term interests of the regime's most dominant forces, market players. This shaping, in turn, reinforces the structuration of power relations within the regime by maintaining the authority of market players over less dominant, non-market non-governmental players.

Advocates of compliance, like Ayres & Braithwaite (1992), argue that the biases generated by cooperative techniques of government can be overcome by empowering non-market non-governmental players so that they are more politically active and can hold the regulator and regulatees to account. Technologies of citizenship, such as tripartism, have been heralded by this group of scholars as a primary means for non-market non-governmental players to punish regulatees directly, or, punish the regulator for failing to defect from cooperation. Consumers, too, can lessen their risk to unscrupulous products and industry practices by deploying their agency so they are more literate

about the products they use and the ways in which they are regulated. However, as *Chapter 7* demonstrates, not only are non-market non-governmental players rendered largely uninformed on issues concerning therapeutic goods and regulatory processes, but their capacity to participate in the regime is severely limited.

7 REDUCED CAPACITY FOR PARTICIPATORY DEMOCRACY

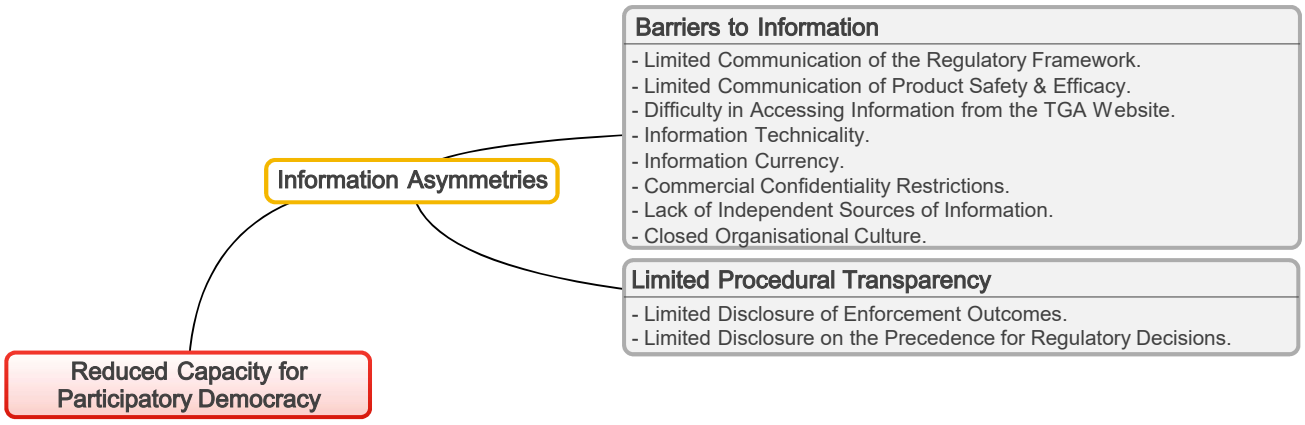
This chapter explores the second of the two over-arching themes generated from the thematic analysis: the limited scope for non-market non-governmental players to participate within the regulatory regime (*Reduced Capacity for Participatory Democracy*). Currently, information asymmetries (*Information Asymmetries*) bar public access to information (*Barriers to Information*) and reduce the procedural transparency of the regime (*Limited Procedural Transparency*). The regime also suffers from structural inequalities (*Structural Inequalities*). Stakeholders and interviewees reported: a lack of opportunities to question and appeal regulatory decisions and oversee the actions of the regulator (*Limited Opportunities for External Review & Oversight*); a lack of engagement of non-market non-governmental players in the regime (*Limited Engagement of Non-Market Non-Governmental Players*); and conflicts of interest between governmental and market players (*Conflicts of Interest*).

In exploring these themes, the chapter draws two major conclusions. First, the chapter finds that non-market non-governmental players are often deprived 'of the information and understanding they need, individually and collectively, to participate' (Medwar 1996; as cited in Lewis & Abraham 2001, p. 71). Consumers and healthcare practitioners are denied access to knowledge necessary for engaging in the rational calculation of the costs and benefits of a medicine, and therefore, exercising the agency necessary to successfully navigate the regulatory terrain. Non-market non-governmental players are also denied access to knowledge which enables them to mediate and hold other players to account. Second, the chapter finds that non-market non-governmental players receive lesser degrees of representation within the regime compared with other regulatory players. These features ultimately decrease the extent to which non-market non-governmental players can effectively participate, and therefore, intercede, in the regime.

7.1 INFORMATION ASYMMETRIES

Information asymmetries have generated power imbalances which have decreased the capacity of non-market non-governmental players to participate within the regime (see *Figure 7.1*).

Figure 7.1: Themes Mapping the Information Barriers Which Prohibit Access to Information.



7.1.1 BARRIERS TO INFORMATION

Information barriers have barred the acquisition of medical and regulatory knowledge.

7.1.1.1 Limited Communication of the Regulatory Framework (Listed and Registered Medicines)

Stakeholders and interviewees indicated that there is a general lack of knowledge among members of the public of the Therapeutic Goods Administration (TGA) and the degree of oversight it exercises (Submissions 1003, 1013, 1020, 1027, 1042-43, 1059-60, 1079-81, 1084, 1088-89, 1095, 1103, 1107, 1112, 1114, 2028, 3011, 3026, 3029, 3115, 6005, 6017, 7057 & 9110, Interviewees 3, 4, 6 & 11). Stakeholders and interviewees also reported low levels of knowledge of spontaneous reporting mechanisms among consumers and healthcare practitioners (Submissions 1001, 1003, 1013, 1030, 1043-44, 1050, 1058, 1068, 1074-75, 1079, 1084, 1086, 1089, 1105, 2009-10, 2012, 2015, 2024, 2028, 2034-35, 4014-15, 6005, 7050 & 7090, Interviewees 3, 4, 6 & 7). Some of these concerns are mirrored in the academic literature. Interviews and surveys conducted by Robertson and Newby (2013, p. 685) found that only 10.4% (520 out of 4,981) of Australian consumers were aware of adverse drug reaction (ADR) reporting mechanisms; only 2.9% (145 out of 4,981) were able to identify the TGA as a site for lodging ADR reports. Studies also demonstrate low levels of knowledge of ADR reporting mechanisms among Australian healthcare practitioners[79] (Bensoussan, Myers, Wu & O'Connor 2004; Kelly, Kaye, Davis & Shenfield 2004; Nita, Batty & Plumridge 2005; Parella, Braunack-Mayer, Gold, Marshall & Baghurst 2013). At a time when spontaneous reporting rates were greatest among this group of reporters,[80] only 34% of doctors and 37% of nurses claimed to be aware of any form of ADR reporting procedure (Kelly et al. 2004, p. 33). No literature exists on the extent

[79] Excluding Australian pharmacists, who have demonstrated significantly higher levels of awareness of ADR reporting mechanisms than any other practitioner group (Kelly et al. 2004; Nita, Batty & Plumridge 2005).
[80] Between 1998-2003, reporting was as high as 26% for general practitioners (Department of Health and Aged Care 1999a; Department of Health and Ageing 2003 & 2005; Department of Health 2016b).

of consumer or practitioner awareness of complaints reporting mechanisms for advertising and promotional breaches, but stakeholders and interviewees have claimed that complaints are rarely ever lodged by consumers or healthcare practitioners (Submissions 1075, Interviewees 4, 6-7 & 9). Interviewee 6 indicated that the industry association which they represent has only received one non-industry complaint in the past ten years (Interviewee 6, p. 1). While many factors contribute to low rates of reporting among consumers and healthcare practitioners (see 7.2.2.1), a lack of regulatory knowledge (i.e. knowledge of the TGA, the degree of oversight it exercises, and the overall regime) is likely to preclude consumers and healthcare practitioners from participating actively in spontaneous reporting processes, particularly in terms of knowing with whom to lodge a report or complaint, and how to lodge a report or complaint.

7.1.1.2 Limited Communication of Product Safety (Listed and Registered Medicines)

Despite the wide variety of sources available to inform consumers and healthcare practitioners of the safety risks associated with registered medicines, including Australian Public Assessment Records (AusPARs), Product Information (PI) and Consumer Medicines Information (CMI), boxed warnings, medicine safety updates, and public recall and cancellation notices, stakeholders and interviewees believed that the TGA's communication of known safety risks is either delayed or absent (Submissions 1030, 1044, 1047, 1050, 1058, 1069-70, 1074, 1086, 1090, 1097, 1112-13 & 1115, Interviewees 3 & 7). For example, one interviewee recounted an instance where a product had been approved by the TGA in the absence of safety warnings despite having prior awareness that the drug carried an irreversible side effect:

> My concern was the reason why the drug was approved for use in Australia without the test […] being available, and also that the[se] safety issues were not more explicitly stated in the product information […] Because there is no antidote for the drug. So, if you develop a bleeding side-effect from it, […] [there is] no antidote to correct the drug activity (Interviewee 7, p. 4).[81]

> I would have thought that even during the assessment process […] that, you know, somebody would have said "look… what programs are you going to put in, have you got a blood test for it, how are you going to measure this… what happens if someone takes you know gets bleeding from it, how are you going to manage that?" (Interviewee 7, p. 6).[81]

[81] Some of the details surrounding this product, including the brand name, active ingredients, and specific details regarding the side effects, have been removed from this extract to protect the anonymity of the interviewee.

> how can one introduce the drug when there is no test for it? […] [T]he general public don't know, they don't understand […] The GP thinks there's no testing required (Interviewee 7, p. 6).[81]

Other stakeholders referred to cases where safety risks had not been communicated to the public by the TGA despite warnings and cancellations being issued by overseas regulators (Submissions 1030, 1047, 1050, 1069-70, 1115 & 4023), an example of which is outlined below:

> American, United Kingdom and European regulatory authorities have raised concerns about an increase in hepatotoxicity[82] from dronedarone (FDA safety alert, 14/1/2011; MHRA safety warning, 21/1/2011; and EMEA notice of benefit/risk review, 21/1/2011 respectively) but there is no mention of any concern relating to dronedarone on the TGA website to date (Non-for-Profit Organisation, Submission 1115, p. 2).

As of 2018, the TGA had not published an alert concerning the hepatotoxicity of dronedarone on its website, however, all PI/CMI documents for dronedarone now include a warning of an increased risk of hepatic impairment. When these documents were first updated to include these warnings is unknown because backdated versions of PI and CMI documents are not made available to the public. (The latest version of the PI and CMI for dronedarone at the time of writing is current as of January 2015).

While there may be extenuating reasons as to why the TGA will not issue safety information in these circumstances,[83] the absence of this information inhibits consumer and practitioner literacy nonetheless by failing to communicate the presence of possible risks associated with products which could impact purchasing and prescribing decisions. This lack of disclosure can lead to misinformation when warnings are lacking or conflicting, especially when overseas authorities issue their own warnings. Australian consumers and healthcare practitioners have been known to alter their medication and prescribing practices in response to overseas warnings, purely because these warnings have been issued before those of the TGA (Niyomnaitham, Page, La Caze, Whitfield & Smith 2014). In situations where safety advice happens to differ between overseas and Australian markets, the failure of the TGA to provide safety information for comparable products on the Australian market

[82] Liver damage or injury which can be chemically or drug induced (Martin 2007, p. 349).

[83] For instance, risk rationalities imply that not all risks associated with medicinal products are knowable and controllable at the outset, and limited information about the prevalence of a known side-effect may call for added observation and testing rather than the issue of an explicit warning. Differences in dosage and administration requirements between countries could also imply that the same risks would not apply to comparable products on the Australia market.

can lead to illiteracy, especially when consumers and healthcare practitioners are made to fill in knowledge gaps on their own and unnecessarily continue or cease a treatment.

The lack of communication of known safety risks is not exclusive to registered medicinal products. Unlike registered medicines, AusPARs, PI/CMI, and boxed warnings are not a legal requirement for listed products because they are presumed to be low-risk products containing low-risk ingredients. The absence of any safety information on listed medicine packaging—along with their ease of access, capacity for self-administration, and appearance as being government approved—has led to misconceptions among members of the public that listed OTC and complementary medicines are relatively safe and risk-free (Submissions 1009-10, 1030, 1037, 1047, 1079, 1091, 1102, 2010, 2012, 2021-22, 3003, 3020, 3023 & 4023). Stakeholders and interviewees believed that the TGA did not do enough to correct these misconceptions, citing examples, like those below, to demonstrate how perceptions that listed medicines are safe have led to unintended ADRs:

> a 7 month old child presented with a short 24 hour history of being acutely unwell. After detecting salicylates[84] in the urine, and treating appropriately, a thorough investigation of the family's medicine cabinet resulted in the family admitted to using large amounts of Bonjela[85] over the preceding 2 months; going through two to three tubes per week. […] [A] 13 month old infant presented with failure to thrive. An arterial blood gas [test] alerted the clinician to an unexplained metabolic acidosis[86] and respiratory alkalosis[87]. On further questioning, the parents admitted the frequent use of Bonjela, sometimes going through an entire tube in one night to settle the infant to sleep (Practitioner, Submission 1047, p. 3).

Non-disclosure and misinformation issues surrounding the safety of listed and registered medicines have been compounded by several other information barriers. Stakeholders indicate that there is '[p]oor direct availability of information' from the TGA with other channels of distribution (Information provider, Submission 1090, pp. 3-4), particularly, government departments, healthcare practitioners, and medicines information providers (Submissions 1007, 1013, 1043, 1049, 1086 & 1090), which has barred comprehensive, and sometimes accurate, information from being disseminated to the public. One stakeholder, which provides free medicine information to consumers and healthcare practitioners via a telephone hotline, indicated that it often receives 'no direct

[84] A commonly used drug derived from salicylic acid, such as aspirin or anti-inflammatory medicines (Sell, Rothenberg & Chapman 2012, p. 517).
[85] A teething medicine or gel used to relieve gum pain.
[86] Abnormally high levels of acid accumulation (Martin 2007, p. 7).
[87] A 'form of alkalosis (abnormally low hydrogen-ion concentration in the blood) in which there is greater than normal excretion of carbon dioxide' (Sell, Rothenberg & Chapman 2012, p. 503).

communication from [the] TGA' following the issue of a safety alert and when calls to its information hotline are likely to be at its greatest (Information provider, Submission 1090, p. 4). Historically, ADR and clinical trial data have not been made publicly available (Submissions 1003, 1013, 1043, 1047, 1049, 1069, 1113, 1119, 7009 & 9006), despite this being common practice in many overseas jurisdictions (e.g. see the FDA's FAERS and clinicaltrials.gov). Information detailing which products are subject to risk management plans is not made publicly accessible (Advisory Committee, Submission 1003, p. 3), and while the TGA website provides some information on the types of evidence supplied by sponsors at the time of registration, 'these are not referenced as specific citations so [that] users are […] able to access the trial reports' (Not-for-Profit NGO, Submission 1115, p. 1). Other factors, which are explored in more detail in later sections of this chapter, include the fact that: few independent sources of information are available to the public to validate safety and efficacy claims (see 7.1.1.8); current sources of information for registered medicines, like AusPARs and PI/CMI, are highly technical in nature (see 7.1.1.5), are prone to becoming antiquated (see 7.1.1.6), and are often deemed 'insufficient' for conveying the extent and significance of risks (Bauschke 2012, p. 13); and that boxed warnings and medicine safety updates, while helpful in alerting consumers and healthcare practitioners to the risks posed by registered medicines, are retrospective measures applied after consumers are exposed to harm. All these factors limit the capacity of consumers and healthcare practitioners to acquire knowledge necessary for exercising individual agency—for calculating the cost and benefits of products, and developing health literacy.

7.1.1.3 Limited Communication of Product Efficacy (Listed Medicines)

Stakeholders and interviewees have also criticised the lack of information provided on the efficacy of listed medicines which, many believe, has contributed to misconceptions about the effectiveness of listed medicines among the public (Submissions 1005, 1009, 1027, 1030, 1032, 1041, 1043, 1047-49, 1053, 1075, 1077, 1089, 1109, 2010, 2012, 2020-22, 2025, 3011, 3115 & 7050, Interviewees 1 & 10). Many of these stakeholders and interviewees felt that the AUST L label was insufficient for conveying the degree of oversight listed medicines receive, especially given the lack of information and promotion on the extent to which they are evaluated prior to listing (see 7.1.1.1), the extent to which they have been found to contain demonstrable efficacy once reviewed by the TGA (see 7.1.2.1), and, the lack of independent information sources available to enable consumers to verify efficacy claims independently (see 7.1.1.8). The extract below was provided by one stakeholder to illustrate this case:

> One of our members brought along to the meeting with the Review Panel a therapeutic goods product that he had recently purchased from his local pharmacy. The packaging of this product looked indistinguishable in appearance from a prescription medicine, which was obviously a marketing ploy. None of us could find any information on the packet as to whether it was a TGA registered or listed product. Even one of the panel members couldn't find this information either, until she took it to another panel member or TGA officer who found the code for a listed product on one side of the packet in small print. The orientation was such as to require the box to be turned sideways to read the 'AUST L' marking. This is hardly a good example of transparency. Consumers have a right to be unequivocally informed that listed therapeutic goods have not been tested or approved by the TGA for efficacy (Sceptic Organisation, Submission 1089, p. 3).

Similar concerns surrounding the lack of public knowledge of listed medicine efficacy have been raised in the academic literature. A study of complementary medicine use in Australia found that 88% (986 out of 1,121) of consumers who had reported taking a complementary medicine in the preceding 12 months failed to notice whether the product contained an AUST L label (Braun, Tiralongo, Wilkinson, Poole, Spitzer, Bailey & Dooley 2010, p. 243). Of these consumers, 33% (325 out of 986) thought the AUST L label denoted that the product had been tested by a government agency for safety, 26% thought that the label meant the product had been tested for quality, and 24% thought the label identified the product as being Australian made (Braun et al. 2010, p. 243). Approximately 15% of consumers thought that the label meant the product had been tested for effectiveness while 13% did not know what the label represented (Braun et al. 2010, p. 243). The lack of information provided on the extent to which listed medicines are evaluated and can be regarded as efficacious has lessened the capacity of consumers and healthcare practitioners to make informed decisions about their value.

7.1.1.4 Difficulties in Accessing Information from the TGA Website (Listed and Registered Medicines)

Stakeholders and interviewees also reported difficulties in accessing certain types of information from the TGA website which they deem necessary for fostering health literacy and participation by non-market non-governmental players. This included difficulties in accessing public summary documents, PI/CMI, AusPARs, ADR forms, and information on spontaneous reporting procedures. Stakeholders reported that:

> the TGA website is not particularly user friendly and intuitive to find your way around there is often a need to "try and see" before finally, often quite by coincidence, finding what you are looking for. This is frustrating as a Health Professional who might actually understand and recognise what I am

> looking for but would be more so for the general public who are less likely to understand the information that comes up (Governmental Body, Submission 1082, p. 3).
>
> whilst the TGA web site does provide some information on how to lodge a complaint, it is not directly accessible from the home page and some drilling down is required to find it. Even then, there is no provision for an online complaint (Sceptic Organisation, Submission 1089, p. 4).
>
> navigating to the correct adverse reporting page via the TGA website can be a challenge. The online reporting form can be difficult to follow, particularly for the less health literate (Industry Association, Submission 6018, p. 2).

The ARTG's search facilities have also been criticised by some stakeholders for their limited functionality:

> Searching for either an Approved Product Information or Consumer Medicine Information is challenging. For example, when entering "Aspirin", all products that contain aspirin in combination with other drugs were presented but nothing that related to plain and simple aspirin (Governmental Organisation, Submission 1082, p. 3).
>
> You need specific names/brands rather than just a type of thing (for example you can't search "baby pillow", you need the actual brand) which makes searching inefficient (Journalist, Submission 1113, p. 8).

A small number of stakeholders also criticised the TGA website for the limited amount of information it provided; public summary documents, PI/CMI, and AusPARs, for example, are not made available for all listed and registered products on the TGA website (Submissions 1082, 8018-19 & 8022). Difficulties in obtaining this information can discourage the public from utilising the TGA website as an information source and drive them to use third party providers, which may not always provide accurate information (as Submissions 1050, 8003 & 8013 claimed).[88]

7.1.1.5 Information Technicality (Listed and Registered Medicines)

Stakeholders and interviewees believed that much of the information made available by the TGA to the public catered to industry and individuals with medical or regulatory knowledge; information was rarely thought to be provided in ways that were immediately accessible to consumers, and even some

[88] A random selection of PI documents from third party sites by one stakeholder revealed that as many as 36% (16 out of 44) were out-of-date (Hospice, Submission 8013, p. 1).

healthcare practitioners (Submissions 1003, 1019, 1025, 1030, 1049, 1051, 1053, 1059, 1075, 1082, 1084, 1086, 1095-96, 1105, 1107-18, 2015, 3033, 6018, 8008, 8018 & 9110). Some of these concerns are outlined:

> there is already a multiplicity of public information available from the TGA website. However […] the majority of this information is highly scientific in nature and consequently is not provided in a necessarily consumer friendly or simple to understand manner (Industry Association, Submission 1084, p. 1).

> AusPARS are written for a technical audience and are unlikely to be used by most consumers and health professionals (Governmental Body, Submission 1003, p. 3).

> Consumers […] considered current CMI leaflets to be technical and long. These barriers have been identified on many occasions previously (Practitioner Association, Submission 8018, p. 4).

Stakeholders and interviewees also indicated that the workings of the regime can be highly technical for most consumers and healthcare practitioners. Limited knowledge of how spontaneous reporting mechanisms operate has reportedly discouraged some consumers and healthcare practitioners from making ADR reports (Submissions 2015, 4014, 7004, 7050 & 7090). Similarly, limited knowledge of the advertising rules increases the difficulty for consumers and healthcare practitioners in differentiating between appropriate and inappropriate advertising claims for the purposes of lodging a complaint (Submission 2015 & 7092). The technical nature of pharmaceutical regulation can also prohibit consumers from participating in public consultations or on advisory committees. One stakeholder had raised this concern during a consultation where no consumer submissions were made:

> the audience for the guidance document is medicines manufacturers […] While the technical aspects of the manufacturing process may not be of significant interest to consumers, the overarching framework should, at a minimum, be easily understandable. The information available on the TGA's website and the guidance and policy documents in this area are not written in a way that facilitates consumer understanding (Consumer Organisation, Submission 9110, p. 5).

> [Our organisation] sees this process as an important, but ill-defined area of Australia's medicines regulatory regime and an area that consumers, traditionally, have had limited scope to provide input to (Consumer Organisation, Submission 9110, p. 2).

> As the end users, and those who will directly experience any adverse effects from poor manufacturing practices, consumers should have access to easy to understand information as well as to be able to comment on how policies affect them (Consumer Organisation, Submission 9110, p. 8).

An interviewee also conveyed these types of concerns in relation to consumer representatives on advisory committees:

> it's difficult I think for a non-expert consumer person… very difficult […] unless you know the literature and unless you can counter the bullshit... it can be hard to... to make an impact […] [My colleague] she's good but she'll admit that… yeah I've got technical knowledge and knowledge of the history that she just hasn't got (Interviewee 9, p. 10).

Technical knowledge and a lack of access to intermediary sources of information can prohibit consumers and some healthcare practitioners from accessing information which is necessary for exercising agency and participating more actively in the regulatory regime, particularly for spontaneous reporting purposes, making submissions to consultations, and acting on regulatory committees.

7.1.1.6 Information Currency (Listed and Registered Medicines)

Some forms of information made available to the public are prone to becoming antiquated. PI and CMI documents, for instance, are often accused of containing out-of-date information (Submissions 1002, 1013, 1024, 1043, 1045, 1047, 1054, 1075-76, 1079, 1115, 8001, 8003, 8005, 8009, 8011, 8015, 8018 & 8023), simply because they are a reflection of the safety and efficacy profile of a medicine at the time of registration or the point the document was last updated. PI documents are only updated when a variation is made to a medicine or its ARTG entry by the sponsor, when a variation to the PI is requested by the sponsor (e.g. to extend product indications, to register a new generic medicine, or to add a new trade name to a medicine), or based on a safety-related change mandated by the TGA (TGA 2013b & 2013f). Whether a variation is self-assessed or approved by the TGA is dependent on the type of change being requested. Self-assessable changes are permitted when variations are not safety related, do not reduce the quality, safety, or efficacy of the product, and do not require the submission and evaluation of data by the TGA (TGA 2013g, p. 46). These changes may include corrections to ARTG entries, minor editorial changes, and some safety-related requests (TGA 2013g, p. 18). Anything which requires the submission and evaluation of data is not self-assessable (TGA 2013d, p. 18). Outside these periods, there are no independent routine mechanisms for reviewing PI documents—the onus falls on sponsors to ensure that PI documents

contain correct and up-to-date information (TGA 2013f, p. 17). No independent mechanisms are in place to ensure the currency of CMI documents either—the TGA simply mandates that sponsors ensure that CMI documents are consistent with the approved PI (TGA 2013b). Between the 1st of January 2010 and the 31st of January 2013, 28% (3,600 out of 12,654) of PI documents in circulation were approved or re-approved by the TGA, indicating that as many as 'two-thirds of documents on the ARTG are not current within the last three years' (Information Provider, Submission 8003, p. 16). Industry stakeholders insist that low rates of approval and re-approval simply 'reflects the fact that no new information has been generated on the medicine which would require the PI to be updated' (Industry Association, Submission 8004, p. 6). However, the lack of active monitoring (Submissions 1079, 8003, 8006 & 8010), along with the financial cost associated with updating PI/CMI documents (Submissions 1088, 8003, 8009 & 8014-15), have been touted as major reasons why sponsors are less inclined to maintain the currency of PI/CMI. This is especially the case when a medicine has gone off patent; generic medicine sponsors are supposed to 'routinely check the TGA website' for updates to PI/CMI documents by the sponsor of the innovative product as no other mechanisms exist to alert generic medicine sponsors that a PI/CMI document has been updated (Industry Association, Submission 8009, p. 5).

Information supplied on the TGA website is also often accused of being out-of-date (Submissions 1004, 1051, 1075, 1090, 1099 & 1115). For example, the PI/CMI supplied for registered products on the ARTG is not necessarily the most up-to-date version used by the sponsor. Rather than ensure that the documentation supplied on its website is the most up-to-date version available, the TGA uses an exclusion of liability disclaimer—to absolve itself of responsibility for any outdated and inaccurate information obtained from the ARTG—which users must agree to in order to access a PI/CMI document. This disclaimer reads: 'You are responsible for making [Y]our own enquiries to determine whether any PI document or CMI document is accurate, up-to-date and fit for [Y]our purpose' (Health Advocacy Group, Submission 1099, p. 9). Disclaimers also appear at the bottom of all public summary documents supplied with ARTG entries: 'The onus is on the reader to verify the current accuracy of the information on the document subsequent to the date shown' (Information Provider, Submission 1090, p. 5). Out-of-date information is not confined to PI/CMI documents; stakeholders also referred to pages on the TGA website which contained outdated information—one page, which is supposed to contain a running list of substances currently approved for use in listed medicinal products, had not been updated for more than three years (Industry Association, Submission 1051, p. 2).

The lack of up-to-date information can have deleterious consequences for the formation of health literacy and medical knowledge as it denies consumers and healthcare practitioners timely access to information necessary for making rational calculations about the cost and benefits of medicinal products. This renders the information available less effective for risk minimisation purposes. Since information providers are also reliant on much of the information disseminated by the TGA—PI/CMI documents supplied by the National Prescribing Service (NPS) and Monthly Index of Medical Specialists (MIMS), for example, are usually obtained from the TGA website directly—out-of-date information provided by the TGA and passed on to the public via information providers can increase the spread of this misinformation.

7.1.1.7 Commercial Confidentiality Restrictions (Listed and Registered Medicines)

Commercial confidentiality considerations can also prohibit public access to information which may influence purchasing and prescribing decisions. The TGA currently classes all information which is not in the public domain and which has the potential to undermine the economic and competitive interest of the owner as commercial in confidence (TGA 2014d, p. 7). This means certain information concerning the good,[89] the manufacturer or supplier,[90] and the sponsor's financial and commercial dealings[91] cannot be disclosed publicly *unless* this information is necessary for warning the public about the safety, quality, or efficacy of a good (permitted under s. 61 & 61A of the *Therapeutic Goods Act 1989* (Cwlth)) or forms part of a freedom of information request (under s. 11 & 11A of the *Freedom of Information Act 1982* (Cwlth)). However, commercial confidentiality provisions can trump freedom of information requests when a sponsor chooses to exercise these rights under the Freedom of Information Act. Documentation containing commercially confident information can be *exempt* from disclosure if the documents were disclosed to the TGA in confidence (s. 45(1) of the *Freedom of Information Act 1982* (Cwlth)), and/or, would result in the release of trade secrets or any other information deemed to be of commercial value (s. 47(1)). Documents can also be *conditionally*

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[89] Including, Text has been removed due to copyright restrictions. (TGA 2014d, p. 8).

[90] Including, Text has been removed due to copyright restrictions. (TGA 2014d, p. 8).

[91] Such as information concerning Text has been removed due to copyright restrictions. (TGA 2014d, p. 8).

exempt if their release would unreasonably and adversely affect the sponsor and/or would prejudice the future supply of information to the TGA (47G(1)(a)&(b) of the *Freedom of Information Act 1982* (Cwlth)), and the release of this information is considered, on balance, to be contrary to the public interest (s. 31B). While the TGA is permitted to disclose these documents if it so chooses, the agency cannot do so unless the sponsor agrees to their release, or until the sponsor has been granted the opportunity to appeal the decision (internally with the TGA and/or externally with the Australian Information Commissioner or AAT) to release the documents, and the documents are not found to be exempt or conditionally exempt (TGA 2014d, p. 20). This type of scenario has arisen in relation to Straterra, a prescription drug for Attention-Deficit/Hyperactivity Disorder (ADHD) (Academic, Submission 1119, pp. 6-7). The sponsor, Eli Lilly, was successfully able to argue against the release of documentation it originally supplied to the Pharmaceutical Benefits Advisory Committee (PBAC) on the grounds the documents were exempt under section 38(b)(i) of the *Freedom of Information Act* (Academic, Submission 1119, pp. 6-7).[92] A Minister of the Western Australian Parliament was seeking these documents to investigate accusations that Strattera was being over-prescribed and that its side effects were not being properly disclosed (Academic, Submission 1119, pp. 6-7).

Commercial confidentiality provisions currently prohibit the TGA from releasing its full clinical evaluations for registered medicines (Submissions 1019, 1090, 1099 & 1115). As a compromise, the TGA releases a censored version pre-approved by the sponsor, the AusPAR. However, the public are not told whether information has been withheld or the type of information withheld from an AusPAR. Commercial confidentiality provisions also prohibit the TGA from disclosing the content and outcomes of some of its investigations. Explicit reference was made to two instances by a stakeholder and interviewee where the content and outcome of an advertising complaint had been withheld from the public, and even the complainant who lodged the complaint, on the grounds that they were commercially confident in nature (Submissions 2010 & Interviewee 9). This lack of access ultimately bars consumers and healthcare practitioners from information that would otherwise enable them to engage in the rational calculation of the cost and benefits of products.

7.1.1.8 Lack of Independent Sources of Information (Listed and Registered Medicines)

A large proportion of the information available to consumers and healthcare practitioners is generated by industry. Public summaries provided on the ARTG are produced and maintained by the sponsoring

[92] All disclosure is prohibited for those provisions listed under Schedule 3, including section 135A(1) of the National Health Act 1953 (Cwlth) which prohibits persons from 'divulging or communicating information' to a third person about the affairs of the first person in the performance of their duties and in the exercise of their powers or functions.

company, are rarely reviewed by the TGA, and, as a result, are often accused of containing information which lacks evidence basis (Submissions 1044, 1069, 1075, 1079, 2018, 3016, 4023 & 7057). PI/CMI documents are likewise accused of containing non-clinical and promotional information (Submissions 1019 & 8003). One stakeholder cited examples from two arthritis medications (Remicade and Prolia) to demonstrate this point:

> The Remicade PI promotes its use '... for the *improvement in* physical function in patients with active disease'—this is not an indication, it is an outcome. The Prolia PI proclaims 'Prolia *significantly reduces the risk* of vertebral, nonvertebral and hip fractures' this is flagrantly promotional language (Information Provider, Submission 8003, p. 15 [added emphasis]).

Advertising and promotional materials are considered poor sources of evidence-based information despite being classed by many industry and practitioner groups as a necessary source of education for consumers and healthcare practitioners (see *Chapter 8*). For example, listed medicines commonly employ ambiguous terms, on labels and in advertisements, to imply that they have certain effects (e.g. may relieve) or a level of superiority over other medicines (e.g. practitioner only) (Submissions 1019, 1027, 1109, 1117, 2028, 4023 & 7091). Product names can also be misleading by implying they have a specific effect, such as Weight Loss Accelerate (Submissions 2020, 2022, 2037, 3008, 3014 & 3016). Listed medicines are also able to make claims of efficacy based on a medicine's traditional use which may not always be supported by the scientific literature (Submissions 1009, 1047, 1053, 1075, 1089-90, 3001, 3014, 3016, 3023, & 4023). Information provided to healthcare practitioners, through drug representatives and in the form of written promotional materials, has also been criticised for being unbalanced (Submission 2028, 4002, 4010, 4018 & 5011, Interviewee 3, 5 & 7). Interviewee 7 stated that:

> [a] lot of information is not communicated to doctors appropriately and clearly when drugs are released onto the market. Doctors are given a glossy brochure to look at but without the correct information, like the drug is contra-indicated […] It needs to be more scientific and be conveyed with greater clarity to the prescriber (Interviewee 7, pp. 4-5).

Industry can also exert an indirect influence over prescribing practices by providing financial or material incentives, such as gifts, free samples, payments for services, and profits from sales (Submissions 4018-19, 5010-11 & 5015), and by providing and sponsoring continuing professional development opportunities to healthcare practitioners (Submissions 2004, 4018 & 4019), claims which have the support of the academic literature (Adair & Holmgren 2005; Katz, Caplan & Merz 2010; Morgan, Dana, Loewenstein, Zinberg & Schulkin 2006; Lieb & Scheurich 2014; Rutledge,

Crookes, McKinstry & Maxwell 2003; Sah & Fugh-Berman 2013; Wazana 2000). Industry produce and/or sponsor a large proportion of medical research and literature which has a tendency to portray products more positively than those in independent studies (Submissions 1119, 5015 & 9006, Interviewees 7 & 9); issues which are well documented in the academic literature (Davis & Abraham 2013; Braithwaite 1984; Dukes, Braithwaite & Moloney 2014; Faunce, Townsend & McEwan 2010; Loder, Godlee, Barbour & Winker 2013; Lundh, Lexchin, Mintzes, Schroll & Bero 2017; Matheson 2016; Ross, Gross & Krumholz 2012) and in notable case-studies (see 4.3.2).

Industry produced information is problematic because it creates 'an inherent conflict of interest between the legitimate business goals of manufacturers and the social, medical and economic needs of providers and the public to select and use drugs in the most rational way' (WHO 1993; as cited in Mintzes 2002, p. 908). Although non-industry sources of information are available to the public—websites like NPS and Health Direct, and trade medical press like *Australian Doctor* and *Medical Observer*, for example, provide medicines information freely to the public—many of these providers are reliant on information first made available by the TGA, which is not always forthcoming, up-to-date, and is at times produced by industry. The lack of independent and alternate sources of information reduces the capacity of consumers and healthcare practitioners to access information that would enable them to scrutinise products.

7.1.1.9 Closed Organisational Culture (Listed and Registered Medicines)

Multiple stakeholders spoke of a closed organisational culture exuded by the TGA which has prohibited stakeholders from obtaining information from the TGA directly. These perceptions were largely based on the lack of information the TGA provided on its key personnel (Submissions 1075, 1094 & 1113), the TGA's geographical location and isolation (Submission 1113 & Interviewee 4), the TGA's lack of media presence (Submissions 1001, 1017, 1043-44, 1085 & 1113), as well as its general lack of procedural transparency (discussed in 7.1.2).

Those stakeholders with experience in engaging with the TGA spoke of instances where the agency had attempted to control the information they obtained:

> All questions we want to put to the TGA have to be put in writing. Sometimes those responses can be very detailed. Yet at other times we can end up asking ourselves whether it was worthwhile even writing out the questions in the first place either because the answers come too late for deadlines or the answers don't fully address the questions asked (Media Organisation, Submission 1017, p. 1).

> Answers do not often address questions asked. We have to address all questions to the media unit at the DOH [Department of Health], rarely [do we] get to actually talk to the people involved, and instead get short, written responses that sometimes do not address all the questions asked (Journalist, Submission 1113, p. 8).

> Many [of our] journalists complain that they do not have access to TGA officials with the relevant expertise for stories they are researching. All requests must be put in email to a PR consultant, who typically then provides a response in writing (Journalist, Submission 1113, p. 4).

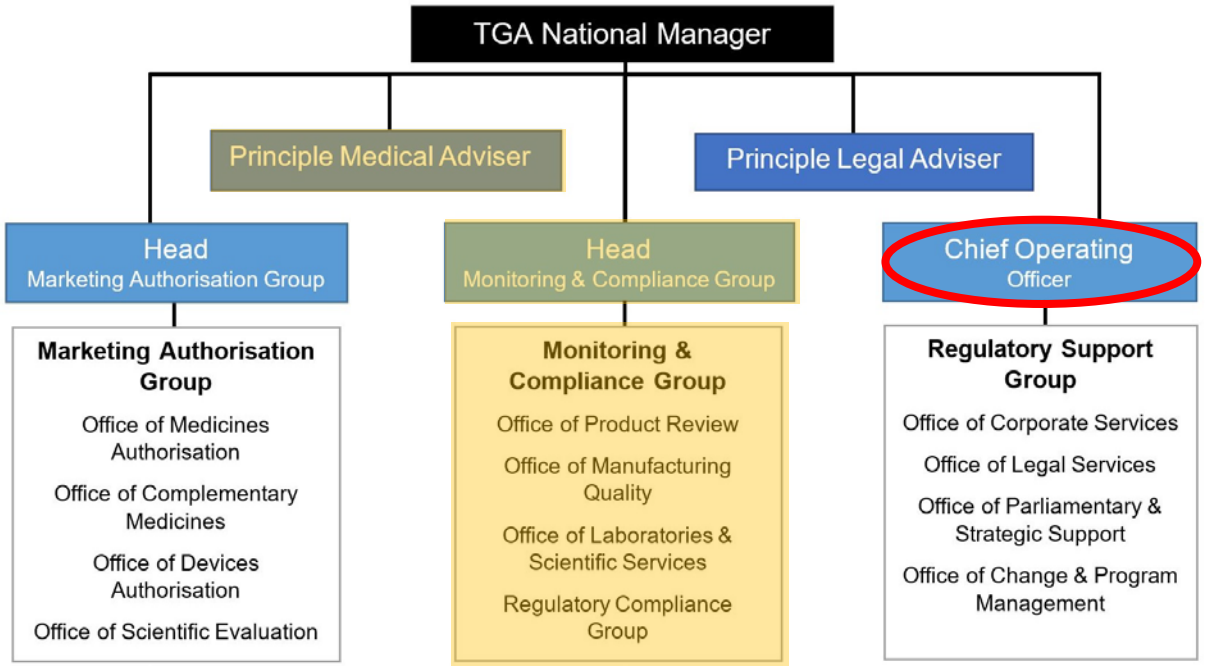
These experiences were reflected in my own dealings with the agency (see 3.3.3.1). I found it difficult to determine who within the TGA I had to approach to obtain permission to interview members of staff, as information on TGA departments, staff members, and their roles was relatively vague and limited to a single page on the TGA website. To identify a potential gatekeeper, I contacted the head of each department by email (highlighted in *Figure 7.2*). Within two hours of sending these emails, I was contacted by phone by the TGA's Chief Operating Officer (circled in *Figure 7.2*) who indicated that I needed to go through the 'appropriate channels' of obtaining consent—the TGA's external relations team—for the purposes of 'centralising' the process. I was then assigned a personal 'escort' (Broadhead & Rist 1976, p. 329), the Chief Operating Officer's Assistant, who acted as my point of contact at the TGA.

The agency made numerous attempts to restrict my ability to obtain data. I was explicitly told that I was not allowed to contact individual members of staff directly and that all communication with the TGA had to occur through the Chief Operating Officer's Assistant (Email Communication, 13 February 2013). I was restricted to a single group interview (rather than individual interviews) and refused the capacity to digitally record the proceedings.[93] I was introduced to 'safe' informants guaranteed to provide me with 'safe' data (Broadhead & Rist 1976, p. 329); all but one of the group interview participants held a managerial position in their respective Office or Unit, and many simply reverted to repeating the agency line (the TGA's in the public interest mantra). One participant, a non-manager, who interjected on multiple occasions during the proceedings to bring into question the

[93] When I first raised the subject of recording the session, the Assistant indicated that this would not be an issue given that the agency had done this on previous occasions (Email Communication, 22 February 2013). In the weeks after obtaining consent on the first ethics modification request (to accommodate the change in format from an interview to a focus group), the Chief Operating Officer 'left' the TGA and my research request was (re)scrutinised by Executive Members of the TGA (Email Communication, 11 April 2013). On the 18th of April, I was informed that the TGA Executive had since decided against the recording of the proceedings (Email Communication, 18 April 2013), however, I was later able to negotiate for a scribe to take notes during the session (which prompted a second ethics modification request). See section 3.3.3.1 for further information.

agency line, was quickly corrected by other participants present to prevent 'incorrect' data from being collected.[94] Attempts were also made to 'obstruct efforts to penetrate the detail' (Encel 1978, p. 47); participants would cut off questions before they could be completed, selected certain aspects of a question to answer rather than address the question as a whole, and often asked to have questions put on notice so that a more considered answer could be given at a later date.[95] Many of the responses provided placed TGA actions in a favourable light in an attempt to 'exaggerate their own influence and achievements' (Encel 1978, p. 47). The participants also used deflective tactics. Questions, intentionally designed to be open-ended, were often criticised by the participants for being too broad and unspecific. Closed questions which elicited simple yes or no answers were considered a more ideal question format.

Figure 7.2: Visual Depiction of Initial Points of Contact (Orange) and Subsequent Points of Contact (Red).



The failure of the TGA to speak publicly on quality, safety, and efficacy issues risks generating illiteracy and irrational behaviour, such as the unnecessary continuation or cessation of a treatment.

[94] This participant contacted me directly by phone two days after I had returned to Adelaide because they wished to have a particular comment, one which had conflicted with the agency line, removed from the transcript on the basis that they had been 'a bit grumpy' that day. Although I was not in a position to determine whether there had been other external factors which may have influenced the call, given the concern expressed by the participant on the phone, I agreed to have the statement removed.

[95] Those questions put on notice were eventually answered by the Assistant in writing. The statement did not address the original questions posed. The questions were answered in an ambiguous and vague manner with little reference to the question itself. A great deal of the information provided was simply material which had been rehashed from the TGA website.

Perceptions that the TGA is relatively closed and unwilling to speak publicly also gives rise to perceptions that the TGA is more responsive to the interests of industry (as stakeholders in Submissions 1043, 1044, 1079, 1119, 4018, 7021 & 9005 believed to be the case).

7.1.2 LIMITED PROCEDURAL TRANSPARENCY

A lack of transparency in regulatory decision-making has deprived non-market non-governmental players of the knowledge necessary to participate, individually and collectively, in the regime. A lack of procedural transparency also has the capacity to reduce the educative and reputational impact of enforcement, which is likely to impact upon the cooperativeness of regulatees.

7.1.2.1 Limited Disclosure on Regulatory Activities (Listed and Registered Medicines)

Stakeholders and interviewees reported a lack of disclosure on regulatory activities. This included a lack of reporting on the outcomes of post-market surveillance activities, including the outcomes of laboratory tests, manufacturer audits, and compliance reviews (Submissions 1101, 1075, 7034 & 7054), as well as a lack of reporting on the outcomes of enforcement, such as those goods cancelled from the ARTG either forcibly by the TGA or voluntarily by the sponsor,[96] and those issued with administrative sanctions, financial penalties, and licence suspensions and revocations (Submissions 1011, 1034, 1075, 1079, 1081, 1097, 2010, 2018, 2022, 2027, 4023, 7034 & 7054, Interviewee 8 & 9). Several issues were also raised with respect to the reporting of complaint outcomes. While the Complaints Resolution Panel (CRP) publishes complaint outcomes on its website, it can take up to several months for a determination to be published (Submissions 1053, 2027, 7024, 7046 & 7070). Little to no information is provided by the TGA on the outcomes of those complaints referred to it by the CRP and industry associations (Submissions 1034, 1043, 1053, 1079, 1101, 1108, 1119, 2009-10, 2012, 2015, 2021-22, 2027, 2031 & 2033). There is limited reporting on complaint outcomes by industry associations (see 5.5.2.3), although, this concern was only expressed by one stakeholder (Submission 2017). Several stakeholders and an interviewee also reported a failure to report the receipt, progress, and outcome of complaints to complainants (Submissions 1016, 1040, 1091, 1104, 2010, 2018, 2027 & 4023, Interviewee 9).

[96] Details of goods and manufacturing licences cancelled by the TGA are currently published in Australian Government Gazettes, however, their availability is not widely publicised, and few stakeholders believed that members of the public would be aware of their availability or would intuitively turn to Gazette notices in an effort to locate this information (Submissions 1034, 1075, 2010 & 4023).

This lack of information has three main implications for stakeholders. First, it reduces the capacity of consumers and healthcare practitioners to make rational decisions concerning products, especially as a consumer's and healthcare practitioner's capacity to alter their purchasing/prescribing behaviour is underpinned by their prior knowledge of the compliance status of the product. Second, it prohibits tripartite techniques of government because non-market non-governmental players are not given access to information, such as whether the TGA has made a decision concerning a product or whether sponsors are complying with a TGA decision, which is necessary for mediating and holding governmental and market players to account. Finally, failing to report enforcement outcomes lessens their educative and reputational impact on sponsors, which is necessary for deterring non-compliance and fostering cooperation with the regulator. This lack of reporting is especially problematic in those aspects of the regime where formal sanctions are not available or used by the regulator.

7.1.2.2 Limited Disclosure on the Precedence for Regulatory Decisions (Listed and Registered Medicines)

Limited information is also provided by the TGA on the precedence for regulatory decisions. Sponsors and industry stakeholders have reported that the TGA often provides discrete comments following an audit, review, or complaint without providing explicit detail as to how these outcomes were achieved (Submissions 1011, 1023, 1029, 1035, 1081, 1085 & 2027); for example, auditees have reportedly received comments as simple as 'you do not meet the requirement' and 'more information is required' without further explanation as to how requirements were not met or the type of information necessary to close out the deficiency (Industry Association, Submission 1011, p. 2). This not only has the potential to reduce the educative nature of enforcement, but it is also less likely to generate cooperativeness from regulatees because TGA decisions are perceived to have less of a connection with established guidance (as stakeholders in Submissions 1025, 1081, 1085, 1094 & 1101 believed to be the case).

The lack of information on the precedence for regulatory decisions can also limit health literacy and regulatory accountability. This deficiency is best demonstrated in the lack of disclosure of advisory committee meeting minutes (Submissions 1011, 1029, 1049, 1070, 1090, 1096, 1108, 1113, 1115 & 9006). Currently, TGA advisory committees are not compelled to release meeting minutes. Those minutes which are released are usually published as public summaries, which one stakeholder labelled as 'totally useless' for informational purposes (Academic, Submission 9006, p. 2). These summaries are 'carefully worded' to remove explicit details about the products being discussed (Interviewee 7, p. 11); as one interviewee explained:

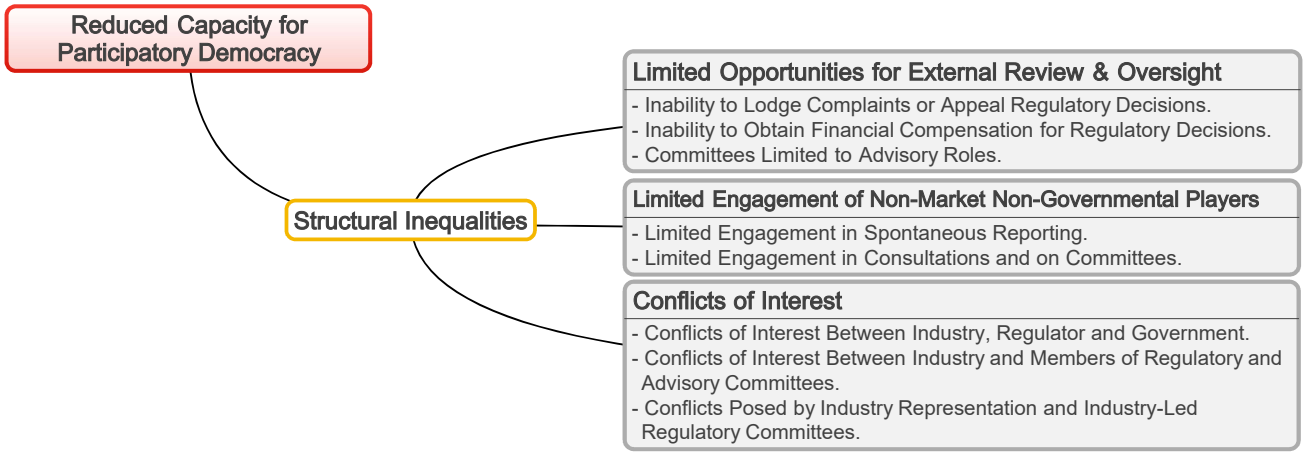
> they couldn't really say that we spoke about [this drug] and we said this, but […] say that the committee considered an application on [this class of drug] (Interviewee 7, p. 11).[97]

The failure to disclose this type of information has several implications for health literacy and regulatory accountability. The public are effectively denied access to information about products which are being subjected to greater amounts of scrutiny than others. This could lead consumers and healthcare practitioners to unnecessarily continue with a course of treatment, unaware of the potential risks associated with that product, or cease a treatment entirely, unaware that the product has been investigated and safeguards have been put in place. Failing to disclose information on a quality, safety, or efficacy issue associated with a product can also discourage spontaneous reporting by failing to make consumers and practitioners aware of the need to report similar issues during their own encounters with these products. Non-market non-governmental players are also denied access to information which enables them to determine whether the TGA is heeding or acting contrarily to the advice provided by its committees. This renders mediating players less capable of holding the regulator to account.

7.2 STRUCTURAL INEQUALITIES

Structural inequalities have decreased the capacity of non-market non-governmental players to participate in the regime (see *Figure 7.3*).

Figure 7.3: Themes Mapping the TGA's Lack of Public Accountability.



[97] Some of the details surrounding this product, including the brand name, active ingredients, and specific details regarding the side effects, have been removed from this extract to protect the anonymity of the interviewee.

7.2.1 LIMITED OPPORTUNITIES FOR EXTERNAL REVIEW AND OVERSIGHT

The lack of opportunities for non-market non-governmental players to review regulatory decisions and oversee the activities of the TGA has rendered these players less able to hold the TGA to account, and therefore, less capable of ensuring that the regime is operating in ways which are representative of the general public health interest.

7.2.1.1 Inability to Lodge Complaints or Appeal Regulatory Decisions (Listed and Registered Medicines)

In some aspects of the regulatory regime, there is a lack of complaint and appeal mechanisms to enable stakeholders to contest the decisions of the TGA or its associated bodies. For instance, in the listed medicines space, there is no mechanism that allows members of the public to lodge complaints against those products approved and listed on the ARTG with inappropriate indications, only the capacity to lodge a complaint against its subsequent advertisement (Submissions 4023 & 7047). Complainants dissatisfied with a CRP determination also have no recourse to appeal a determination (Submissions 1055, 2009, 2027, 7034, 7044, 7047, 7054 & 7066); advertisers, on the other hand, can appeal the CRP's determination with the TGA delegate and then the AAT (Complaints Body, Submission 7047, p. 3). The absence of complaint and appeal mechanisms limits the capacity of non-market non-governmental players to ensure that the regime operates in ways that are representative of public interests.

7.2.1.2 Inability to Obtain Financial Compensation for Regulatory Decisions (Listed and Registered Medicines)

Regulatory players also unable to bring a claim against the TGA in the event of an adverse regulatory decision because section 61A of the Therapeutic Goods Act provides the Commonwealth and protected persons with immunity from civil litigation. The Australian Government largely construes section 61A as a public interest mechanism because it allows the TGA to carry out its quality, safety, and efficacy functions without fear of litigation by sponsors (Australia, Senate 2010, p. 2188), particularly in those cases of an inadvertent breach of confidence and commercial damage resulting from the public release of information (TGA 2014c, p. 14). However, 61A raises substantial issues for regulatory accountability. Section 61A is a risk-averse technique of government which insulates the regulator from adverse decisions—including the failure to make a decision—which results in public (and even private) harm by limiting liability to those acts which are committed in bad faith (i.e. with the intent to cause damage or injury). All financial risk associated with an adverse regulatory decision is therefore borne by the public and regulatees (and away from the state). For regulatees,

61A can reduce the perceived fairness of the regime and potentially destroy regulator-regulatee cooperation. An example of this type of impact was provided by one interviewee:

> My particular client had to make the transition from ANAO code [designed for registered medicine manufacturers], from the old code [designed for listed medicine manufacturers] […] And that was very difficult for it [the client] to do [because the PIC/S code was incompatible] and it [the client] was slowly making that transition. Anyway, cut a long story short, there was a series of audits and… which finally led to the TGA imposing a licence condition on this manufacturer that they weren't allowed to sell product, release product for sale, unless certain criteria had been met […] [The company had] worked with a well-known external GMP consultant who was helping them become GMP compliant to PIC/S, and they wrote to the TGA three times giving them an update on where their state of compliance was. […] after a personal meeting with Skerritt [head of the TGA], tended by a regulatory consultant and letters written by me for the client pointing out some of the wrong… conclusions drawn […] they suddenly accepted, with no explanation, that the most recent explanation of GMP compliance by the client was acceptable. And therefore, the licence condition could go away. But in the meantime, for a… for about five or six weeks, the client couldn't release any product […] I can't even sue the TGA for the client who has lost hundreds and thousands or millions, because unless I can show malice, 61A protects them. […] I can take them to the AAT and I can I can get an order that they made the wrong decision, but if that wrong decision cost my client 10 million… bad luck (Interviewee 8, p. 11).

Section 61A also reinforces the notion that risk is a contingency of risk society; by framing risk as unforeseeable, and therefore, uncontrollable, this diffuses the responsibility of the state for any adverse decisions.

While the extent to which the TGA should be held accountable for any adverse decision it makes is up for debate, the fact remains, as the regime currently stands, there is no material recourse for an adverse decision the TGA makes, and therefore, no real force which compels the agency to consider the consequences of its decision-making. This renders the TGA less accountable to stakeholders, and, in the case of the public, less likely to act in ways which are representative of the public interest.

7.2.1.3 Committees Limited to Advisory Roles

One stakeholder and two interviewees believed that regulatory committees were gradually being disempowered by being delegated advisory, rather than decision-making, roles:

> when ADRAC was the committee, ADRAC made decisions […] They actually made decisions. Now ACSOM in this new iteration does not make decisions; they give advice (Interviewee 3, p. 15).

> We don't have any sort of statutory or executive powers. It's more the TGA's reviewed some applications, they've got some questions and asked us for advice (Interviewee 7, p. 2).

> the ACPM resolution no longer carries the same weight or signal of a pending decision as it previously did (Industry Association, Submission 1084, p. 3).

Interviewee 3 indicated that this was likely to be a risk-aversive move in response to the Pan Pharmaceuticals fallout (see 4.3.1), aimed at insulating the TGA from liability in those situations where the TGA chooses to act contrary to committee advice. These views were in part confirmed by Interviewee 7, who indicated that the TGA had not always been transparent on the types of action it takes following a committee recommendation:

> the TGA will ask us for some advice and we'll provide it, but it may not follow this through or [we] hear about… about the outcome or how the information is used (Interviewee 7, p. 5).

> the comments made by the committee […] it's hard to know whether any of those recommendations were implemented (Interviewee 7, p. 5).

The wearing down of advisory committee powers renders the regulator less accountable to the public, making it more difficult for non-market non-governmental players to ensure that the regulatory agency is acting in ways representative of the public interest.

7.2.2 LIMITED ENGAGEMENT BY NON-MARKET NON-GOVERNMENTAL PLAYERS IN REGULATORY PROCESSES

A lack of engagement by non-market non-governmental players has reduced their degree of representation within the regime, allowing the regime to become organised 'around the core interests of the hegemonic fraction' (Mahon 1979, p. 192).

7.2.2.1 Limited Public Engagement in Spontaneous Reporting

Several factors have discouraged consumers and healthcare practitioners from having greater involvement in spontaneous reporting processes. Few consumers and healthcare practitioners are aware of adverse reporting or complaints mechanisms (see 7.1.1.1) or know how to lodge a report or complaint (see 7.1.1.5). A lack of awareness and understanding of advertising requirements can also make it difficult for consumers and healthcare practitioners to differentiate between appropriate and

inappropriate types of advertising for reporting purposes (see 7.1.1.5). Other factors reported by stakeholders and interviewees include: the complexity of complaints lodgement (i.e. being able to identify which body to complain to) as a result of the decentralisation of complaints processes (Submissions 2015, 4014, 7004, 7050 & 7090); the lack of formal requirements for healthcare practitioners to report all ADRs (Interviewees 1 & 7); and perceptions that the TGA is generally disinterested in collecting ADR reports and advertising complaints (Submissions 1075 & 6005, Interviewees 3 & 4).[98]

Stakeholders and interviewees have also indicated that consumers and healthcare practitioners are often discouraged from making spontaneous reports because of a perceived lack of return on time invested (Submission 2015, Interviewees 1, 7 & 9). This was not only because reporting mechanisms were considered poor for capturing patient experiences (Submissions 6005, Interviewees 3 & 4), but also because complaints resolution and enforcement outcomes were perceived to be poor, as these interviewees explained:

> I lodged a complaint and it took about six months for it to wind its way through the process and they came back and said "well we don't have any evidence to say that any of these things were committed. So, we are unable to uphold your complaint or sanction this person in any way" […] So I mean really it got me nowhere, the fact that I took the trouble to do it even was probably more than many other people would do (Interviewee 1, p. 7).

> she put in a complaint and it didn't get up […] so we decided to appeal, which again involved a lot of time and effort in trying to counter the craziness of the… the Committee's determination. And then I had to fly to Sydney… because she couldn't come from Perth […] I had to fly to Sydney at my own expense to go to the appeal. […] it got up and eventually a $40,000 fine was put against the company […] so I mean, it's not surprising that very few medics or consumer people complain (Interviewee 9, p. 4).

[98] One interviewee claimed that the TGA is:

> all in favour of clerks taking consumer medicine complaints over the phone and just cataloguing them—you know, they're just recording them. So they are not actually interested in saying, "well that sounds a bit scary" or you know, actually giving support or [obtaining] the important detail of the story since there can be a good deal of information gleaned from hearing the story […] they now say they are interested in adverse events and side effects and all the rest of it. They're interested, but in the clinician's minds, they still believe they're not particularly interested (Interviewee 3, p. 8).

Although a fear of reprisal had not been raised by stakeholders or interviewees, it is possible that a recent case like Sensaslim (see 6.2.3.3) could have the effect of discouraging consumers and healthcare practitioners from making a complaint. All complainants, except for corporate entities, have the capacity to submit complaints to the CRP and industry associations anonymously. The 'dangerous precedents' set by the Sensaslim case, however, have exposed complainants who choose to identify themselves when going public with an advertising and promotional breach to similar types of action in future (Dowden 2012, p. 39). Even when the cases brought by the company and its director were eventually dismissed by the court, the complainant was left to pay the legal costs when the company went into liquidation (Dowden 2012, p. 39). As the complainant had lodged similar complaints against companies in the past, the complainant has since been dubbed a 'serial complainant' by the TGA, CRP, and Medicines Australia (MA) (Creswell 2010, para. 20). According to one stakeholder, the CRP has (unofficially) refused to entertain future complaints from this person on the basis that complaints were labelled as being motivated by a 'personal political agenda' (Industry Consultant, Submission 1101, p. 7).

Although ADRs and complaints reporting by industry can (in part) make up for the lack of reporting by consumers and healthcare practitioners, industry reporting is generally driven by self-interests which do not always align with the greater public health interest. As Interviewee 9 (p. 4) argued:

> It's industry concerned about, someone's got a competitive advantage, so they'll put in a complaint. […] if everyone's doing it then no one's going to complain.

Sponsors have also been accused of failing to report all ADRs within mandatory timeframes or completing ADR reports with the amount of detail necessary to monitor and evaluate ADRs (see 6.2.1.2). Therefore, not all sponsors are inclined to report ADRs. As Interviewee 4 (p. 5) argued:

> the highest number of reports come from industry because most people report back to the company who they assume report back. Now that's fine if you trust that process, but how do they know [that the company reports back]?

Limited involvement by consumers and healthcare practitioners in spontaneous reporting processes reduces the extent to which public health interests are represented in these processes.

7.2.2.2 Limited Public Engagement in Consultations and on Committees

Participation by non-market non-governmental stakeholders in public consultations and on regulatory committees has also been relatively limited. Of the 451 submissions analysed as part of this study, 41% (185) of submissions were made by sponsors, and industry associations and consultants. While practitioner associations represented the next largest category of submissions (14%, or 66 out of 451), healthcare practitioners and practitioner associations also have their own separate interests which do not always align with the greater public health interest (see *Chapter 8*). Low levels of participation by non-industry stakeholders in consultation processes can be attributed to the lack of promotion of opportunities to make submissions to open consultations, a problem demonstrated in the quote below:

> Despite having had a number of interactions with the TGA in the past 12 months, I've only just learned of the opportunity to make a submission to the TGA Transparency Review today (one day prior to the submission cut-off) after noticing an article in today's *Sydney Morning Herald* […] The promotion of the opportunity to make submissions to this inquiry should have been far more widespread—you would have thought that the TGA would have notified those who have had interactions with the organisation recently? I have a suspicion that given the lack of public visibility and promotion that submissions to this review from the public will be minimal (Unknown, Submission 1109, p. 1).

The technicality of information (see 7.1.1.5) and limited awareness or understanding of the regulatory framework (see 7.1.1.1) can also discourage members of the public from participating in consultation processes.

Representation by consumers, consumer groups, and healthcare practitioners on regulatory committees is also relatively small compared with the degree of industry representation, as this stakeholder and interviewee explain:

> a Technical Working Group (TWG) under the TGA's Office of Manufacturing Quality has drafted the guidance document. The TWG appears to be comprised of technical experts from industry and the regulator, with no consumer representation on any of the six TWGs (Consumer Organisation, Submission 9110, p. 5).

> We didn't get up the one code because the industry, not surprisingly, thought … "we want to look after all our own codes thank you very much" […] industry have the numbers, I mean you know there were the nine, the nine reps of the industry bodies there. So, they have the numbers (Interviewee 9, p. 7).

Non-industry stakeholders are also discouraged from participating in consultations and on committees because of the lack of perceived return on time invested. One interviewee, who had substantial experience in both TGA consultative and committee processes, conveyed some of the difficulties in encouraging consumers, public interest groups, and healthcare practitioners to participate in these processes:

> who's got the time? I mean I do encourage a number of colleagues to you know… told them the closing date, said it would be really helpful if you put in some thoughtful submissions—even just a paragraph or two. But who's got the time? (Interviewee 9, p. 20).

> he was coming up with reasons why to do nothing […] "Oh… we take a long time to decide whether we should be doing anything about transparency" and "oh anyway, it's probably more important to get politicians to look at [the] underlying objectives". This is the fucking Senate enquiry, what better opportunity have you got to put some of these views up to some parliamentarians with some interest. But… nothing happened and no one… no one put anything in [laughs] as far as I'm aware […] you certainly don't achieve anything if you don't engage. But regrettably that is, it's a convenient view from some of my colleagues that, you know, we don't want to dirty our hands and it's not going to do anything and [so it's] better to be pure (Interviewee 9, p. 21).

> there's a limit to how long you can bang your head against a brick wall and it's very hard to encourage younger colleagues to get engaged because where's the return on investment? I mean… it's depressing (Interviewee 9, p. 10).

In this respect, these technologies of citizenship have both an 'enabling and constraining' effect on non-market non-governmental players; they are 'modes of constituting and regulating citizens' (Cruikshank 1999, p. 2) in line with neoliberal rationalities of government that argue that all subjects should be able to compete equally except when this conflicts with the interests of the dominant hegemony. The abject failure of the TGA to actively seek out non-market non-governmental stakeholders to participate in consultative and committee processes has contributed to the unequal representation of these interests in these processes.

7.2.3 CONFLICTS OF INTEREST

Perceived conflicts of interest between governmental and market players has led to perceptions that market players are receiving greater representation in the regime than non-market non-governmental players.

7.2.3.1 Perceived Conflicts of Interest between Industry, Regulator and Government

Several stakeholders believed that a level of clientelism exists between the TGA and industry where industry is viewed as *the* principle client of the TGA (Submissions 1044, 1069, 1070, 1075, 1112, 1119, 3106, 4018, 7021 & 9005). A reliance on cost-recovery (see 6.2.7.1), a lack of stakeholder engagement (see 7.2.2), and the TGA's closed organisational culture (see 7.1.1.9), have largely given rise to these perceptions of clientelism among stakeholders.

Claims of conflict have been refuted by some industry stakeholders on the grounds that current cost-recovery arrangements do not allow the TGA to generate profits from the services they render (Interviewee 6, pp. 3-4), and, that industry would have very little reason to complain if they were truly benefiting from such arrangements (Interviewee 11, p. 10-11). However, clientelism was evident in a small number of submissions made by industry stakeholders who explicitly framed themselves as the clientele of the TGA:

> It may be fair to say that the consumer is the TGA's principle stakeholder. It may also be fair to say that industry in general is a client rather than a stakeholder, and we believe that the service levels provided to a client in a cost for service situation should be constantly monitored to ensure that the services are delivered in the most efficient, timely and cost effective manner (Industry Association, Submission 1051, p. 3).

> Given the entire Biologicals Sector will become paying customers of the TGA […], the provision of timely services, appropriate information and clear communication will be expected and needs to be provided (Industry Association, Submission 1011, p. 2).

> we pay to support the Government through fees and GST (Sponsor, Submission 3031, p. 2).

Public and private sector interviewees also confirmed the presence of a revolving door between industry and regulator (Interviewees 10 & 11), however, high rates of transition were not believed to be the norm because staff turnover within the TGA was generally perceived to be low (see 6.3.1.2).

Given the degree of power wielded by the TGA and its overall position within the structure of government (i.e. as an apparatus of the state), it is possible that conflicts are more likely prevalent between industry and upper levels of government. Interviewee 10 (p. 16) believed this to be the case insofar as the TGA falls under the Department of Health and Australian Government, and that 'industry influences the politicians':

> a lot of contact is between the industry and TGA, but I mean that's what's in the back of the TGA's mind […] politicians want to have the industry on side as far as possible (Interviewee 10, pp. 16-7).

Conflicts of interest between industry and the Australian Government are well publicised. Several State and Federal Ministers and their employees have transitioned from politics to the pharmaceutical industry (Ferguson & Johnston 2010; Pash 2014). Many pharmaceutical companies and industry associations are known to make regular donations to the two major political parties.[99] Interviewee 10 indicated that 'a number of major pharmaceutical companies were [based] in John Howard's electorate' during his time as Prime Minister, and though the extent of contact between the then Prime Minster and members of the so called Bennelong Group at the time is difficult to know, Interviewee 10 indicated that there had been 'a lot of suspicion in the Department and in the TGA that there was influence there in the… in the Howard years' (p. 17). There are also several opportunities available to industry that enable them to interact with politicians on a much more exclusive basis. Interviewee 11 stated that industry regularly held sponsored events that enabled industry representatives to interact directly with parliamentarians:

> [our organisation] has an Annual Parliamentary Dinner… which we… fully fund ourselves where we invite… a number of stakeholders across the sector, across the whole spectrum of the health-care paradigm from… public health, nursing, medicine, patient support groups and other sectors of the… medicines industry […] where we invite a number of key decision makers and bureaucrats and politicians from both parties, or all parties rather, and… provide opportunities for people to, you know, discuss their issues and, and talk about their policy concerns (Interviewee 11, p. 11).[100]

Interviewee 11 also indicated that the industry association which they represent has attended several events hosted by politicians and their political parties in full knowledge that payments to attend these events go directly to that party:

> all politicians will offer opportunities to meet with them… and pay for that privilege and that constitutes a donation. […] [W]e have attended a number of fundraising events or, or business

[99] In the 2015-2016 financial year, Roche (AU$70,600), Merck Sharpe Dohme (AU$68,130), Boehringer Ingelheim (AU$66,455), Novartis Pharmaceuticals Australia (AU$62,781), Pfizer Australia (AU$45,600), and Medtronic Australasia (AU$24,720) made donations to political parties (Hanrahan, Elvery, McGhee & Liddy 2017). Marcus Blackmore, Chairman of Blackmores Limited, made an individual donation of AU$113,900 (Hanrahan et al. 2017).

[100] Some of the details surrounding this organisation have been removed from this extract to protect the anonymity of the interviewee.

> forums… which we have had to pay to attend… knowing that that money does go into that… that political party (Interviewee 11, p. 11).

Interviewee 11 (p.11) argued that these opportunities were 'provided fairly evenly' across all stakeholder groups, and that these types of interactions were neither exclusive to the pharmaceutical industry nor certain industry sectors:

> I think it's part of our democratic political process to allow those opportunities to occur […] people will go to fund raising events to get some, some exclusivity in the sense that they may be smaller, but we also know that our, our… political process allows people to meet with them for free at Parliament House or at their electoral offices. So, I don't think that our democratic process denies anyone the opportunity to… have some exclusive time with the people they think will influence the decision-making in their sector (Interviewee 11, p. 11).

> [Our organisation] creates opportunities for all of those stakeholders to have that… chance as well. So, you know, as a sector, [our] industry doesn't deny other parts of the sector opportunities to interact with influencers and decision-makers in the political and bureaucratic sphere (Interviewee 11, p. 11).[101]

Not all companies and industry associations take up these types of opportunities; this was emphasised by Interviewee 6 (p. 5) who stated that the industry association that they represented did not make donations to political parties or sponsor events with politicians. Although, an argument can be made that industry overall may benefit from the lobbying of a select few.

These types of interactions between politicians and industry, something which cannot be afforded by all stakeholders, have given rise to an unequal structure of representation, which has rendered the state more amendable to the interests of industry.

7.2.3.2 Perceived Conflicts of Interest between Industry and Members of Regulatory and Advisory Committees

Concerns were also raised about the impartiality of those representatives on TGA advisory committees and the CRP (Submissions 1119, 2028, 7021 & 7050). None of the participants interviewed for this study held current or prior positions on the CRP, however, many of the

[101] Some of the details surrounding this organisation have been removed from this extract to protect the anonymity of the interviewee.

interviewees did hold current positions on TGA advisory committees (Interviewees 1, 3, 4, 7 & 9). All these interviewees felt that the TGA had a comprehensive conflict of interest policy and that the process for declaring conflicts had become even more rigorous of late (Interviewees 1, 3, 4, 7 & 9). One interviewee indicated that current conflict of interest policies are 'possibly even excessive' (Interviewee 7, p. 3) and explained the extensiveness of these procedures:

> Interviewee 7: So, when I became a member on this committee we had an induction program, ah up there [indicating to a large folder on the shelf above].
>
> Researcher: Yeah, the big folder.
>
> Interviewee 7: Yes, so we had to read through all the different scenarios and we were explained all the different situations in which a conflict of interest could be a possibility. Every year we declare an annual conflict of interest based on any relevant activities we've undertaken in the previous five years. […] [A]t and prior to every meeting, we're asked to review potential conflicts of interest based on specific agenda items […] one can sometimes forget minor events that might constitute a conflict of interest, and so I keep a diary of any events, so that I can recall and record it when required. […] [C]onflict of interest is reviewed at every meeting. We're asked clearly you know if is there anything you want to declare […] when I joined there was… one or two people who had to be… had to keep on leaving the room because they were deemed as having a conflict of interest […] As committee members, we're generally told to not engage in activities that might lead to a conflict of interest (Interviewee 7, pp. 2-3).
>
> […] [I]f you've had a dinner, or had a cup of coffee or anything, everything's meant to be declared… and then they make a judgement on whether that's appropriate or not (Interviewee 7, p. 3).

Perceptions of conflict on TGA committees are likely to have arisen because conflict of interest policies are not publicly disclosed by the TGA. Failing to publish these policies, along with the declarations of current members, has most likely given rise to perceptions that industry interests may be influencing its members.

7.2.3.3 Conflicts posed by Industry Representation and Industry-led Regulatory Committees

Views were mixed among stakeholders and interviewees on the perceived impartiality of industry representatives on regulatory committees and industry-led regulatory committees. Several stakeholders felt the mere presence of an industry representative on a committee constituted a conflict of interest irrespective of whether these conflicts were necessarily acted upon (Submissions 2013,

2028, 4029, 7050, 7057 & 7082). Having industry associations adjudicate on issues involving members (Submissions 2028 & 7050), or non-members (Submissions 2001, 2036, 7050 & 7082), 'does not create a sense of independence', especially 'for those companies which are not members' (Industry Association, Submission 2036, p. 2). The sheer weight of industry representation on regulatory committees can also sway decisions in favour of private interests, as this stakeholder explained:

> the membership of committees might be arranged to ensure that a majority decision would protect the industry as a whole whenever a complaint raises issues which might have ramifications for the whole industry. […] [A] minority of the Appeals Committee thought the [Bayer testosterone] advertisement advertised prescription products to the public, but the majority did not. Had the matter been heard by a judge under the law rather than Medicine Australia's code, I think Bayer would have been found guilty of advertising prescription medicines to the general public (Academic, Submission 4029, p. 2).

Other stakeholders, however, have argued that there is little empirical evidence to suggest that industry representation and involvement in regulatory processes can influence decision-making processes. A range of stakeholders have also pointed to the fact that there have been no formal complaints disputing the quality of CRP determinations on a basis of industry membership (Submissions 2010, 2017, 2021-22, 2037 & 7038); in fact, one stakeholder felt that the diversity of the CRP panel was a 'beneficial attribute' because it allowed a greater range of expertise to be represented in complaints processes (Industry Association, Submission 7034, p. 11).

Industry representation and industry-led committees are problematic when industry is placed in a position where it is expected to act in ways consistent with the public interest. When public interests happen to conflict with private interests, industry may be more inclined to protect their own interests in the first instance. Even if these conflicts are not necessarily acted upon by industry representatives, the degree of representation industry receives over other stakeholder groups can lead to an over-representation of private interests in these decision-making processes. This over-representation generates an unequal structure of representation which affords industry more power and opportunity to assert its interests.

7.3 SUMMARY

Participation by non-market non-governmental players has been limited due to the presence of information asymmetries and structural inequalities within the pharmaceutical regulatory regime. Information asymmetries have been a direct consequence of information barriers and the lack of

procedural transparency, which has deprived non-market non-governmental players of the medical and regulatory knowledge they need to participate. For consumers, who have the least amount of medical and regulatory knowledge of all players within the regime, these information asymmetries make them less capable of exercising individual agency—for the purposes of self-governance and rationally calculating the costs and benefits of medicines, for forming health literacy, regulating (or, at least, monitoring) the actions of other players within the regime, for organising and unifying consumers, and similar points. Though healthcare practitioners possess a greater amount of knowledge of pharmaceutical products and the workings of the regime than consumers, these information asymmetries still impact on their ability to thoroughly scrutinise products, and therefore, to adequately advise consumers on their costs and benefits, and to act on consumers' behalf when representing their general health interests. Collectively, non-market non-governmental players are placed in less of a position where they can adequately represent the general public health interest because information asymmetries render them less able to hold the TGA and industry to account. These deficits to knowledge have exacerbated power-knowledge relations within the regime by creating discrepancies between those who possess this knowledge and those who do not.

These power-knowledge relations have produced a governmentality which defines the field of action for dominant and less dominant players in ways which conform with neoliberal rationalities of government. Those with less power and medical and regulatory knowledge, and therefore, less of a capacity to exercise individual and collective agency, are rendered reliant upon those with this power and knowledge to represent their interests and to provide them with information. In this case, market players use this power to control, produce, and shape knowledge, and therefore, less dominant regulatory actors more generally, in ways which align with their interests. This enables market players to more effectively elicit support (and therefore, less resistance) from non-market players, which allows market players to maintain their dominance (and hegemony) over less dominant players.

Similarly, the structural inequalities generated by the regime, due to its lack of accountability to and engagement of non-market non-governmental players, and the presence of conflicts of interest between governmental and market players, have only perpetuated these power-knowledge relations. Here, power-knowledge relations have generated an unequal structure of representation which has rendered the regime less representative of non-market non-governmental players. This structuration allows market players to exercise greater power within the regime (and therefore, the ability to maintain their dominance).

These power-knowledge relations and unequal structures of representation effectively restrict the capacity of non-market non-governmental players 'to maneuver and to act to change' these structures of power (Hayward 1998, p. 21). This depoliticisation and disorganisation of citizenry, by limiting the capacity of non-market non-governmental players to oppose dominant interests and form a counter-hegemony, is a product of a hegemonic project which attempts to maintain the dominance of the dominant faction. Combined with the regulator and regime's reduced capacity to act on compliance issues, all non-market forces, governmental and non-governmental alike, are rendered less able to intercede in and challenge the workings of the regime, allowing the regime to become organised around the long-term hegemonic interests of more dominant market forces.

Marxists argue that the inequalities generated by these unequal structures of power can be overcome through the dismantling of these structures. Since the period of data collection for this thesis, the TGA has attempted to reform the regime to address the regime's failures in securing compliance, as well as to increase its overall transparency. *Chapter 8* examines the TGA's attempts to reform the Australian pharmaceutical regulatory regime in the period immediately following data collection for this thesis. This discussion is based on six key features that were identified during the qualitative thematic analysis, which stakeholders and interviewees believed to be necessary for enhancing the success of the current regime. However, at the time of writing, many aspects of the regulatory regime remain unchanged, and in some cases, have undergone greater deregulation.

8 INSTIGATING CHANGE WITHIN A CLIMATE OF NEOLIBERALISM

This chapter examines the Therapeutic Goods Administration's (TGA) attempts to reform the Australian pharmaceutical regulatory regime following the period of data collection for this thesis. Six key features were identified during the qualitative thematic analysis which stakeholders and interviewees believed to be necessary for enhancing the success of the current regime. Despite the TGA's attempts to implement these six features, much of the regime either remains unchanged or less regulated than it had been prior to reform. This chapter discusses the reasons why such change is difficult to achieve within a climate of neoliberalism and why an alternate regime may be necessary to truly realise fundamental public needs.

8.1 THE WAY FORWARD?

In the consultation submissions and interview transcripts analysed for this thesis, stakeholders and interviewees identified six features which they believed would enhance the success of the regime in achieving compliance from industry. These were greater oversight, punitiveness and range of sanctions, co-regulation, centralisation, resourcing, and transparency and public awareness. Since the period of data collection, the TGA has considered reforming the regime so that it contains the six features recommended by stakeholders and interviewees. However, as the following sections demonstrate, this has been achieved with a limited amount of success, as neoliberal rationalities of government have distorted the intentions of these reforms by continuing to shape the regime in line with the interests of the dominant hegemony.

8.1.1 INCREASED OVERSIGHT

Stakeholders and interviewees have predominantly advocated for an increase in regulatory oversight beyond current self-regulatory mechanisms. This was particularly the case in the areas of pre- and post-market efficacy evaluation for listed medicines, advertising pre-approval, and promotion.

8.1.1.1 Greater Pre- and Post-Market Evaluation of Listed Medicine Efficacy

Most stakeholders and interviewees agree that to better detect and punish sponsors who make false and misleading claims about listed medicine efficacy the TGA should evaluate efficacy prior to approval by requiring sponsors to submit evidence of efficacy at the time of application (Submissions 1030-31, 1062, 1075, 1087, 1090, 1103-04, 1109, 1114, 2006, 2010, 2012, 2017-18, 2020-22, 3003, 3008, 3011, 3016, 3023, 3026, 3029, 3032, 3038, 3103, 3115, 3120, 3122 & 7050, Interviewees 1, 6

& 10). Stakeholders and interviewees also advocated for an increase in the rate of post-market compliance review (Submissions 1030, 1044, 2002, 2009, 3011, 3016, 3112, 3115 & 7050, Interviewee 9) to better detect non-compliance post-marketing. Evaluating efficacy and increasing the rate of review has several benefits. Obtaining evidence from sponsors at the point of application enables the TGA to initiate a review at any time without first having to approach sponsors to supply evidence voluntarily (Bandiera 2015, p. 12). The evidence provided by sponsors can be used to direct enforcement—those sponsors who produce applications which provide fewer sources of evidence, supply evidence which is outdated or superseded by newer sources of evidence, and are not reputable, could be a target for review. As the TGA would have the capacity to initiate a review at any time, and because the likelihood of being subject to a compliance review has increased, sponsors are more likely to be deterred from making applications for products which lack evidence basis (Bandiera 2015, p. 12). Most importantly, these changes would decrease the likelihood of consumers being exposed to inefficacious products because they are being evaluated prior to entering the market.

To clarify the type of evidence that sponsors are required to hold, the TGA introduced a proposal in the two-part consultation paper *Evidence Required to Support Indications for Listed Medicines* which would require sponsors to produce (but not submit) an expert report which summarised evidence of efficacy. In the first consultation, this report had to be prepared by an expert independent of the sponsor and take the form of either 'a literature review of the existing body of evidence backing an indication for a particular ingredient' or an 'analysis of new, unpublished clinical trials' (TGA 2012b, p. 10). Industry argued against this proposal on several grounds. Most sponsors and industry associations felt that the increase in evidence requirements was not commensurate with product risk because listed medicines were believed to be highly complex chemical entities (i.e. listed medicines contain multiple ingredients, each of which vary in strength and therefore size of effect from batch to batch) which would make it difficult for sponsors to conduct clinical trials for, and apply conventional clinical indicators to, listed medicines in the same way a sponsor would for registered medicines (Submissions 1085, 2001, 3001-02, 3004, 3007, 3009-10, 3012, 3015, 3017, 3021-22, 3024-25, 3027, 3031, 3033-35 & 3037-39). These difficulties, in turn, have limited the amount of literature available to sponsors to support indications, as well as the pool of suitably qualified experts available to sponsors to produce reports on their behalf (Industry Consultant, Submission 3012, p. 4). Examples of these sentiments are outlined below:

> government action should be proportional to the issue being addressed. The requirements […] appear to be equivalent to or higher than those for registered over-the-counter medicine, yet are applied to listed medicines which may only carry listable indications/claims. [Our organisation] considers this to

> be inappropriate for listed medicines which are low risk by definition (Industry Association, Submission 3009, p. 7).
>
> [l]istable complementary medicines are at the lower end of the risk continuum and any regulatory intervention should be consistent with that level of risk (Industry Association, Submission 3007, p. 2).
>
> any indication previously considered to be general, such as a health maintenance claim, will now require the same rigour of evidence to be presented as a claim to cure or treat, which was previously considered a high level claim. By this reasoning a claim that Vitamin C may assist with the maintenance of immune function will require a full literature review […] to validate this claim. In this way the level of evidence and analysis required is beyond the scope of the types of indications allowed to be made, or that are intended to be made on listed products (Anonymous, Submission 3025, p. 5).

Sponsors and industry associations have also argued that an increase in evidence requirements will not only lead to an increased cost for sponsors, in terms of the cost of compiling a report for each ingredient and/or indication, hiring an expert with the prescribed level of qualifications, and running clinical trials (Submissions 1001, 1031, 1094, 1101, 3001-02, 3004, 3006-07, 3009-10, 3012-13, 3015, 3017-19, 3021-22, 3024-28 & 3031-40), make Australian requirements greater than overseas requirements (Submissions 3001, 3007, 3009, 3013, 3019, 3024, 3028 & 3038-39), and most likely prompt rule evasion because sponsors can de-list products and market them as foods (Submissions 3007, 3017, 3021 & 3039), but it would also have low deterrent impact because sponsors are required to hold and not supply the expert report (Submissions 3002-04, 3007-09, 3014, 3016-17, 3022-23, 3026, 3029, 3033, 3035 & 3037). Some industry stakeholders argued that there was insufficient evidence to warrant government intervention in the first place (Submissions 1001, 2005, 2032-33, 3001, 3013, 3031, 3033-34, 3103-04, 3110, 3112, 3116-17, 3124, 7027, 7029-30, 7037, 7040, 7089 & 9208); for example:

> when the complaints data is analysed, the number of complaints received on an annual basis to the TGACC CRP—the overall number is quite small in comparison to the advertising which takes place. This would indicate that in general, a problem does not exist (Industry Association, Submission 1001, p. 4).

In the second iteration of the consultation, the TGA removed several of the original requirements proposed for the export report, including, that reports be based on the outcomes of new or unpublished clinical trials—reviews of existing literature would suffice—and that reports be written by an expert independent of the sponsor (TGA 2012c, pp. 14-5). Sponsors were also offered the alternative of

using established sources of evidence (rather than produce an expert report altogether) to support an indication (TGA 2012c, pp. 12-3). However, industry maintained that many of the requirements remained disproportional to product risk as levels of evidence were still equivalent to those required for registered medicines (Submissions 3101, 3103-04, 3107, 3109-10, 3112-13, 3116-19, 3121, 3123-24, 7027, 7058, 9202 & 9205). Industry argued that the report would still generate compliance costs as the list of established sources of evidence was not comprehensive enough and would still require many sponsors to generate a report (Submissions 3101-10, 3112-14, 3116-19, 3121 & 3123-24), would still make Australian requirements greater than those overseas (Submissions 3101, 3110, 3112, 3118, 3124, 7002, 7004, 7028, 7034, 7054-55, 7065, 7069 & 7072), prompt rule evasion (Submissions 3103, 3113 & 3117), and have low deterrent effect (Submissions 3101, 3107, 3109, 3110, 3112-15, 3117-21 & 3124).

The TGA has since abandoned the idea of an expert report, and instead, has created a list of established sources of evidence and coded indications to restrict industry to using indications pre-approved by the TGA. Only 14% (153 out of 1,091) of the coded indications developed by the TGA require substantiation by scientific evidence (Haggan 2018, para. 13); traditional evidence suffices for the vast majority of indications approved by the TGA. This alternative to evaluating listed medicine efficacy remains problematic because it continues to rely on the assumption that consumers are 'omnicompetent' (Lippman 1993, p. 11) and capable of deciphering product efficacy independently. Without greater transparency and awareness of the agency and its role (see 8.1.6), it is difficult to see how the new system makes consumers more capable of self-governance and navigating the costs and benefits associated with listed medicine efficacy.

8.1.1.2 Greater Pre-Approval of Advertising

Stakeholders and interviewees expressed mixed responses towards the potential expansion of the pre-approval process to all advertising mediums. Most agree that the pre-approval process should be extended (Submissions 2006, 2009, 2015, 2028-30, 2032, 2034, 7003, 7012-16, 7027, 7034, 7036, 7046-48, 7050, 7054-56, 7065-66, 7068, 7070, 7076, 7082, 7086-87, 7090 & 7092). These stakeholders argue that the 'demarcation between advertising which requires pre-approval, and the advertising which does not, is arbitrary and reflects a practical decision regarding resources rather than a decision based on protecting consumers' (Industry Association, Submission 2009, p. 4). Expanding the pre-approval process would provide greater consistency in the standard and quality of advertisements appearing in different mediums, lessen the burden on complaints processes because advertisements are pre-screened prior to publication, reduce public exposure and harm caused by inappropriate advertisements, reduce the impost on the public to identify non-compliant

advertisements, and create added certainty for sponsors that an advertisement will not be subject to a complaint. It is also a highly feasible proposal—the Australian Self-Medication Industry (ASMI) already pre-approves all advertisements in specified and other media for every ASMI member.

Opponents, however, have argued that the expansion of the pre-approval process is well beyond current levels of resourcing:

> [we] would not support arrangements that required pre-approval for all advertising material as this is practically not possible with the range of advertising and marketing communications within a campaign or new forms of advertising e.g. social media. It would also be an unacceptable cost and imposition to commercial operations (Industry Association, Submission 2003, p. 4).

> To subject all advertisement to pre-approval would greatly increase the cost of advertising […] Removing the restriction on pre-approval would mean that advertisers of nonprescription medicines would be able to get to market much quicker and with less cost (Industry Association, Submission 2024, p. 6).

Several stakeholders also argued that it would not only lead to an increase in compliance costs for sponsors (Submissions 2024, 2028, 2034, 7022, 7034, 7086 & 7092), but expanded pre-approval would make the regime incommensurate with the risks posed by advertisements published in low risk mediums (Submissions 1001, 2001, 2016, 7027, 7042-43 & 7053).

In 2016, the Australian Government abolished the pre-approval process 'to ease [the] regulatory imposts on sponsors' which resulted from inconsistent pre-approval requirements (Sansom, Delaat & Horvath 2015, p. 60). The Australian Government has 'left it open' to industry associations or other commercial providers to implement a self-regulatory pre-approval framework (Department of Health 2016a, p. 9). This decision was conditional on the grounds that sanctions were increased, post-market monitoring and complaints processes are enhanced, the permitted coded indications project is implemented, and that advertising claims are consistent with permitted indications (Sansom, Delaat & Horvath 2015, p. 60). However, even if these conditions were implemented, the proposal still raises concerns for regulatory oversight. First, the proposal ignores a fundamental problem associated with the current regime: that sponsors are not compelled to become members of industry associations and can choose not to subscribe to an industry code of conduct (Bandiera 2016, p. 4). The proposal therefore does little to address the issue of non-members who continue to escape regulatory oversight (Bandiera 2016, p. 4). Second, a de-formalised and voluntary pre-approval process which advises sponsors of their level of compliance with advertising requirements is less likely to have merit in the

eyes of sponsors because the time and financial costs of obtaining informal and voluntary pre-approval will most likely exceed the degree of assurance sponsors receive that an advertisement will be unlikely to be subject to a successful complaint (Bandiera 2016, p. 3). This may discourage sponsors from seeking pre-approval of advertisements and render informal pre-approval processes redundant (Bandiera 2016, p. 3). Third, if industry associations and commercial providers are not granted the official and formal capacity to pre-approve advertisements under law (because pre-approval will no longer be a formal requirement), industry associations and commercial providers may be less inclined to take-up pre-approval functions because they risk exposing themselves to liability in the event that they provide adverse advice. Ultimately, the deformalisation of the pre-approval process and offering it on some voluntary basis exposes consumers to a greater amount of false and misleading advertising claims because there is a greater reliance on post-market techniques to identify non-compliance (Bandiera 2016, p. 8). In essence, the proposal only shifts the responsibility of government further away from the state.

8.1.1.3 Greater Oversight of Industry-Practitioner Interactions

Stakeholders and interviewees have advocated for greater oversight of the interactions between industry and practitioners by having sponsors report payments to healthcare practitioners, and, imposing greater restrictions on industry-practitioner interactions (Submissions 1065, 2004, 4002, 4007, 4009-10, 4019, 4021, 4027-28, 5008, 5010 & 7079).

In 2013, the Senate Finance and Public Administration Legislation Committee opened the Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013 (Cwlth), originally put forward by the Greens, to public consultation. The Bill proposed to amend the *Therapeutic Goods Act 1989* (Cwlth) to make it an offence for a sponsor: to arrange or sponsor overseas conferences, conventions, educational events, or other forms of events, where the majority of attendees are medical practitioners; to provide hospitality to medical practitioners at conferences, conventions, educational events, or other forms of events, including payment for meals or entertainment of more than AU$100 per head; and to pay for medical practitioners to attend conferences, conventions, educational events, or other forms of events, including travel or accommodation expenses, unless the practitioner is at the event representing the sponsor (Australia, Senate Finance and Public Administration Legislation Committee 2013, pp. 2-4). The Bill would also require sponsors to publicly report each payment made to a healthcare practitioner, including those payments for: attending conferences, conventions, educational events, or other forms of event; the provision of a service; travel or accommodation; medical research; charitable donations on the behalf of or in relation to a medical practitioner; and gifts greater than AU$25 (Australia, Senate Finance and Public Administration Legislation

Committee 2013, pp. 2-4). The Bill never became law because industry were able to argue that the Bill was duplicative and undermined current efforts of industry to strengthen self-regulation in this area (Submissions 5001-05, 5007, 5016-17, 5019, 5021 & 5025), was not as comprehensive as industry codes (e.g. it only covered certain types of healthcare practitioners) (Submissions 5004, 5006, 5016, 5018-19 & 5022), and effectively criminalised the relationships between industry and healthcare practitioners, which many believed were essential to the continuing professional development and education of healthcare practitioners (Submissions 5003, 5005, 5007, 5012, 5016-19, & 5021-24).

Since the proposed Bill, Medicines Australia (MA) has updated its Code to make it mandatory for MA members to report all payments to healthcare practitioners. However, the way in which the information has been reported by sponsors more closely resembles a form of 'fishbowl' transparency—'the full disclosure of information without explanatory information or contextualization'—than 'reasoned' or 'managed' transparency—'keeping sight of the impact of openness and disclosure on the wider audience' (Löfstedt & Bouder 2014, p. 75). For instance, reports are published on MA members' websites and not on a central website, which makes it difficult to compare promotional spending across sponsors. Healthcare practitioners are also de-identified in reports, so consumers are not able to identify which practitioners have been on the receiving end of promotional payments. Much of the data has therefore been provided 'with little regard to what the public will actually do with it' (Löfstedt & Bouder 2014, p. 83); it does not enable consumers to better understand promotional practices and alter their decision-making processes. What's more, an increase in transparency does not reduce or prohibit the level of industry influence on healthcare practitioners and their prescribing practices; this can only be achieved with the implementation of rules which reduce or prohibit these interactions.

In the consultation *Regulation Impact Statement: Regulating the Advertising of Therapeutic Goods to the Public*, the TGA attempted to ban promotion to healthcare practitioners dealing in listed and low-risk registered medicines by restricting the term 'healthcare practitioner' to practitioners accredited under the National Registration and Accreditation Scheme (NRAS). This was on the grounds that NRAS practitioners were 'appropriately qualified' to 'exercise specialist judgement when either treating consumers with advertised therapeutic goods or advising consumers about the use of advertised therapeutic goods', and, because NRAS practitioners are 'restricted by conditions of registration, … [or] via insurance policies, from using or advertising therapeutic goods in relation to which they are not appropriately qualified' (TGA 2013a, p. 28). While many stakeholders saw merit in the proposal because it established a minimum level of education and training for all

practitioners (Submissions 2028, 7011, 7021, 7024, 7035-36, 7039, 7046, 7062, 7070, 7073, 7079, 7084, 7087 & 7091), practitioners and industry stakeholders impacted by the proposal condemned the move (Submissions 7005, 7007-09, 7012-16, 7018-20, 7022-23, 7025-27, 7029-34, 7038, 7040-45, 7048-49, 7052, 7054, 7058-61, 7063-64, 7067, 7071-72, 7075, 7078, 7081-83, 7086, 7088, 7090 & 7093-94), arguing that these promotional activities and materials formed an integral part of continuing education for practitioner groups (Submissions 7012-16, 7019, 7025-26, 7029, 7032-34, 7040-42, 7048-49, 7059, 7061, 7071, 7083 & 7093). For example, one stakeholder argued that healthcare practitioners:

> must be able to access technical and scientific information, including contraindications, around the medicines they prescribe […] [because] if health professionals were not able to access this information, as would be the case under option 2, that this would increase the potential for harm to consumers (Industry Association, Submission 7048, p. 13).

The TGA has since backed down on this proposal.

8.1.2 INCREASED PUNITIVENESS AND RANGE OF SANCTIONS

The lack of severe sanctions in medicines advertising and promotion prompted many stakeholders and interviewees, including members of TGA staff, to advocate for harsher and a more extensive range of penalties (Submissions 1030, 1034, 1040, 1057, 1069, 1077, 1079, 1090-91, 2002, 2008-10, 2012-17, 2019-20, 2024, 2027, 2029-2034, 3011, 3014, 3022-33, 3026, 3112, 3120, 4002, 4011, 4013, 4015, 4018, 4023, 7002, 7006, 7011, 7024, 7027, 7033-36, 7039, 7041, 7043-44, 7046-48, 7050-51, 7053-55, 7057, 7061, 7064-66, 7068, 7070, 7075-76, 7079, 7082, 7086-87, 7089, 7090-91, 7095, 9204 & 9206, Interviewees 3-5, 9 & 11, TGA 5). Their recommendations include: the introduction of fines, particularly on-the-spot fines for straightforward violations; the introduction of civil and criminal penalties, including jail terms; demanding the issue of corrective statements in the same medium as the original advertisement; the issue of infringement notices and enforceable undertakings; and the publication of enforcement outcomes on the TGA website. Stakeholders have also advocated for added enforcement powers, including powers to issue substantiation notices (i.e. require sponsors to provide supporting documentation capable of substantiating a claim), to suspend and remove products from the Australian Register for Therapeutic Goods (ARTG), and to refuse the listing and registration of similar products.

Since the *Transparency Review*, the *Therapeutic Goods Act* has twice been amended to include new civil and criminal penalties[102] for advertising-related offences. The TGA has also proposed several other advertising-related changes to the Act in response to the *Review of Medicines and Medical Devices Regulation*, including: increases to the level of penalties for current advertising offences;[103] the creation of civil penalties where previously criminal penalties have only applied;[104] powers to issue substantiation notices;[105] powers to issue interim, consent, and permanent injunctions to restrain advertisers from breaching and continuing to breach advertising requirements; powers to suspend and cancel advertised products without notice; powers to order advertisers to undertake corrective action within a specified time frame; and powers to issue infringement notices for strict liability and civil offences (TGA 2016b & 2017d). While the enhancement of penalties and agency powers will go some way towards increasing the punishment payoff for sponsors, they will have little impact on compliance if the certainty and celerity of sanction remains low (Bandiera 2016, p. 6). The Australian Government has indicated that it plans to enhance post-market processes, including the rate of post-market review (Department of Health 2016a, pp. 34-5), but little to no information has been provided publicly as to how these post-market processes will be increased, let alone resourced, in the long term (Bandiera 2016, p. 6).

Since 2012, the number of post-market reviews conducted by the TGA per year has increased from 509 to 948 (TGA 2017a, para. 9). Although this is well above the desired 24% review rate for all *new* listings, less than 10% of all *active* listings on the ARTG remain at risk of being subject to a compliance review.[106] An emphasis on post-market processes to identify acts of non-compliance also places greater strain on complaints bodies, which, in the absence of greater resourcing, are likely to impact upon the timeliness in which complaints are adjudicated and penalties are applied (see 8.1.4). Problems also arise in the agency's retainment of product suspension and cancellation as a principle mode of punishment because of the limited deterrent impact these penalties have on listed medicine

[102] For breaching a condition of a licence (13F), the failure to provide requested information or documents within a specified period (14M), the failure to comply with a direction of the Secretary (15C), and supplying a drug not labelled in accordance with a direction of the Secretary (15D).
[103] A maximum of 5 years prison and/or 4,000 penalty units for criminal offences, 1,000 penalty units for strict liability offences, and 50,000 penalty units civil offences (for a body corporate) (TGA 2016b, pp. 15-6). These revisions are specific to the following offences: advertising a medicine for a purpose not included in the ARTG entry (s. 22(5), 41ML & 32BJ(3)); advertisements requiring pre-approval (s. 42C); false or misleading advertising (s. 42C); failing to comply with corrective action ordered by the Secretary (Regulation 9); the publication of restricted representations, references to prescription substances, or unapproved products (s. 42DL); advertisements which do not comply with the Code (s. 42DM); and the publication of generic information which does not comply with the code (s. 42DP).
[104] s. 22(5), 32BJ(3), 41ML, 42DL & 42DM.
[105] This includes corresponding criminal and civil penalties (15 penalty units), and infringement notice (60 penalty units) for failing to comply with a substantiation notice (TGA 2017d).
[106] This is based on the assumption that there are 10,000 active listings for complementary medicines alone.

sponsors (Bandiera 2016, p. 7). These increases to penalties and powers also fail to address pre-existing loopholes that enable sponsors to avoid detection and penalty (i.e. through the de-listing and re-listing products) and reap the rewards of non-compliance (i.e. by selling off any residual stock found to contain non-compliant claims) (Bandiera 2016, p. 6). If these issues continue to remain un-addressed, increases in punishment severity alone will have little impact on rates of compliance.

A similar civil and criminal penalty regime for promotional practices has not been implemented for the reasons outlined in section 8.1.3 below.

8.1.3 INCREASED CO-REGULATION

Stakeholders and interviewees have stated that greater government intervention in prescription and non-prescription medicines advertising and promotion is necessary to overcome the inherent conflicts of interest posed by self-regulation and the capacity of sponsors to avoid being subject to self-regulation (Submissions 2013, 2017, 2020, 2034, 4001-02, 4009-10, 4016, 4018-19, 4021, 4027, 4029, 5010-11, 7021 & 7092, Interviewees 4, 8 & 9).

In non-prescription medicines advertising, industry stakeholders maintained that while they do not object to greater co-regulation, they prefer that emphasis remain on industry self-regulation (Submissions 2001, 2003, 2006, 2009, 2011, 2014, 2029, 2033, 4005-06, 4012-13, 4032, 5002-03, 5006-07, 5012, 5016-17, 5019-22, 5024, 7003-04, 7006, 7008, 7034, 7048, 7054-55, 7065, 7072 & 7086-87, Interviewee 6 & 11). Industry stakeholders also argue that, rather than increase the degree of government intervention, the Australian Government could simply make adherence with industry codes of conduct mandatory under law (Submissions 2009, 2027, 4020, 4032, 5006, 5016, 5018-19, 5025, 7006, 7048 & 7087). This would effectively allow industry associations to act on non-members who fail to comply with industry codes of conduct—a precedence which already exists in the prescription medicines sector. Non-industry stakeholders agree that mandatory adherence to industry codes is necessary for ensuring greater compliance by sponsors, irrespective of whether government intervention is also increased (Submissions 2008, 2010, 2012, 2021-22, 2025, 2037, 4002, 4005-4006, 4009, 4015, 4018-19, 4021, 4027-28, 5008-09, 5010 & 7079).

However, the Australian Government has opposed mandatory adherence to industry codes of conduct for non-prescription medicine sponsors. In response to these recommendations in the Transparency Review, the Australian Government chose to reinforce its support for industry self-regulation and initiatives to harmonise all industry codes, stating that:

> [f]urther changes will [only] be considered if it is found that there is a need to provide greater encouragement to non-members of industry associations to nominate and sign up to an appropriate industry code, including […] notification of a sponsor's nominated code of conduct at the point of including a product on the ARTG (Australian Government 2011, p. 12).

In response to the *Position Paper on the Promotion of Therapeutic Goods*, the Department of Health further stated that companies should 'not be obliged to become members to elect to be covered by a code of conduct' and that all code breaches, irrespective of whether they were committed by members or non-members, can simply be referred to the relevant code of conduct committee (Department of Health 2011, p. 2). At the time of writing, adherence with industry codes by non-prescription medicine sponsors remains voluntary. Other than the increases to penalties and powers outlined in the previous section, government intervention in advertising and promotion has not been increased, and the current arrangement of the Complaints Resolution Panel (CRP) (or equivalent body, see 8.1.4.), ASMI Marketing and Ethics Subcommittee, and Complementary Medicines Association (CMA) Complaints Resolution and Monitoring Committee remains in place.

The prescription medicines sector has been successful in arguing against proposals aimed at creating legislative underpinning for promotional requirements when this was demanded by non-market non-governmental players (see 8.1.1.3). The Department of Health, in turn, has continued to pledge support for industry self-regulation in this space. In its own submission to the Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill, the Department of Health (2013, p. 8) stated that:

> [t]he TGA's current enforcement powers are not designed or adapted to detect, enforce and prosecute contraventions of the type proposed. As well as requiring additional amendments to the Act, development and implementation of such a monitoring and enforcement role would require significant resources and would result in additional costs to industry through TGA's cost recovery arrangements.

8.1.4 INCREASED CENTRALISATION

The vast majority of stakeholders and interviewees agree that pre-approval and complaints processes should be centralised so that there is a single code and body charged with pre-approval and complaints handling (Submissions 1060, 1075, 1090, 1097, 2001-05, 2008-11, 2013-18, 2020-22, 2024-25, 2027-37, 4001-02, 4005-06, 4008-10, 4012, 4014-15, 4017-22, 4025-28, 4030, 4032, 5003, 5005-06, 5008-10, 5012, 5018, 7002-04, 7006-09, 7011-16, 7021, 7024, 7027, 7033-34, 7036, 7038, 7040-44, 7046-48, 7050-51, 7054-55, 7058, 7061, 7065-66, 7068, 7070, 7072, 7075-77, 7079, 7080, 7082, 7085-87, 7089, 7090-91 & 7095, Interviewees 2, 4, 6, 9 & 11, TGA 5). This action would reduce the

complexity of current arrangements and remove the perceived inconsistencies associated with pre-approval and complaints bodies (Bandiera 2016, p. 5). However, little consensus exists among stakeholders and interviewees as to who should be charged with pre-approval and complaints handling, which has inevitably stalled progress towards the centralisation of these processes.[107]

Some industry associations have demonstrated strong resistance towards the relinquishing of their codes of conduct, and by extension, their pre-approval and complaints powers:

> The controls that are in our Code are different to the controls in other Codes and this is a reflection of the differences between industry sectors. In [our] view it is inappropriate to apply a one-size-fits-all solution to a diverse industry (Industry Association, Submission 5006, p. 5).

Industry stakeholders, practitioner associations, and a small number of academics have argued that discrepancies associated with the pre-approval and complaints process can be resolved simply by creating a common set of high-level principles which can be incorporated into each individual industry code of conduct (Submissions 2009, 2027, 2029, 2033, 4001-02, 4005-06, 4012, 4017, 4020, 4025-26, 4030, 4032, 5006, 5012, 5018, 7048 & 7089, Interviewee 11). While such a proposal, if ever implemented, would have the benefit of standardising procedural requirements and penalties between the industry associations, pre-approval and complaint processes will continue to remain decentralised under this model, and thus, open to inconsistency by virtue of having multiple bodies adjudicating the pre-approval and complaints processes. The proposal also does little to address the issue of non-members who escape enforced self-regulation (Bandiera 2016, p. 4). Failing to address this issue will only exacerbate the difference in treatment between members and non-members. A significant degree of compulsion, either by the regulator or non-market non-governmental players, would also be required to ensure that this proposal is fully realised.

The Australian Government's plans to abolish the pre-approval process and rely on industry associations or commercial providers to implement a self-regulatory framework will do little to address the current inconsistencies associated with the regime. The success of the proposal largely hinges upon each of the industry associations adopting a consistent pre-approval framework. The ad hoc implementation of informal pre-approval processes by multiple industry associations could lead to differences in the types of advice provided to sponsors as well as the decisions handed down by

[107] Since 2014, two further consultations have debated the issue of pre-approval and complaints handling: The Review of Medicines and Medical Devices Regulation in 2015 and The Regulatory Framework for Advertising Therapeutic Goods in 2016.

authorising bodies (Bandiera 2016, p. 3). Multiple adjudicating bodies continue to remain involved in the pre-approval process under this model. Non-members will also continue to avoid being subject to industry self-regulation (Bandiera 2016, p. 4). It is difficult to see how a decentralised pre-approval process implemented at the discretion of industry associations will achieve a greater level of consistency (and therefore, equity in the treatment of sponsors) than the current pre-approval framework.

The Australian Government has agreed to the recommendation of abolishing the CRP and creating a single body charged with receiving and managing advertising complaints (Department of Health 2016a, p. 17). However, removing the formal requirement of pre-approval and relying upon post-market techniques (e.g. compliance reviews and spontaneous reporting) to identify non-compliant advertisements will lead to an increased workload for the new complaints body simply because fewer advertisements are being pre-screened and greater reliance is being placed on post-market techniques (Bandiera 2016, p. 8). The CRP's incapacity to remediate non-compliant advertising in a timely manner was the principle motive for its abolition in the first instance (Bandiera 2016, pp. 8-9), and the centralisation of the complaints process is likely to increase the demand on its resources more than current arrangements (Submissions 7004, 7006, 7009, 7024, 7046-48, 7050, 7053, 7070, 7079 & 7090-92). Unless the new complaints body receives a level of resourcing beyond that currently provided to the CRP—something which the present Government has been unwilling to supply—it is unlikely to have the capacity to deal with the current level of complaints, let alone a potential increase in complaints as a result of the shift in emphasis to post-market oversight (Bandiera 2016, p. 9).

8.1.5 INCREASED RESOURCING

While several stakeholders agree that additional resourcing is necessary to enhance the enforcement capacity of the regulator (Submissions 1002-04, 1043-44, 1048, 1051, 1068, 1074, 1079, 1081, 1084, 1095, 1108-09, 2002, 2009, 2015, 2017-18, 2024, 2031, 2033-34, 3003, 3005, 3025, 3029, 3118, 7021, 7024, 7038, 7046-47, 7050, 7053, 7061, 7065, 7070, 7079, 7090-91, 8007, 9005 & 9203, Interviewee 1, 4-5, 9 & 11), suggestions on how best to source this funding remain highly controversial. Industry stakeholders have remained strongly opposed to an increase in fees to cover the cost of any proposal or regulatory activity from which they will not derive direct benefit:

> access to TGA information will largely be for public benefit rather than the benefit of industry who are reasonably familiar with the details [...] These costs, which could be quite substantial, should not be from industry (Sponsor, Submission 1004, p. 1).

> These activities should [...] be subject to government funding as general public health initiatives are not as (sic) part of TGA fees for evaluations (Sponsor, Submission 1108, p. 3).

The Australian Government has likewise indicated that it prefers to maintain the current cost-recovery arrangement and will not allocate any additional long-term funding.[108] The Department of Health has stated publicly that any decision to alter the agency's funding structure from a 100% cost-recovery model will need to be deferred until the Portfolio Charging Review scheduled for 2018 (Australian Government 2016, p. 28).

8.1.6 INCREASED TRANSPARENCY

Stakeholders and interviewees have overwhelmingly advocated for increased transparency of the regulatory regime.[109] This included greater access to and disclosure of information relating to: TGA regulatory activities and their outcomes; the precedence for regulatory decisions; and, committee meeting minutes and conflict of interest policies. Stakeholders and interviewees called for greater access to and disclosure of certain types of information, including: information evaluated by the TGA during an application, as well as the evaluations themselves; adverse drug reaction (ADR) data; clinical trial data; and information on medicines safety and efficacy. This included calls to review current commercial confidentiality policies to reduce information access barriers, to expand Product Information (PI), Consumer Medicines Information (CMI) and Australian Public Assessment Records (AusPARs) to a wider range of products, and, to create explicit labels indicating the safety and efficacy status of listed products. There were also calls for increased opportunities for stakeholder involvement in regulatory processes.

To enhance health literacy, stakeholders and interviewees advocated for greater promotion of: the regulatory agency and the extent of its remit, including a greater media presence; the information available to consumers (e.g. PI/CMI, and AusPARs); and spontaneous reporting mechanisms. There were also calls to overhaul the delivery of information, including: the provision of more consumer-friendly and contextualised sources of information; that the TGA website be re-designed so that it is more user-friendly; and, that greater amounts of independent, non-industry sources of information be provided.

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[108] In the 2016-17 Federal Budget, the Australian Government pledged a total of AU$20.4 million to fund the recommendations of the Review of Medicines and Medical Devices Regulation over the next four years; the ongoing costs of the recommendations will be met by cost recovery arrangements (Australian Government 2016, p. 106).

[109] Due to the number of stakeholders and interviewees advocating for these transparency features, a detailed list containing those submissions and interview transcripts advocating for these features is listed in *Table 8.1*.

Table 8.1: List of Stakeholders and Interviewees who Advocated for Certain Transparency Features in Section 8.1.6.

Transparency Feature	List of Stakeholders and Interviewees who Advocated for these Features
Greater access to and disclosure of TGA regulatory activities and their outcomes.	**Submissions** 1002, 1004, 1011, 1013, 1016, 1020, 1029, 1034, 1043-44, 1049, 1055, 1060, 1078-79, 1081-83, 1085-86, 1090-91, 1096-97, 1104, 1108, 1119, 2002-03, 2006, 2008-09, 2011, 2012, 2015-17, 2024, 2027-31, 2034, 2037, 3023, 3026, 3115, 3120, 4014-15, 4023, 7034, 7050, 7054, 7065, 8019 & 9110, **Interviewees** 1 & 4-5.
Greater access to and disclosure of the precedence for regulatory decisions.	**Submissions** 1001, 1019, 1044, 1058, 1060, 1069-70, 1074, 1080-82, 7006, 7012-16.
Greater access to and disclosure of committee meeting minutes and conflict of interest policies.	**Submissions** 1029, 1069-70, 1081, 1085, 1100, 1108, 1113, 1119, 2010, 2017, 2027, 2037, 3016, 3106, 7043 & 7054.
Greater access to and disclosure of information evaluated by the TGA during an application, in addition to the TGA evaluation.	**Submissions** 1058, 1069-70, 1090, 1113, 1119 & 9006.
Greater access to and disclosure of ADR data.	**Submissions** 1003, 1013, 1037, 1043, 1047, 1050, 1069, 1090 & 1119.
Greater access to and disclosure of clinical trial data.	**Submissions** 1090, 1113, 1117, 1119, 4002, 400-10, 4019, 4021, 4027-28 & 9006.
Greater access to and disclosure of information pertaining to medicines safety.	**Submissions** 1003, 1009, 1010, 1013, 1020, 1025, 1030, 1037, 1043, 1045-46, 1050, 1052, 1058, 1079, 1090, 1096, 1114, 1116, 1119, 3029, 3117, 6005 & 9110.
Greater access to and disclosure of information pertaining to medicines efficacy.	**Submission** 1005, 1009, 1027, 1031-32, 1041, 1043, 1057, 1079, 1087, 1089-91, 1097, 1103, 1109, 1114, 1118, 2010, 2012, 2019-22, 2025, 3016, 3022-23, 3026, 3029, 3120, 4023, 7050, 7079 & 9110.
Review current commercial confidentiality policies.	**Submissions** 1097, 1119, 9005-06 & 9008.
Expand PI/CMI and AusPARs to a wider range of products.	**Submissions** 1010, 1013, 1115, 7080, 8001, 8008, 8015, 8020 & 8022.
Creation of explicit labels indicating the safety and efficacy status of listed products.	**Submissions** 1005, 1027, 1031-32, 1041, 1043, 1057, 1079, 1087, 1089-91, 1097, 1103, 1109, 1114, 1118, 2010, 2012, 2019-21, 3016, 3022-23, 3026, 4023 & 7050.
Increased opportunities for stakeholder involvement in regulatory processes.	**Submissions** 1079, 1086, 2015, 2017 & 2034.

Greater promotion of the regulatory agency and the extent of its remit.	**Submissions** 1001, 1010, 1013, 1020, 1025, 1042-44, 1049, 1059-60, 1079-81, 1084, 1088, 1095, 1103-05, 1112, 2028, 3001, 3011, 3023, 3029, 3120, 6017, 7050, 8011 & 9110, **Interviewees** 3-4 & 11.
Greater media presence.	**Submissions** 1001, 1017, 1043, 1055, 1058, 1083, 1090, 1094 & 1113.
Greater promotion of the information available to consumers.	**Submissions** 1050, 8011, 8014 & 8016-17.
Greater promotion of spontaneous reporting mechanisms.	**Submissions** 1013, 1030, 1043, 1050, 1058, 1079, 1084, 1086, 1105, 2009-10, 2012, 2015, 2028, 2034-35, 4014, 6005, 6018 & 7050, **Interviewee** 6.
Provision of consumer-friendly and contextualised sources of information.	**Submissions** 1025, 1049, 1051, 1084, 1086, 1095-96, 1105, 1108, 2030, 3033, 6018, 7050, 8003, 8010, 8013, 8018 & 9110, **Interviewee** 3.
Re-design the TGA website.	**Submissions** 1004, 1011, 1013, 1019, 1020, 1030, 1042, 1044, 1049-51, 1059-60, 1079, 1084, 1086, 1094, 1096, 1105, 1108, 2020-22, 2034-35, 2037, 8002, 8011-12 & 8014.
Provision of independent, non-industry sources of information.	**Submissions** 1031, 1044, 1050 & 1057.

Most industry stakeholders have been reluctant to disclose information beyond the level that is already provided to the public. Industry have argued that further disclosure will increase compliance costs for sponsors (Submissions 1060, 1084, 3001, 3033, 3103, 6001-02, 6008, 6010-12, 8006, 8009 & 8014), would render Australian requirements out of step with those overseas (Submissions 1013, 1084, 6002, 6004, 6009, 6011-13, 7004, 7028, 7034, 7054-55, 7065, 7069, 7072, 8003-04, 8010-12, 8019 & 8022), and may in fact hinder health literacy because of its technical nature and the misconceptions consumers could draw from the release of such information (Submissions 1001, 1042, 1060, 1084-85, 3022, 6002-07, 6010-11 & 6015-17). Industry stakeholders continue to class a large proportion of this information as commercial-in-confidence, even if it is not necessarily defined as such under law (Submissions 1001, 1004, 1008, 1021, 1025, 1029, 1042, 1051, 1060, 1063, 1079-81, 1083-85, 1094-95, 1101, 1108, 3001, 7034, 9001-04, 9007, 9009-13 & 9116); for example:

> [Our organisation] does not support disclosure of product information in relation to ingredients/formulas as this encroaches on commercial-in-confidence details. The complementary medicine industry already struggles with the lack of exclusivity/data protection available impacting on competitiveness and innovation in the market. The [organisation] believes publicly disclosing additional product information would not benefit consumers but lessen the forces of competition (Industry Association, Submission 1042, p. 1).

> the process for supporting indications should be carefully explained to the public, a sponsor's information on evidence for specific products is commercially sensitive, and should not be made

> public. Considerable time, expertise and expense can be involved in obtaining suitable evidence of efficacy, therefore, details should remain confidential (Sponsor, Submission 1004, p. 1).
>
> Most product registration information is a trade secret, except for the limited information published by TGA after registration. To the extent to which any of the information in a product dossier is not a "trade secret", that information is nevertheless of significant commercial value (for example, but without limitation, the filing date, shelf life, bioequivalence justifications, indications claimed, formulation and manufacturing process information) (Industry Association, Submission 9007, pp. 8-9).
>
> the CCI [commercially confidential information] property interests at stake represent fundamental rights accorded the owners of the information. Setting these rights aside by disclosing CCI, even in cases of an overriding public interest, results in total destruction of the property right, and consequently real injury. This means that an abstract "public interest in transparency" cannot justify release of CCI in any specific case (Sponsor, Submission 9001, p. 2).

Many industry stakeholders also argued that a large amount of information is already made available to consumers and that the problem is simply communicating existing information to consumers in a more consumer-accessible manner (Submissions 1001, 1025, 1042, 1051, 1063, 1079, 1083-85, 1095, 1108, 3001, 3025, 3033, 8004 & 8007). For example:

> the focus of the transparency initiatives should be on providing existing information in a more consumer friendly format rather than disclosing ever more details where there is already broad disclosure […] The TGA should approach extended information disclosure with caution, to ensure that unintended consequences of unnecessary and inappropriate disclosure does (sic) not unduly damage the innovative capability of the pharmaceutical industry and act as a disincentive to bring medicines to Australia. […] AusPARs appropriately provides detailed disclosure on a product including the objective assessment of benefit and risk (Industry Association, Submission 1084, p. 2).
>
> We strongly believe that if the TGA would clearly and effectively communicate to the consumer the way it assesses and regulates CM listed medicines compared to registered medicine—including why different considerations apply and highlighting the strong safety record of CM, the different nature and purpose of these types of medicines—the consumer could make a better informed choice (Sponsor, Submission 1095, p. 4).

With these reservations in mind, the TGA has attempted to increase the amount of information it disseminates to the public. This action has included the creation of consumer-friendly sources of information on the TGA website designed to educate consumers on its role and remit. The homepage

of the TGA website now contains quick links to direct consumers and healthcare practitioners to important aspects of the site, such as the ARTG and the page containing instructions on how to lodge ADR reports. The TGA and Department of Health have developed the phone app MedSearch which allows consumers to access and download PI and CMI directly to their phone. The agency has also generated databases for ADR reports (the Database of Adverse Event Notifications or DEAN) and recalls (System for Australian Recall Actions or SARA). While the contextualised information provided by the TGA on its role and remit is a positive step forward for the agency, simply providing consumer-friendly information is not enough to increase health literacy when there is little promotion of the agency and its website. What's more, not all this information provided by the TGA is contextualised—information provided on the ARTG, DEAN, and SARA is still largely tailored to audiences with technical knowledge of pharmaceutical products and the regime.

In 2011, the TGA began publishing the outcomes of compliance undertakings, court actions, cancellations, suspensions, and advertising complaints on its website. However, the agency only appears to be publishing those outcomes concerning complementary medicines and medical devices.[110] What's more, information on the compliance undertakings and advertising complaints referred to the TGA by the CRP is only available up until December 2014—either the TGA has not performed any of these types of actions since 2014 or the agency is failing in its commitments in reporting these activities to the public. The TGA began publishing the outcomes of laboratory tests for listed and registered medicines on its website in mid-2017. However, there is a minimum 6 to 12-month delay between test outcomes and their publication, which the agency claims is supposed to allow it time to undertake further investigations and follow-up actions (TGA 2017f, para. 12). While the publication of these enforcement outcomes on the website is greater than the level the agency had published prior to the Transparency Review, this reporting still falls short of the amount necessary for generating greater deterrence and the responsibilisation of consumers. The deterrent effect of publishing enforcement outcomes on the TGA website remains questionable given that few members of the public are currently aware of the TGA or use their website as a source of information. Unless these activities are coupled with active campaigns to increase public awareness—of the agency, its website, and of the information available to consumers—the publication of enforcement outcomes is likely to have a negligible shaming effect on sponsors. Inconsistencies and delays in the reporting of enforcement outcomes also does little to aid consumer responsibilisation because the TGA and its

[110] The TGA's cancellations page, for example, lists cancellations against listed medicine and device sponsors only (TGA 2017b). The TGA does provide a page containing a list of those cancellations which were conducted at the request of sponsors, which includes cancellations requested by registered medicine sponsors (see TGA 2018). These cancellations are not necessarily conducted on compliance grounds.

website continues to remain an untimely and uncomprehensive source of information to aid consumer decision-making.

8.2 SUMMARY

Despite the promise of the *Blueprint Reforms* and the consultations that followed, many aspects of the pharmaceutical regulatory regime either remain unchanged or less regulated than they were prior to reform. Listed medicines continue to be approved on a self-regulatory basis, and while the TGA has introduced established sources of evidence and coded indications to restrict a sponsor's ability to include false and misleading information in applications, sponsors can continue to rely on non-scientific sources of evidence to substantiate claims of efficacy. As advertising pre-approval is no longer a formal requirement, and rates of post-market review remain low, there are few pro-active measures in place to ensure that sponsors continue to adhere to regulatory requirements post-marketing. Formal pre-approval for listed and low-risk registered medicines advertisements has been abandoned entirely in favour of an informal and decentralised pre-approval framework that fails to address the lack of compulsion on sponsors to subscribe to an industry association and a code of conduct. Listed and registered medicines promotion continue to remain self-regulated without legislative underpinning. Increases to the range and severity of penalties have failed to address the lack of certainty and celerity of sanctions, and existing loopholes which have allowed sponsors to avoid detection and to profit from non-compliance. The regulation of advertising and promotion remains decentralised except in the area of advertising complaints, where a new body has been appointed in place of the CRP—albeit, with a greater workload and no increase in resourcing. And while efforts have been made to increase the transparency of the regime, not all of the information provided is contextualised, only certain outcomes are being reported, and even then, reported outcomes are not always published in a timely manner to aid rational cost-benefit calculations.

Each of the features proposed by stakeholders and interviewees to enhance the success of the regime and better regulate industry were evaluated, and dismissed, in accordance with neoliberal rationalities of government. Each feature was viewed by industry in cost-benefit terms, such as the negligible effect regulatory techniques would have on deterrence, the increased resource and financial cost to the regulator, and by extension the state, and the increased time and financial cost to industry just so that it could comply with new requirements. The harms resulting from industry promotional practices were also rationalised in terms of their costs and benefits. Promotion was perceived by industry to be integral to practitioner education and introducing legislation was believed to criminalise the industry-practitioner relationship. Risk rationality was specifically used to reject the implementation of

features perceived to be incommensurate with the risk posed by products—since industry perceived product risk to be low, regulation had to be in keeping with this level of risk. Responsibilisation was used to justify the rejection of features which aimed to increase intervention by the state—industry generally believed that it was capable of self-regulation and that state intervention only undermined industry's ability to self-regulate. Knowledge was also used to shape the extent to which non-market non-governmental players could access information necessary for exercising self-governance and participating in the regime in line with the neoliberal rationality of limited market intervention. For instance, knowledge about products was often deemed too technical for the inexpert and something which should remain exclusive to those who produced it. In effect, the implementation of many of these features has been thwarted by the very rationalities they seek to address.

The extent to which these neoliberal rationalities of government have been able to shape the regime in the interests of capital demonstrates the pervasiveness of the dominant hegemony and the degree to which market forces can exercise power within the regime. What's more, the extent to which neoliberal rationalities of government have been *allowed* to shape the regime demonstrates the degree to which the state is conditioned by these rationalities of government to operate in ways that primarily serve the interests of capital. The prioritisation of capital in the interests of the dominant hegemony has ultimately prohibited the development of a robust regulatory regime which is better able to generate compliance from sponsors and provide consumers with the level of government-protection they need to insulate themselves against unscrupulous industry practices.

9 CONCLUSION

The central aims of this thesis have been to establish why the pharmaceutical regulatory regime in Australia, underpinned by the theories of risk-based and responsive regulation, has failed to achieve compliance from sponsors, and how the regime may be congruent with neoliberal rationalities of government that aim to limit forms of market intervention by non-market forces detrimental to the accumulation of capital.

9.1 OVERVIEW OF THE FINDINGS

In an historical overview of the emergence of the Australian pharmaceutical regulatory regime, the thesis found that it was the capacity of market forces to articulate private interest issues as the general public health interest that enabled private interest issues to become a chief object of biopolitical concern. Because of this framing, health administration has been increasingly viewed in economic terms, which has enabled the regime to become shaped in ways that are generally supportive of governmental techniques that have the least amount of impact on the capacity of market forces to accumulate capital. This governmentality has ultimately led to: the decentralisation of the regulatory regime through the formation of state apparatuses like the Therapeutic Goods Administration (TGA), the empowerment of industry associations, and the responsibilisation of sponsors and consumers; the development of risk-based, cooperative, and graduated techniques of government; and the development of technologies of citizenship that encourage participation by non-market non-governmental players.

Themes derived from the qualitative thematic analysis of public consultation submissions and interview transcripts suggest that the Australian pharmaceutical regulatory regime is congruent with neoliberal rationalities of government. In those aspects of the regime where compliance-based techniques are often used, and where non-compliance has traditionally been greatest, the capacity of the regime to achieve compliance has been severely reduced due to: the limited amount of oversight exercised in these aspects of the regime; the capacity of regulatees to avoid being subject to the regime; the reactive nature of the regime; the regime's limited centralisation and proportionality; the incapacity of the regime to escalate responses beyond lower-level persuasive techniques; and the operational constraints placed on the TGA. These techniques of government are at odds with the rationalities of risk-based and responsive regulation theory and have more in common with neoliberal rationalities of government that aim to limit forms of market intervention by the state which are detrimental to the interests of capital. This congruence with neoliberal rationalities of government

indicates that the risk-based and responsive regulatory techniques which underpin the Australian pharmaceutical regulatory regime do not adhere to the tenets of the original theories, and instead, form part of a governmentality (and ultimately, a hegemonic project) which seeks to limit forms of market intervention detrimental to the accumulation of capital.

Participation by non-market non-governmental players was also restricted due to the presence of information asymmetries and structural inequalities within the regime. Information asymmetries generated discrepancies, and therefore, power-knowledge relations, between those in possession of the medical and regulatory knowledge needed to participate actively in the regime and those who did not. These power-knowledge relations restricted those who lacked this knowledge from participating with the fullest effect. Similarly, structural inequalities, which have generated an unequal structure of representation within the regime, have physically rendered the regime less representative of the interests of less dominant forces. These power-knowledge relations and unequal structures of representation have defined the extent to which non-market non-governmental forces can exercise power within the regime, and therefore, intercede in ways that are counter to hegemonic interests.

This governmentality has continued to shape the pharmaceutical regulatory regime in line with the interests of the dominant hegemony by functioning as a series of disciplinary techniques or disciplinary regime. As argued in *Chapter 6*, the regulator's inability to achieve compliance from regulatees has reinforced the notion that state intervention should be kept minimal and regulatees should be responsible for their own regulation. This is despite the fact that this regime failure is a direct consequence of a neoliberal governmentality. Cooperative and risk rationalities have also reinforced notions that regulatees are cooperative and law-abiding, and risks are unpredictable and well outside state control, all because the regime is incapable of acting on compliance and product risks. Even responsibilisation has afforded sponsors and industry associations the degree of autonomy that enables them to exploit the laxity of current arrangements and define the scope of their criminality so that they appear to be cooperative and law-abiding. These disciplinary techniques contribute to the ongoing construction of the regime by rationalising the exercise of this particular type of government. This construction, in turn, helps shape non-market forces in ways that align with the long-term interests of the dominant hegemony.

This degree of shaping was also present in *Chapter 7*. Deficits in power-knowledge have restricted the capacity of non-market non-governmental players to exercise agency at an individual and collective level. Not only has this reduced the capacity of non-market non-governmental players to effect change in the relations of power, rendering them less able to organise and act in ways that are

counter to the interests of the dominant hegemony, but it has also rendered them reliant upon those players who possess this power and knowledge to represent their interests and to impart information. The dependence generated by this structuration of power and knowledge ultimately renders non-market non-governmental players more susceptible to being shaped by the interests of the hegemonic faction.

The limited capacity of the regulator to act on compliance issues, and non-market non-governmental players to participate effectively in the regime, has rendered all non-market forces less able to intervene in the regime in ways that are contrary to the interests of capital. These failures have allowed the regime to become shaped around the interests of the dominant hegemony, enabling market forces to maintain their dominance over less dominant non-market forces.

9.1.1 A MORE TRANSFORMATIVE SOLUTION?

Attempts to enhance the regime to better regulate industry in the period immediately following data collection for this thesis found that many of the enhancements proposed by stakeholders and interviewees were often subordinated to the interests of capital. Each of these features was evaluated against neoliberal rationalities of government, such as cost-benefit calculation, risk rationality, and responsibilised autonomy. The submission of these features to neoliberal rationalities of government effectively enabled 'sources of opposition to, and mere modulation of, capitalist rationality [to] disappear' (Brown 2005, p. 46). The extent to which these neoliberal rationalities of government have been allowed to shape the regime in the interests of capital is not only indicative of the pervasiveness and power of the dominant hegemony, but the extent to which the state is conditioned by neoliberal rationalities to operate in ways that facilitate the accumulation of capital.

Solutions proposed by the regulatory literature to address these types of structural inequalities are generally premised on the development of 'a better regulated capitalist order' (Garside 2013, p. 248), or, a 'new capitalism' (Dukes, Braithwaite & Moloney 2014, p. 363), rather than solutions which address the underlying structural causes of these harms. Even advocates of deterrence, who are generally more critical of these structural inequalities, often propose solutions which call for greater amounts of punitiveness and intervention on the part of the state (e.g. see Bakan 2004; Hillyard & Tombs 2004; Pantazis & Pemberton 2009; Pearce & Tombs 1990 & 1997; Pemberton 2007; Steinzor 2015). Bakan (2004), for instance, has argued that, until the time there is social change, the 'most realistic' solution to corporate crime is to improve government regulation in the hope that this generates an impetus for change. Bakan argues that:

> government regulation should be reconceived [redacted]
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> [redacted] [and] be reformed to improve accountability and avoid both "agency capture" and the centralized and bureaucratic tendencies of current and past regimes (Bakan 2004, pp. 161-2).

Many regulatory scholars also advocate for an empowerment of citizenry (Abbot & Snidal 2012; Ayres & Braithwaite 1991 & 1992; Bakan 2004; Barak 2017; Dukes, Braithwaite & Moloney 2014; Grabosky 2017; Scott 2017; Tombs & Whyte 2015), so that non-market non-governmental forces are able to exercise greater oversight over governmental and market forces and place limits on their capacity to act.

However, Garside (2013, p. 253) has been an avid sceptic of such projects and argues that any suggestion that capitalist states 'should simply cho[o]se to pursue different policies that, in reality, would work counter to the interests of capital is unrealistic' because 'capitalist states are not neutral'. Since states are a representation of the structuration of power relations inside the state, they generally act in ways that are expressive of these power relations. Even though capitalist states make concessions in the interests of the dominated faction, they predominantly act in ways that represent the interests of the capitalist class (Poulantzas 1974; as cited in Mahon 1979, p. 171). This unequal structure of representation was observed in *Chapter 7*; the lack of representation non-market non-governmental forces received in the Australian pharmaceutical regulatory regime enabled market forces to receive greater representation and exercise a greater degree of authority. This bias, in turn, allowed the regime to become organised around the interests of market forces. Capitalist states have also been 'conditioned' (Kilman 2012; as cited in Garside 2013, p. 253) by neoliberal rationalities of government to act like market actors. Not only is the basis for state legitimacy and action predicated upon its ability to sustain the market, but cost-benefit calculations are the measure of all state practices. Capitalist states have therefore been key actors in the creation and maintenance of markets that have remained favourable to the interests of capital (Garside 2013, p. 253).

Neoliberal governmentality has also facilitated the depoliticisation and erosion of participatory democracy so that there are fewer sources of opposition to the dominant hegemony. As *Chapter 7* demonstrated, power-knowledge relations have played a key role in shaping the extent to which certain players have been able to exercise power within the pharmaceutical regulatory regime. Non-

market non-governmental players were often found to lack the medical and regulatory knowledge necessary to participate effectively in the regime. Not only has this lack of knowledge limited the extent to which non-market non-governmental players can challenge the dominant hegemony (and therefore, intervene in the regime in the interests of the public), but risk rationalities have diminished the severity of the differences in these power-knowledge relations by contending that non-market non-governmental players are ultimately responsible for their own health literacy.

Neoliberal governmentality further facilitates this 'dismantling of democracy' by submitting all sources of opposition to economic calculation (Brown 2005, p. 47). Because market rationality is advanced as the only organising principle of the social domain, all sources of opposition, or non-market rationalities, must 'be founded in an alternative table of values' (Brown 2005, p. 57). Brown (2005, pp. 46-7) argues that since '[t]here is nothing in liberal democracy's basic institutions or values … that inherently meets the test of serving economic competitiveness or inherently withstands a cost-benefit analysis', sources of opposition can easily be 'trumped by … cost-benefit and efficiency rationale[s]'. This rationality of government has allowed the hegemonic faction to place greater constraints on the actions of those who challenge market rationalities and enable the actions of those who conform with neoliberal governmentality (Brown 2005, p. 43).

The capacity of capital to penetrate every aspect of the social domain 'implies the need for far more profound material, political and ideological transformations' (Garside 2013, p. 253). Capitalist structures cannot simply be rendered 'more humane' (Garside 2013, p. 254), as any positive advance against the interests of capital accumulation will continuously be shaped by, and subordinated to, the interests of capital. It is only by instigating a much larger transformational agenda, whereby the structural features which support capital accumulation are dissolved, that a regime which truly addresses fundamental public needs can be achieved.

9.2 CONTRIBUTIONS, LIMITATIONS, AND FUTURE DIRECTIONS

In analysing the Australian pharmaceutical regulatory regime, the thesis makes several important contributions to the criminological and regulatory literature. The analysis has revitalised criminological debate on the corporate crimes of the pharmaceutical industry, a field of inquiry which has largely been neglected by the criminological literature (Braithwaite 1984; Dukes, Braithwaite & Moloney 2014; Rawlinson 2015, 2017a & 2017b), despite the capacity of these crimes to cause wide-scale harm. The findings add to the state-corporate crime literature by reinforcing the critique on the symbiotic relationship between state and corporations (Kramer, Michalowski & Kauzlarich 2002;

Tombs & Whyte 2015; Tombs 2016). The findings also add to critical debates on compliance-based regulatory techniques, originally developed in Pearce and Tombs (1990 & 1997) and developed further in publications such as Mascini (2013), Tombs and Whyte (2015), and Tombs (2016), by reinforcing the critique that compliance-based techniques of government are 'compatible with neoliberalism' (Mascini 2013, p. 55).

This thesis builds upon this criminological and regulatory literature in three ways. First, the analysis employed a unique theoretical framework of Marxist and Foucauldian theory, and critical realist ontology, which has only been employed previously in the sociological and political science literature by scholars such as Marsden (1999), Jessop (2007), Joseph (2004 & 2010). Given that regulatory scholars have used both Marxist (Pearce & Tombs 1990 & 1997; Tombs & Whyte 2015; Tombs 2016) and Foucauldian (Scott 2004) theory in analysing regulatory regimes, this theoretical framework provides a useful lens in which regulatory scholars can approach future scholarship. Second, the analysis develops its critique of compliance-based techniques of government from an abductive starting point of regime failure. This abductive line of reasoning has allowed the thesis to search for premises for these high rates of non-compliance instead of engaging in the usual debate of whether or not risk-based and responsive regulation in fact generates compliance. Finally, this investigation has broadened the scope of regulatory inquiry by examining corporate regulation beyond the bilateral regulator-regulatee relationship. This investigation has focused on analysing regulatory regimes, and therefore incorporates an analysis of other regulatory players, beyond public interest groups. Its critique on the participatory aspects of regulatory regimes is particularly unique to the regulatory literature. Many regulatory scholars skip an analysis on participatory democracy within regulatory regimes entirely, and instead, focus almost exclusively on evaluating the regulator-regulatee relationship and the capacity of regulatory techniques in generating compliance. This neglect is to the detriment of regulatory scholarship since many regulatory scholars suggest that empowering citizenry through tripartite techniques of government can overcome the failures of regulation (Abbot & Snidal 2012; Ayres & Braithwaite 1991 & 1992; Bakan 2004; Barak 2017; Dukes, Braithwaite & Moloney 2014; Grabosky 2017; Scott 2017; Tombs & Whyte 2015).

Due to the lack of quantitative data available, this thesis has been limited to a qualitative analysis of stakeholder and interviewee perceptions towards the regulator and regime. It is therefore restricted in its ability to evaluate the effectiveness of risk-based and responsive regulatory techniques of government on actual rates of non-compliance. Future research will need to draw on quantitative sources of data to establish the links between risk-based and responsive regulation and rates of non-compliance. Such a depth of analysis would provide greater grounding to arguments that risk-based

and responsive regulatory techniques are vulnerable to degradation by the dominant hegemony, and that a much larger program of social transformation is necessary to overcome these interests.

This analysis is also restricted to those aspects of the Australian pharmaceutical regulatory regime where non-compliance was high and documented evidence of these high non-compliance rates was available. It has therefore been unable to examine the success of risk-based and responsive regulatory techniques in those aspects of the regime where non-compliance may actually be low or where documented evidence of non-compliance has been unavailable. These findings should not be treated as evidence that risk-based and responsive regulatory techniques are unable to compel compliance at all; this thesis simply suggests that risk-based and responsive regulatory techniques are susceptible to being weakened by the interests of the dominant hegemony, in much the same way as deterrence-based techniques, so that they are rendered less effective at achieving compliance and conform with the neoliberal program. Again, analysing quantitative sources of data would assist in reinforcing these claims, however this may require obtaining more detailed data from the TGA and Department of Health through Freedom of Information Requests.

Although the thesis has touched upon the disagreements between risk-based and responsive regulation in theory and practice, future research should focus on exploring these hybrid frameworks in depth to determine whether they are feasible, or just convenient for the neoliberal program. The TGA is not the only industry regulator to employ a combined risk-based and responsive framework in Australia (see Gunningham 2011), so this type of research would have broad applications.

The thesis also reaches its conclusions with two questions remaining relatively unanswered: how might social transformation be achieved and what would an alternate regulatory regime look like? These questions are outside the scope of this thesis, but some regulatory scholars have suggested that these types of transformations should begin by attacking the legal basis for hegemonic power, the corporate form, by abolishing corporate personhood and limited liability (Tombs & Whyte 2015). Critics who remain ‘closed off’ to the prospect of transformation often perceive this level of change as too idealistic and too difficult to implement (Garside 2013, p. 251). However, such attitudes only limit the ‘critical openness’ necessary to realise the possibility for social transformation (Garside 2013, p. 251). Future research must therefore focus on finding answers to these difficult questions as a program of profound transformation will only be achieved once scholars engage in this task

APPENDIX A: LIST OF TGA CONSULTATIONS CONDUCTED BETWEEN 1 JANUARY 2010 AND 30 JUNE 2014.

Consultation Area	**Consultation Name**	**End Date**	**Publication Status**	**Within Parameters**	**Grounds for Inclusion or Exclusion**
Advertising	Improving Advertising Arrangements for Therapeutic Goods.	27-08-2010	Published	Y	Concerns post-market processes.
	Regulation Impact Statement: Regulating the Advertising of Therapeutic Goods to the General Public.	19-07-2013	Published	Y	Concerns post-market processes.
ANZTPA	Joint TGA & Medsafe Project – Trans-Tasman Early Warning System of Safety Concerns with Medicines and Medical Devices.	07-04-2013	Published	N	Concerns a proposal which has since been disbanded.
	ANZTPA Implementation – Release of High-Level Description of a Possible Joint Regulatory Scheme.	21-02-2013	-	-	-
Complementary Medicines	Australian Regulatory Guidelines for Complementary Medicines. A: General Guidance. B: Listed Medicines. C: Evaluation of Complementary Medicine Substances for Use in Listed Medicines. D: Registered Complementary Medicines.	 07-11-2012 18-02-2013 14-05-2013 22-07-2013	 Published Published Published Published	 N N N N	Does not concern post-market processes (involves an update to guidance documentation only).
	Permitted (Coded) Indications for Listed Medicines	15-03-2013	Published	N	Does not concern post-market processes.
	Evidence Required to Support Indications for Listed Medicines	25-05-2012	Published	Y	Concerns post-market processes.

	(Permitted Coded Indications for Listed Medicines), Consultation 1.				
	Evidence Required to Support Indications for Listed Medicines (Permitted Coded Indications for Listed Medicines), Consultation 2.	22-10-2012	Published	Y	Concerns post-market processes.
	Draft Compositional Guidelines (Multiple).	Multiple	-	-	-
	Options for Reform of the Regulatory Framework for Pharmacy Compounding.	26-07-2013	-	-	-
	International Harmonisation of Ingredient Names.	10-07-2013	-	-	-
	Mechanisms to Maintain the Currency of Approved Product Information (PI) and Consumer Medicines Information (CMI).	13-06-2013	Published	Y	Concerns post-market processes.
Labelling and Packaging	TGA Medicine Labelling and Packaging Review.	24-08-2012	Published	N	Does not concern post-market processes (concerns the physical layout of medicine labelling/packaging).
	Required Advisory Statements for Medicines Labels.	13-05-2011	-	-	-
Manufacturing	TGA Guidance on Release for Supply for Medicines Manufacturers.	06-09-2013	Published	Y	Concerns post-market processes.
	Proposal for Automatic Adoption of New Versions of the PIC/S Guide to Good Manufacturing Practice for Medicinal Products.	12-08-2013	-	-	-
	Options for reform of the regulatory framework for pharmacy compounding.	26-07-2013	Published	N	Does not concern medicine sponsors and manufacturers (concerns the regulation of pharmacy practice).
Medical Devices and IVDs	Changes to Pre-Market Assessment Requirements for Medical Devices (Proposal Paper).	15-03-2013	Published	N	Does not concern prescription or non-prescription medicines.

	Reforms in the Medical Devices Regulatory Framework.	17-12-2010	Published	N	Does not concern prescription or non-prescription medicines.
	Regulation Impact Statement: Changes to Pre-Market Assessment Requirements for Medical Devices.	03-06-2013	Published	N	Does not concern prescription or non-prescription medicines.
	Proposed Amendments to the New Regulatory Framework for In Vitro Diagnostic Medical Devices.	07-06-2013	Published	N	Does not concern prescription or non-prescription medicines.
National Coordinating Committee on Therapeutic Goods	Seeking Information from Compounding Pharmacies.	30-07-2010	-	-	-
Over the Counter Medicines	Proposed Advisory Statements for Medicines				
	Cetirizine.	13-06-2013	-	-	-
	Loratadine and desloratadine.	07-12-2012	Published	N	Involves product specific requirements (not applicable to all products).
	Kunzea ambigua.	18-01-2013	-	-	-
	Famciclovir.	07-12-2012	-	-	-
	Azelastine.	07-12-2012	-	-	-
	Fexofenadine and Loperamide.	04-06-2012	-	-	-
	Cough and cold medicines for use in children.	22-02-2012	-	-	-
	Changes to the TGA Sunscreen Guidelines and Related Legislation.	09-11-2012	Published	N	Does not concern prescription or non-prescription medicines.
	Australian Regulatory Guidelines for Over-the-Counter Medicines (ARGOM) – Stage 1.	10-02-2012	Published	N	Does not concern post-market processes (involves an update to guidance documentation only).
	Over-the-Counter (OCT) Medicines Business Process Reform.	07-11-2012	Published	N	Does not concern post-market processes.

	OTC N2 Application Requirements and OTC Medicine Monographs for Aspirin, Paracetamol, and Ibuprofen.	16-07-2013	Published	N	Does not concern post-market processes.
	Draft OTC medicine monographs for tropical imidazole antifungals, tropical nasal decongestants and pholcodine.	10-01-2014	-	-	-
	Chloramphenicol, propamidine, dibromopropamidine and sulfacetamide for ophthalmic use: proposed advisory statements for medicines.	10-01-2014	Published	N	Involves product specific requirements (not applicable to all products).
	International harmonisation of ingredient names.	10-07-2013	-	-	-
Prescription Medicines	Minor Variations to Prescription Medicines: Guidance and Application Forms.	22-02-2013	Published	N	Does not concern post-market processes (involves an update to guidance documentation only).
	Risk Management Plan Guideline	06-01-2012	-	-	-
	Electronic Submission Dossier Requirements.	01-05-2011	-	-	-
	Proposed Changes to Product Information (PI)	26-07-2010	-	-	-
	Consultation on Adoption of European Union Guidelines in Australia	19-08-2013	-	-	-
Scheduling of Medicines and Poisons	Scheduling Advisory Committees Invitations for Public Comment.	Multiple	Published	N	Does not concern post-market processes.
	Review of the Arrangements for Scheduling Medicines and Poisons.	29-04-2013	Published	N	Does not concern post-market processes.
TGA Processes and Procedures	Transparency Review of the TGA.	20-07-2011	Published	Y	Concerns post-market processes.
	TGA Internet Site Redevelopment: Consultation on Content and Structure.	01-12-2010	Published	N	Does not concern post-market processes
	Draft TGA Approach to Disclosure of Commercially Confidential Information (CCI).	29-08-2013	Published	Y	Concerns post-market processes.

	Evaluating the Feasibility of a New-to-Market Risk Communication Scheme for Therapeutic Goods.	13-06-2013	Published	Y	Concerns post-market processes.

APPENDIX B: LIST OF ORGANISATIONS REPRESENTED IN THE PUBLIC CONSULTATIONS ANALYSED.

Organisation Type	Name
Advisory Committees	Advisory Committee on Prescription Medicines (ACPM)
	Advisory Committee on the Safety of Medicines (ACSOM)
	Council of Australian Therapeutic Advisory Groups
	Drug Utilisation Sub-Committee of the Pharmaceutical Benefits Advisory Committee (PBAC)
Complaints Bodies	Advertising Standards Authority of New Zealand
	Advertising Standards Bureau
	Complaints Resolution Panel (CRP)
Consumer Groups	Consumers Health Forum (CHF)
	CHOICE
State and Federal Governmental Departments/Organisations	Australian Commission on Safety and Quality in Health Care (ACSQHC)
	Australian Customs & Border Protection Services
	Australian Health Practitioner Regulation Agency (AHPRA)
	Australian Pesticides and Veterinary Medicines Authority (APVMA)
	Department of Health, Australia
	Department of Health, Western Australia
	Department of Health, Victoria
	Medication Services Queensland
	Optometry Board of Australia
	National Blood Authority
	Northern Territory Government
	New South Wales Government
	Optometry Board of Australia
Health Advocacy Groups	BUKO Pharma-Kampagne
	Public Health Association of Australia (PHAA)
	Health Action International (HAI)
	Health Action International (HAI) Asia-Pacific
	Public Interest Advocacy Centre
	New South Wales Therapeutic Advisory Group
	Standards Australia
	Therapeutic Guidelines Limited
	Real Health Care Reform
Healthcare Providers	Australian Red Cross Blood Service
	Australian Health & Education Centre
Hospices	Alfred Hospital

	Sydney Children's Hospital
Industry Associations (One Anonymous)	ACCORD Australasia
	Active Pharmaceutical Ingredient Manufacturer's Association of Australia (APIMAA)
	AusBiotech
	Australasian Tissue & Biotherapeutics Forum
	Australian Association of National Advertisers
	Australian Food and Grocery Council (AFGC)
	Australian New Zealand Industrial Gas Association (ANZIGA)
	Australian Self-Medication Industry (ASMI)
	Australian Subscription Television and Radio Association (ASTRA)
	Chinese Medicine Industry Council of Australia (CMIC)
	Complementary Healthcare Council of Australia (CHC) [now Complementary Medicine Association (CMA)]
	Direct Selling Association of Australia (DSAA)
	Free TV Australia Ltd
	Generic Medicines Industry Association (GMiA)
	IVD Australia
	Medical Technology Association of Australia (MTAA)
	Medicines Australia (MA)
	Medicines New Zealand (NZ)
	New Zealand Self-Medication Industry (NZSMI)
	Outdoor Media Association (OMA)
	Pharmacy Guild of Australia
	Publishers' Advertising Advisory Bureau
	The Communications Council
	The Newspaper Works (TNW) [now NewsMediaWorks]
	The Communications Council
Industry Consultants	Advantage Medical Products Consulting Pty Ltd
	Archer Emery & Associates
	David Tan & Associates
	John Miller Consulting
	Quality Matters Safety Matters Pty Ltd
	Regulatory Solutions Pty Ltd
	Stolair Research and Consultancy Services
	Sue Akeroyd & Associates
Information Providers	Australian Medicines Handbook
	MIMS Australia Pty Ltd
	National Prescribing Service (NPS)
Media Organisations	Australian Doctor

Patient Advocacy Groups	Arthritis Australia
	Asthma Australia
	Breast Cancer Network Australia
	Cancer Council WA
	Cancer Voices NSW
	Chronic Illness Alliance
	Endocrine Society of Australia
	Mental Health Council of Australia
Professional Associations	Australian & New Zealand Association of Physicians in Nuclear Medicine (ANZAPNM)
	Australian Acupuncture & Chinese Medicine Association (AACMA)
	Australian Association of Massage Therapies (AAMT)
	Australian Dental Industry Association (ADIA)
	Australian Homeopathic Association (AHA)
	Australian Integrative Medicine Association (AIMA)
	Australian Medical Association (AMA)
	Australian Natural Therapists Association (ANTA)
	Australian Naturopathic Practitioners Association (ANPA)
	Australian Nursing Federation (ANF)
	Australian Orthopaedic Association (AOA)
	Australian Register of Naturopaths & Herbalists (ARONAH)
	Australian Rheumatology Association (ARA)
	Australian Society of Anaesthetists (ASA)
	Australian Society of Clinical & Experimental Pharmacologists and Toxicologists (ASCEPT)
	Australian Traditional-Medicine Society (ATMS)
	Carers Australia, Western Australia
	Centre for Evidence-Based Complementary Medicine (CEBCoM)
	Cosmetic Physicians Society of Australia (CPCA)
	CRANAplus
	Dieticians Association of Australia (DAA)
	Governance, Risk & Compliance Institute
	International Aromatherapy & Aromatic Medicine Association (IAAMA)
	Medical Oncology Group of Australia (MOGA)
	Natural Herbalists Association of Australia
	Pharmaceutical Society of Australia (PSA)
	Royal Australasian College of Physicians (RACP)

	Royal Australian & New Zealand College of Psychiatrists (RANZCP)
	Royal Australian & New Zealand College of Radiologists (RANZCR)
	Royal Australian College of General Practitioners (RACGP)
	Royal College of Pathologists of Australasia (RCPA)
	Society of Hospital Pharmacists of Australia (SHPA)
	Society of Natural Therapists & Researchers (SNTR)
Professional Development Bodies	ARCS Australia
	Australasian College of Natural Therapies (ACNT)
	Southern School of Natural Therapies (SSNT)
Public Advocacy Groups	Friends of the Earth
	Friends of Science in Medicine (FSM)
Sponsors (Five Anonymous)	Abbott Australasia Pty Ltd
	AbbVie Pty Ltd
	Allergan Australia Pty Ltd
	Amgen Australia Pty Ltd
	Amway of Australia
	Amway of Australia and New Zealand
	Arola, Travis, RTI Biologicals Inc
	Baxter Healthcare
	Bayer HealthCare
	BioCeuticals Ltd
	Biogen Idec Australia Pty Ltd
	BioMedica Nutraceuticals Pty Ltd
	Blackmores Ltd
	Boehringer Ingelheim Pty Ltd
	Bristol-Myers Squibb
	Care Pharmaceuticals
	Comvita New Zealand Ltd
	Cook Medical Australia Pty Ltd
	CSL Behring Pty Ltd & bioCSL Pty Ltd
	CSL Ltd
	Ego Pharmaceuticals Pty Ltd (EGO)
	GlaxoSmithKline Pty Ltd (GSK)
	Global Therapeutics Pty Ltd
	Go Vita Distributors Limited
	Health World Ltd
	Integria Healthcare Pty Ltd
	Janssen-Cilag Pty Ltd
	Johnson & Johnson Family of Companies (J&J)

	Lipa Pharmaceuticals Ltd
	Lundbeck Australia Pty Ltd
	Medtronic
	Melrose Laboratories Pty Ltd
	Merck Serono Australia Pty Ltd
	Merck Sharpe Dohme Australia (MSD)
	Mylan New Zealand
	Naturopathx Pty Ltd
	Nestlé Australia Ltd
	Novartis Pharmaceuticals Australia Pty Ltd
	Novo Nordisk Pharmaceuticals Pty Ltd
	Pfizer Australia Pty Ltd
	PharmaCare Laboratories Pty Ltd
	ResMed Ltd
	SANOFI
	Sanofi-aventis Australia Pty Ltd
	Soho Flordis International (SFI)
	Stryker South Pacific
	Swisse Vitamins Pty Ltd
	The Hydration Pharmaceuticals Trust
	The Pharmaceutical Plant Company
	Vifor Pharma
	Webstercare
	Weleda Australia Pty Ltd
Sceptic Organisations	Australian Skeptics Inc
	Australian Skeptics Inc, Victorian Branch
	Australian Skeptics Inc, New South Wales Branch
	Health Skepicism
	Hunter Skeptics
	Mordi Skeptics
Steering Committees	Electronic Distribution Working Group (EDWG)
Universities	University of Sydney
Uncategorised	Bruce Graham Consulting
	CMC Regulatory
	Foundation of Advertising Research (FAR)
	GS1 Australia

APPENDIX C: LIST OF ORGANISATIONS WHICH MADE MULTIPLE SUBMISSIONS TO THE CONSULTATIONS ANALYSED.

Name	No. of Submissions
Australian Self-Medication Industry (ASMI)	12
Consumers Health Forum (CHF)	12
Complementary Medicines Australia (CMA)	10
Australian Dental Industry Association (ADIA)	8
Medical Technology Association of Australia (MTAA)	7
Medicines Australia (MA)	7
Pharmaceutical Society of Australia (PSA)	7
Generic Medicines Industry Association (GMiA)	6
GlaxoSmithKline Pty Ltd (GSK)	6
Pfizer Australia	6
Sanofi-aventis Australia	6
ACCORD Australasia	5
Australian Medical Association (AMA)	5
Direct Selling Association of Australia (DSAA)	5
Johnson & Johnson	5
Pharmacy Guild of Australia	5
AbbVie	4
Amway of Australia	4
Australian Skeptics (Victorian Branch)	4
IVD Australia	4
Australian Homeopathic Association (AHA)	3
Australian Naturopathic Practitioners Association (ANPA)	3
Australian Nursing Federation (ANF)	3
Australian Orthopaedic Association (AOA)	3
Health World	3
Medicines New Zealand (MNZ)	3
National Proscribing Service (NPS)	3
Novartis Australia	3
PharmaCare Laboratories	3
Royal Australian College of Physicians (RACP)	3
Society of Hospital Pharmacists of Australia (SHPA)	3
Swisse Vitamins	3
Advisory Committee on Prescription Medicines (ACPM)	2
Amgen Australia	2
Arthritis Australia	2
Australian Society of Clinical & Experimental Pharmacologists and Toxicologists (ASCEPT)	2
Australian Acupuncture & Chinese Medicine Association (AACMA)	2
ACSQHC	2
Australian Medicines Handbook	2

Bayer HealthCare	2
BUKO Pharma-Kampagne	2
Comvita New Zealand	2
Department of Health, Australia	2
Ego Pharmaceuticals	2
Friends of Science in Medicine (FSM)	2
Friends of the Earth	2
Health Action International (HAI)	2
Merck Serono Australia	2
MIMS Australia	2
Mordi Skeptics	2
Public Health Association of Australia (PHAA)	2
Quality Matters Safety Matters	2
Real Health Care Reform	2
Royal College of Pathologists of Australasia (RCPA)	2
The Communications Council	2
Total No. of Multiple Submissions:	**210**

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