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Marx, Foucault, and state–corporate harm: a case study of regulatory failure in Australian non-prescription medicine regulation

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Abstract
Risk-based regulation has underpinned Australian prescription and non-prescription medicine regulation for over three decades. However, data consistently demonstrate high rates of non-compliance among non-prescription medicine sponsors, with most breaches a result of inappropriate labelling and advertising, a lack of evidence to substantiate therapeutic claims, and product formulation and manufacturing. This paper seeks to understand why the regime fails to achieve compliance from non-prescription medicine sponsors. Using a state–corporate harm lens, and Marxist and Foucauldian perspectives, it is argued that regulatory failure is the product of the regime's congruence with neoliberal governmentality. This governmentality is inextricably linked to a neoliberal market hegemony that attempts to minimize forms of market intervention detrimental to the accumulation of capital.

Introduction

Australia's national drug regulatory authority, the Therapeutic Goods Administration (TGA), is claimed to have a 'world-class' risk-based regulatory framework for regulating prescription and non-prescription medicines on the Australian market (Medicines Australia 2015 cited in [1], p. 1). However, data suggest that regulatory compliance is low among sponsors—the prescription and non-prescription medicine companies that import, export, manufacture, and supply medicines in Australia. For example, in the non-prescription sector, where medicines are largely classified as low-risk and self-regulated, up to 90% of complementary medicines[1] and 80% of

[1] Also known as 'traditional' or 'alternative' medicines and include vitamin, mineral, herbal, homeopathic, naturopathic, and aromatherapy medicines and nutritional and dietary supplements.

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non-prescription medicines[2] are found to be in breach of quality, safety, and efficacy requirements in TGA random and targeted desktop audits [2–7]. These high non-compliance rates have 'endured for some years', demonstrating that non-prescription medicine regulation 'has been of limited effectiveness' ([2], p. 16–17).

Using a state–corporate harm lens, and a Marxist–Foucauldian theoretical framework, this paper examines the cause of this regulatory failure. It is argued that such failure is a product of the regime's congruence with neoliberalism, specifically, the neoliberal rationality to limit market intervention by non-market forces—state and non-state actors, such as consumers, health professionals, and consumer and health professional associations—detrimental to capital accumulation. This neoliberal governmentality[3] forms part of a hegemonic strategy designed to secure support for governmental techniques that advance the long-term interests of market forces—industry and those sympathetic to industry interests. Ultimately, this failure of the pharmaceutical regulatory regime can be understood as a form of state–corporate harm since the state is a key agent in the regime's formation and maintenance.

This paper comprises two parts. Part 1 outlines the Marxist–Foucauldian theoretical framework underpinning this inquiry. Part 2 applies this framework to the Australian pharmaceutical regulatory regime. This paper focuses on the pre-market regulation of non-prescription medicine quality, safety, and efficacy. Here, the meaning of *quality* and *safety* is presumed to be self-evident, while *efficacy* refers to the extent to which a medicine produces a therapeutic effect or benefit for the condition for which it is indicated. Part 2 begins with an overview of the regime and risk-based pre-approval process. It then demonstrates how market interests are articulated as non-market interests to secure support for a regime favourable to neoliberal market hegemony; how the regime, congruent with neoliberal governmentality, restricts non-market forces from intervening in the non-prescription medicine market; and how neoliberal hegemony is maintained by gauging proposed reforms against neoliberal rationales. This theoretical analysis not only draws on the literature but also a larger study encompassing a qualitative thematic analysis of semi-structured interviews with 18 participants and 451 submissions to 12 public consultations conducted between 2010 and 2014 [9].

This subject matter is pertinent to critical criminology and harm scholarship in many ways. Though non-prescription medicines do not pose the same risks as prescription medicines, they are not without risk. Many traditional Chinese medicines on the Australian market have been found to contain heavy metals, toxins, and other undeclared ingredients [10]. Weight loss supplements and protein powders containing seemingly innocuous ingredients have been linked to deaths and serious liver injury requiring transplantation [11–13]. Complementary medicines making unsubstantiated claims, such as weight loss supplements promoting rapid weight loss, and vitimans claiming to protect eyes from electronic screens, reportedly cost Australian consumers hundreds and thousands of dollars a month [12, 14]. The state's failure to restrain, and indeed facilitation of, these harmful practices render this

[2] Known as listed medicines, see *Overview of the Regulatory Regime*.

[3] Defined here as 'taking the formal principles of a market economy and … projecting them on to a general art of government.' ([8], p. 131).

state–corporate relationship 'a site of constant harm production' and 'criminality' ([15], p. 86, 89) that merits criminological inquiry. Yet, aside from notable exceptions [15–18], few criminologists have examined the corporate crimes and harms of the pharmaceutical industry, let alone the non-prescription medicine industry. This prescription medicines focus is also characteristic of key works outside the discipline [19–22]. This paper adds to this scholarship, and though it adopts an Australian focus, it is internationally relevant since the neoliberalization of the Australian pharmaceutical regulatory regime is not unique and reflects shifts in corporate regulation occurring globally [19, 20, 23]. It is also particularly relevant to those localities employing similar risk-based, tiered approval processes.[4]

Interpreting regulatory regimes through a Marxist, Foucauldian, and state–corporate power lens

To identify the cause of this regulatory failure, it is necessary to employ both Marxist and Foucauldian perspectives. The benefit of a Marxist–Foucauldian approach is that Marxism explains the "why", that is, 'the imperative of the social structure that facilitates and constrains social action', and Foucault explains the "how", or 'the mechanism of power' ([24], p. 149). As a standalone approach, Marxism cannot explain the actual techniques and practices by which power is achieved and the less powerful are subjugated, essentially 'the mechanics of capital's motion' ([24], p. 149). In contrast, Foucauldian approaches cannot explain the intentions that guide this exercise of power because Foucault does not locate power with any particular relation or class; as such, 'it is never clear exactly what power is exercised for and … what it is that any possible resistance may be exercised against' ([25], p. 153). A combined approach therefore provides a more comprehensive explanation of the production and maintenance of power.

The framework employed herein combines structural Marxism and Gramscian hegemony with Foucauldian governmentality. Structural Marxism views states as functioning in ways that primarily serve the long-term interests of the powerful. Hegemony is used to describe a particular idea or vision and its dissemination by the powerful through 'the creation of consensus' ([26], p. 66, 69), or a hegemonic project. Governmentality refers to the explicit techniques and rationalities of government through which subjects are governed. Using this combined framework, it is posited that governmental techniques and rationalities are inextricably linked to a particular hegemony of how government should be exercised. This hegemony has been established by the powerful for the purposes of furthering their interests.

Applying both Marx and Foucault to the analysis of state–corporate crime is not new to criminology; indeed, some criminologists have referred to Foucauldian governmentality while working within a predominately Marxist

[4] Such as the European Union and United Kingdom for herbal medicines. The United States employs a risk-based, tiered approval process, however, complementary medicines are classified as foods, so they do not require pre-market approval. Similar quality, safety, and efficacy issues to those experienced in Australia therefore arise due to this lack of pre-approval.

framework (for examples in Marxist political economy, see [27–30]). However, the framework employed here builds upon the work of scholars outside the discipline, for two reasons. First, in those works listed prior, Marxist perspectives are used more so than Foucauldian perspectives; in some cases, few explicit references are made to Foucault. This is despite the usefulness of perspectives like governmentality for explaining how power is exercised through government and how government, as a series of techniques and practices, can produce certain power relations. Second, as Marxist and Foucauldian perspectives approach power from different ontological positions—from a structuralist and post-structuralist position, respectively—something additional is required to use these perspectives together, especially if Foucauldian perspectives are used extensively (more so than in the aforementioned works). To overcome these ontological differences and utilize Marxist and Foucauldian perspectives to greater effect, scholars such as Marsden [24], Jessop [31], and Joseph [25, 32] use a critical realist ontological framework.

Critical realist ontology conceives power as a product of structure *and* agency; power is 'a capacity to act, bestowed by real, if nonempirical, social structures and mechanisms, exercised by people' ([24], p. 42). Social structures are a necessary condition for agency but are also an emergent property which is 'continually reproduced and occasionally transformed' through agency ([25], p. 151). This approach to interpreting power means that social structures shape the capacity of an individual or collective to act and are a 'material cause' of these acts ([24], p. 27). Importantly, it treats individual and collective action as causal, and thus structure and agency as equally transformational. In this way, an ontology of critical realism allows for a structural account of social phenomena without reducing said phenomena to social structures. It therefore overcomes the rigid structuralism of Marxist perspectives and accommodates the post-structuralist position adopted by Foucauldian perspectives. Since critical realism is 'based on Marxism' ([24], p. 43) and there are 'several points of resemblance' (p. 181) between Foucault and critical realism, including an 'implicit' (p. 187–88) understanding by Foucault that power is exercised by someone over another, these perspectives are compatible and can be used together with a critical realist ontology.

A critical realist ontological framework has additional benefits when it comes to analyzing state-corporate crime. It acknowledges the active role of states as key agents in shaping regulatory regimes in ways that give rise to failure. This acknowledgement is relatively absent in scholarship on pharmaceutical regulation; Braithwaite [16], Dukes et al. [17], and Davis and Abraham [20], for instance, use capture and corporate bias theories when formulating their critique. This framework is also helpful for explaining how consumers are subjugated but are still able to exercise agency (albeit, in ways that are compatible with neoliberal rationales).

Adopting this framework, it is possible to make several assumptions about power, government, and their exercise. It is the formation and configuration of social structures within society give rise to certain, often asymmetric, power relations. This power is relational and relative to the power of other more or less powerful forces. Social structures shape and reproduce this power, while also being an effect of this power. Agents use their agency, either at an individual

(consumer or sponsor) or a collective (consumer and health professional association, industry association, industry, or state) level, to effect change in these power relations. Power is therefore contingent on factors *other* than structure—in this case, the exercise of agency, its non-exercise, or its exercise 'without producing an empirical effect … because of a countervailing power or the ineptitude of the actor' ([24], p. 41). The structuration of these power relations confers a level of authority that enables the powerful to establish and maintain their hegemony over the less powerful. However, this hegemony is not forcibly imposed on the less powerful, as this could lead to their mobilization and the formation of a counter-hegemony. Instead, it involves the development of a hegemonic project designed to secure the support of the less powerful by way of consensus formation. Hegemony thus involves taking the interests of the less powerful into consideration; making compromises in favour of some of these interests, without sacrificing dominant interests, to maintain the support of the less powerful; incorporating the interests of the less powerful into the dominant interest by framing the former as part of a common interest; and having the less powerful actively assist in the implementation of this project [26, 33]. Micro-level techniques and rationalities of government form part of this macro-level, hegemonic strategy. Hegemony shapes governmentality but also 'determines how governmentality develops and why' ([32], p. 15). Hegemony is therefore produced and reproduced through governmentality, and vice versa.

As the organizer of these various relations, the state is a 'form-determined condensation' of the relations among forces ([34], p. 45). When these relations are unequally structured, it is their 'structurally inscribed strategic selectivity' that renders the state more amenable to the interests of certain forces than others ([34], p. 45). And this 'bias', or articulation of power inside the state, 'produces the authority of the hegemonic … fraction' ([35], p. 165).

Under neoliberal capitalism, corporate power is contingent upon the power of capitalist states, and vice versa. Capitalist states rely on corporations for generating the capital indispensable to the exercise of its power which is dependent upon 'a "healthy" accumulation process' ([36], p. 120). Capitalist states willingly facilitate neoliberal governmentality, not only because they are neoliberalized and conditioned to 'think and behave like a market actor' ([37], p. 42), but because it is in the interest of the capitalist state to establish and maintain the conditions that enable capital accumulation. Corporations, in turn, rely upon this state work for their everyday existence. States and corporations therefore exist in a 'symbiotic' relationship ([38], p. 27, 162); they 'adhere to shared goals whose attainment would be hampered by aggressive regulation' ([39], p. 272). Regulatory agencies are just one of many powerful actors who participate in this cooperative venture [40]. In the context of the state-corporate relationship, the regulatory agency is an apparatus of the state; regulatory agencies 'simultaneously represent and regulate' corporations while acting as a '"politically insulated" framework for the ongoing negotiation of this special compromise' ([35], p. 163, 177).

The state's failure to restrain and facilitation of harmful capital accumulation practices can be conceived as state-facilitated corporate crime ([39], p. 271–72). Harm occurs by way of the state's:

> formal legalization … of this harm, their licensing of harm production, their failure to develop adequate law and regulation which might mitigate these harms, their failures to enforce adequately such laws as do exist, and/or their failures to impose effective sanctions where violations of law are proven. ([41], p. 19)

The Australian pharmaceutical regulatory regime: a case study

This section provides a brief overview of the Australian pharmaceutical regulatory regime and, by drawing on the Marxist-Foucauldian framework, examines its evolution, the reasons for its failure in achieving compliance from sponsors, and its attempted reform. It examines the regime between 2011 and 2014 during a period of extensive public consultation and reform triggered by the release of the Australian National Audit Office (ANAO) [2] report. Studying the regime at this crucial juncture allows for an analysis of the restructuring of the regime (and lack thereof) post reform.

Overview of the regulatory regime

The TGA employs a combination of risk-based and responsive regulation. Under the Marxist-Foucauldian framework, compliance-based regulatory approaches, such as risk-based and responsive regulation, can be conceived as forms of governmentality. Risk-based techniques are used to prioritise regulatory activity towards those sites which pose the greatest risk to the achievement of regulatory objectives ([42], p. 2). In the Australian pharmaceutical regulatory regime, risk-based techniques are employed in both the pre- and post-market regulation of prescription and non-prescription medicines. Risk is primarily determined based on the risks inherent to the medicine, or product risk. Medicines with greater product risk therefore receive greater oversight than medicines with lower product risk. Risk is also determined based on the sponsor's likelihood of non-compliance with regulatory requirements, or compliance risk (though, this is less of a determining factor in pre-market regulation, as explained in later paragraphs). In contrast, responsive regulatory techniques involve incremental increases and/or decreases in the severity of the regulator's response to non-compliance depending on the level of cooperation, or compliance risk, shown by the regulatee [43]. These techniques are used in post-market prescription and non-prescription medicine regulation.

Despite their popularity within the literature and among policy makers, risk-based and responsive regulation are subject to numerous criticisms [42, 44–49]. The most pertinent of these criticisms to this analysis is the 'unintended congruence' ([47], p. 56) between risk-based and responsive regulation and neoliberal governmentality. Since it focuses upon pre-market non-prescription medicine regulation, this analysis is confined to the risk-based aspects of the regime and how it legitimates neoliberal governmentality.

The TGA regulates medicines according to two levels of product risk. High-risk or *registered* medicines are medicines containing scheduled substances.[5] Most registered medicines are prescription medicines, but they also include some non-prescription medicines, such as over-the-counter (OTC)[6] medicines and scheduled complementary medicines. By comparison, low-risk or *listed* medicines do not contain scheduled substances and are mostly complementary medicines. Registered medicines are identifiable through the designation of an 'AUST R' number on product packaging and listed medicines by an 'AUST L' number.

All therapeutic goods must be approved and registered or listed on the Australian Register for Therapeutic Goods (ARTG) prior to their supply on the Australian market. Applications for registered medicines are submitted online and assessed by TGA staff for quality, safety, and efficacy. Listed medicines, however, are not subject to independent oversight and applications are assessed by way of online software, known as the Electronic Lodgement Facility (ELF). The application form requires sponsors to supply details such as the medicine's name, manufacturer(s), route of administration, dosage, ingredients, indications,[7] and warnings, as well as the steps performed during the medicine's manufacture ([50], p. 57–58). In the production of listed medicines, sponsors can only use ingredients that are pre-approved by the TGA. Indications can either be selected from a standard list or entered manually using the free text fields. Sponsors are legally required to hold, but not supply, evidence to support each indication listed in the application; however, 'the type and level of evidence required is not specified in the law', so sponsors may base an indication 'on whatever evidence they believe appropriate' ([2], p. 51–52), including evidence of a medicine's traditional/historical use. Indications for listed medicines are usually supported by traditional evidence, rather than scientific evidence such as clinical studies (which includes systematic reviews, controlled/uncontrolled clinical trials, and observational studies) and peer-reviewed articles [51]. However, it is difficult to conduct clinical studies for, and apply conventional clinical indicators to, listed medicines in the same way as occurs for registered medicines because listed medicines contain multiple ingredients which vary in strength and size of effect.

Prior to submission, ELF scans applications for the presence of restricted and prohibited terms.[8] Sponsors are directed to complete a Statutory Declaration indicating their agreement to several conditions, including that they hold evidence to support each indication. Upon submission and the payment of an application fee of AU$760, applications can be processed in under 24 hours, depending on the payment method used ([2], p. 73). Currently, there are over 11,000 active listings on the ARTG.

[5] Identified under the *Poisons Standard 2013* (Cwlth) as a pharmacy, pharmacist-only, or prescription-only medicine or prescription animal remedy, cautionary substance, poison, dangerous poison, controlled drug, or prohibited substance.

[6] Those medicines that are not complementary or prescription medicines and are available from a supermarket or pharmacy. Examples include analgesics, such as aspirin and paracetamol, and cough and cold preparations.

[7] Statements describing a medicine's specific therapeutic uses.

[8] ELF does not detect inappropriate or extravagant claims entered into the free text fields. Sponsors can 'game' the system by entering information to identify which terms prohibit an application from being accepted ([2], p. 80).

Table 1 The number of compliance issues identified in listed medicine compliance reviews completed in 2014

Compliance issue:	No.	%
Information provided in ARTG entry	7	3.7%
Manufacturing, quality, and/or formulation	14	7.4%
Labelling and/or advertising	83	43.9%
Evidence	39	20.6%
Safety[a]	0	0%
Other	46	24.3%
Total:	189	100%

Closely adapted from TGA ([3], p. 21)

[a]Refers to the availability of documentary evidence demonstrating that a medicine is not safe for its indicated use

To compensate for the lack of pre-market regulation they receive, each year a proportion of listed medicines are subject to compliance review and/or laboratory testing by the TGA, once approved. A compliance review involves a desktop audit of those documents held by the sponsor not supplied at the time of listing.[9] Compliance reviews are either conducted at random or targeted because of a complaint, information entered into the application form, or the sponsor's compliance risk. At the time a listing is approved, sponsors receive automatic notification of whether their medicine has been selected for random review. In 2014, the TGA completed random and targeted reviews for 11% (or 222 out of 1992) of all new listings ([3], p. 17–19). This figure excludes existing listings (making the rate of review less than 2%).

Historically, compliance reviews have revealed high rates of non-compliance among listed medicine sponsors in random and targeted reviews. Most non-conformities are the result of the failure to comply with labelling and advertising, and evidence requirements. This was the case in 2014 when 75% (123 out of 164 reviews) of listed medicines were found to be non-compliant (see Table 1).

These rates exclude those reviews initiated and terminated by the TGA when a sponsor cancelled the medicine from the ARTG. In such cases, all investigation into the medicine is ceased because the TGA is not able to determine the compliance status prior to cancellation. This occurred for 16% (36 out of 222) of all reviews initiated by the TGA in 2014 ([3], p. 19). No civil or criminal penalties apply when sponsors cancel a medicine prior to the completion of a review.

When non-compliance is found, the TGA commonly issues a notice proposing to cancel the listing, however the TGA can also suspend or cancel the listing,[10] as in the case of Catmedia's Reducta Fatblaster and Swisse's Ultiboost Appetite Suppressant.[11] The TGA can also recall a medicine, but it has yet to do so following a compliance review. Around half of all sponsors rectify the compliance issue(s)

[9] Such as the product's labelling, specifications, certificates of analysis, manufacturing formulae, evidence held by the sponsor to support each indication, and promotional and advertising material.

[10] According to 2015 data, 97.4% and 2.6% of compliance actions against listed medicine sponsors involved the issue of a cancellation notice or the outright cancellation of the medicine by the TGA, respectively ([3], p. 22).

[11] These medicines were cancelled in 2012 and 2013 under s. 30(2)(ba) of the *Therapeutic Goods Act 1989* (Cwlth) for providing insufficient evidence to support the indications (see [52]).

voluntarily.[12] Though many of these compliance issues attract civil and criminal penalties under the *Therapeutic Goods Act 1989* (Cwlth), in the case of labelling and advertising non-compliance, penalties have never been applied [2, 53].[13]

The TGA also conducts targeted and routine laboratory testing on samples of listed medicines to ensure their compliance with pharmacopeial requirements. The frequency of laboratory testing is determined on a product risk basis, meaning registered medicines and medicines subject to an adverse drug reaction report are prioritized. Complementary medicines have generally displayed a higher failure rate than other medicine types. In 2014, 28% (77 out of 277) of complementary medicines sampled failed TGA laboratory testing, compared to 23% (8 out of 35) of OTC and 1% (9 out of 917) of prescription medicines ([3], p. 47). In the case of laboratory testing, no civil or criminal penalties exist for non-compliance.

To understand why these risk-based techniques fail to generate compliance, it is necessary to examine the wider context in which these techniques emerged. Such context is vital in state-corporate crime research since that there are 'interests well outside the state-corporate relationship … [which] play an important role in creating the environment in which state and corporate decision making takes places' ([56], p. 423). The following section incorporates an analysis on reforms to both prescription and non-prescription medicines, for two reasons. First, the reforms to non-prescription medicine regulation emulated those to prescription medicine regulation. Second, companies can be a sponsor of both prescription and non-prescription medicines, and so, these interests can and do intersect.

Evolution of the regulatory regime

Prior to the 1990s, the lack of complementary medicine regulation and known supply of substandard prescription medicines on the Australian market[14] had generated public concern about pre-market medicine evaluation. These concerns prompted the introduction of the Therapeutic Goods Act, which led to the establishment of the TGA and ARTG, as well as the two-tiered approach to market entry for listed and registered medicines. Provisions were created within the Act to require sponsors to supply certain information as part of applications for listing and registration and when specifically requested by the Secretary of the Department of Health (hereafter, the Department), and to cancel a listing or registration when sponsors failed to comply with these provisions. The Act also required Australian and overseas manufacturers to be licensed and adhere to the Code of Good Manufacturing Practice ([59], p. 57–58, 137).

[12] In 2015, 56.8% of listed medicines were voluntarily rectified and 27% were voluntarily cancelled by the sponsor upon receipt of a notice, and 16.2% were cancelled by the TGA ([3], p. 22).

[13] According to the TGA, legal action 'is not cost-effective' due to the low financial penalties available; yet prosecution remains 'the only available option where administrative requests fail' ([2], p. 130–31). Historically, the TGA has not maintained a record of its enforcement activities [2, 54, 55], let alone permitted this information to be released publicly. The extent to which the TGA has successfully applied civil and criminal penalties to listed medicine sponsors therefore cannot be determined. Outside of the courts, the only recourse available to the consumer is to lodge a complaint to the TGA against a product's advertisement or an adverse drug reaction report when they experience an adverse drug reaction.

[14] For examples immediately prior to the Therapeutic Goods Act, see [57] and Tickner in [58].

When the Act came into force, the Department and TGA came under increasing attack for their adversarial approach toward the prescription medicine industry. The industry association representing prescription medicine sponsors, the Australian Pharmaceutical Manufacturers Association (APMA, now Medicines Australia), was critical of the TGA, claiming 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' (cited in [22], p. 2401). The Australian Government's Industry Assistance Commission (now Productivity Commission) had carried out three separate inquiries into the productivity of the pharmaceutical sector (in 1974, 1976, and 1986), all of which criticized the stringency of regulatory requirements. For example, when obtaining market approval, sponsors had to submit individual patient data (a requirement in Australia and the United States) by parameter and not by subject (unique to Australia) ([60], p. 557). The Australian Department of Industry also admonished the Department publicly for its entrenched views, arguing that it prioritized consumer welfare 'without primary concern for the profits of multinational drug manufacturers' (Johnston 1986 cited in [22], p. 2400).

This 'power bloc' [61], or alliance of forces based on shared interests, secured support for a decentralized and deregulated prescription medicine market by articulating the adversarial approach of the Department and TGA as detrimental to public health. For example, the APMA framed the lack of industry involvement in prescription medicine regulation as a failure to capitalize on its specialist knowledge, which would be of benefit to public health, as the following quote illustrates:

> 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. (cited in [22], p. 2401–402)

Similarly, the stringency of regulatory requirements was framed in terms of the public health implications. Delays in the approval of prescription medicines were criticized by industry for prolonging medicine availability in Australia ([60], p. 557). Clinical trial requirements, which industry believed had discouraged investment in the research and development around new prescription drugs, were claimed to have negatively impacted upon patients insofar as they 'were unable to access possible treatments for potentially life-threatening illnesses' ([60], p. 558). By articulating decentralization and deregulation as being in the public health interest—and thus incorporating non-market interests into the broader agenda of market forces—market forces were able to elicit greater support for a decentered and deregulated pharmaceutical regime. The fusing of market interests, such as timelier drug approvals, with the needs of the population also helped to facilitate the marketization of society, as health became increasingly viewed as a 'consumer object' ([62], p. 16) associated with market supply and demand. This framing was 'indispensable' to neoliberal governmentality—'first, in terms of disciplining bodies to fit into the machinery of capitalist production, and second … facilitating the regulation of various population trends to economic processes' ([63], p. 189).

This successful fusing was evident in several ways. For example, the intergovernmental committee the Australian National Council on AIDS was particularly vocal in its support for streamlining prescription medicine evaluation. In 1990, the committee published a report criticizing the speed with which prescription medicines were evaluated for the impact upon the availability of HIV/AIDS treatments in Australia [59, 60]. The pressure applied by bodies like the Australian National Council on AIDS prompted the Minister for Health to commission further inquiries into pre-market prescription medicine evaluation. In 1991, when addressing the International Conference on Drug and Device Regulations, the Minister justified the streamlining of prescription medicine evaluation on the grounds that:

> [p]rotect[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 (Staples 1991 cited in [64], p. 9).

The shift in the overall standpoint of these non-market actors demonstrates the degree to which non-market forces were able to identify with and appropriate market interests as if these interests were their own, and how active they were in implementing neoliberal ideas.

The Baume Report [65], commissioned by the Department in March 1991, made a total of 164 recommendations to streamline prescription drug evaluation by reducing approval times and gauging TGA performance against key performance indicators. The Department's adoption of all the Report's recommendations ensured that neoliberal rationality was extended to the regulatory agency itself, allowing the agency's success (and failure) in sustaining and fostering the market 'to become the criteria for governmental action' ([8], p. 16). This rationality ensured the market became the 'organizing and regulating principle of the state' ([8], p. 116).

To increase its efficiency and 'lower the workload' (*TGA Strategic Management Plan 1994–1997* [hereafter TGA SMP] cited in [64], p. 9), the TGA adopted risk-based techniques. This involved greater 'trust in, and acceptance of, summary reports and overseas evaluation reports … [and] using international standards and harmonization with other regulatory authorities'. Products therefore received accelerated approval in Australia when approved by regulatory agencies who were members of the European Free Trade Association or Pharmaceutical Inspection Convention and the Pharmaceutical Inspection Cooperation Scheme. Greater emphasis was placed on post-market monitoring to compensate for pre-market deregulation. Electronic technologies were also increasingly applied to what the TGA considered to be 'lesser tasks' (TGA SMP cited in [64], p. 9). Risk governmentality gave the agency an entrepreneurial form, subjecting all aspects of its decision making to cost–benefit calculation.

Following the release of the Baume Report, 'purposeful interventions' by successive Labor and Liberal governments bolstered the regime in ways beneficial to neoliberal market hegemony ([22], p. 2399). Statutory time frames were introduced to reduce the time needed for prescription medicine approval—if the TGA failed

to finalize an application within the mandated time frame,[15] it would forfeit 25% of the total application fee ([64], p. 9). These time frames saw a reduction in the number of days it took the TGA to approve applications—from 702 to 106 business days between 1990 and 1995 ([64], p. 14)—and resulted in a higher proportion of positive application outcomes as cost recovery through fees and charges to industry increased [21].

During this period, the Australian Government developed a greater appreciation for complementary medicine. Complementary medicine was an embodiment of the neoliberal rationale of individualism; it promoted self-determination through 'consumer choice' and 'empowerment' ([66], p. 174). In turn, this individualism allowed the state to divest from some healthcare expenditure and governance functions by according everyone the same unequal opportunity to 'take on and confront risks' ([8], p. 144).

Though it did not report on the regulation of non-prescription medicines, the Baume Report was the major impetus for the deregulation and decentralization of the sector. Prior to 1995, the time frame for processing listed medicine applications had been around five months ([67], p. 15). Each application would undergo a physical check prior to being approved; applications were forwarded to the Australian Listed Drugs Unit within the TGA to ensure medicines did not contain prohibited ingredients or inaccurate therapeutic and advertising claims and contained relevant warning statements where necessary ([68], p. 2). However, as risk governmentality had by this time become an 'attitude' that 'must be adopted across all of TGA' (TGA SMP cited in [64], p. 23), techniques of government, such as physical checks, were increasingly articulated as 'unnecessary barriers' and 'impediments' to accessing listed medicines ([69], p. 1, 3). These techniques were detrimental to 'persons suffering from serious or terminal diseases', which was seen as problematic given that the 'intrinsic safety [of a listed medicine] is not in doubt' ([69], p. 1). Following the Alternative Medicines Summit[16] and amendments to the Therapeutic Goods Act, ELF was introduced to enable applications to be lodged and evaluated electronically. Since ELF 'is predicated on self-assessment' and 'relies heavily on information provided by applicants … rather than the TGA checking every detail to establish whether the medicine meets statutory requirements' ([70], p. 3), it reduced the TGA's capacity to assess applications prior to approval. Following the introduction of ELF, processing times fell to less than 10 days by 1997–98. Over this same period, the number of listed medicine applications received by the TGA more than doubled ([67], p. 15).

The KPMG *Review of the Therapeutic Goods Administration* in 1997 led to changes in the type and extent of evidence required to support claims for listed medicines. These changes included 'an acceptable degree of flexibility' in the range of claims that could be used and the tolerance of 'a lower level of evidence' ([71], p. 213). Reforms to existing advertising arrangements in the form of the delegation of advertising pre-approval and complaints handling to industry associations, known

[15] 255 business days is permitted under the Act.

[16] Commissioned by the Department and attended by representatives of the pharmaceutical industry, among other stakeholders.

today as Complementary Medicines Australia (CMA) and the Consumer Healthcare Products Australia (CHPA), represented 'a shift in emphasis from pre-market evaluation to post-market monitoring' ([71], p. 214). The Parliamentary Secretary's Working Party on Complementary Medicines, which included representatives of Australia's largest listed medicine sponsors (such as Blackmores and SmithKline Beecham, now GlaxoSmithKline) and industry associations (CMA and CHPA), was also formed to advise the Secretary on the implementation of the reforms [71].

Reasons for regime failure

The risk governmentality adopted by the TGA is congruent with neoliberal governmentality in two principal ways. First, it incorporates a calculative rationale. The formal classification of medicines as low- or high-risk determines how TGA activity is prioritized and limits this activity to desired levels—that is, to those commensurate with product risk. Second, risk-based regulation promotes greater self-regulation as well as other indirect forms of government, consistent with a decentred, and, significantly, an individualist and responsibilized, rationale. Regulatees—sponsors and consumers—are construed as rational, calculating entities, capable of evaluating the costs and benefits of their actions, and thus navigating the variables of the pharmaceutical market. Encouraging regulatees to self-regulate not only allows risks to be privatized, rendering regulatees fully responsible for all risk 'no matter how severe the constraints' ([37], p. 42–43), but it also redners regulatees governable. For consumers, it disorganizes and depoliticizes opposition to neoliberal market hegemony; consumers are cast as either model neoliberal citizen-subjects who exercise agency in ways that are compatible with neoliberal rationales or non-citizens ([37], p. 43). Failing to manage risk, or engaging in risky behaviour by exercising agency in ways that are incompatible with neoliberal rationales, is thus construed as a failure on the part of the consumer.

This risk governmentality limits the scope for market intervention by non-market forces. In the case of the TGA, regulatory activity is prioritized away from listed medicines due to the framing of risk—specifically, through the classification of listed medicines as low-risk and determination of their risk based on product risk, rather than compliance risk. Risk rationality 'organize[s] uncertainty into manageable "risk objects"' ([72], p. 401), and this 'organizing implies *generalizing*', or 'the subsumption of heterogeneous particulars under generic categories' ([73], p. 124). Risk organization therefore involves an abstraction of risk which can lead to risks being oversimplified, even normalized. Further, when risks are unforeseen or do not fit prescribed categories, they are 'reinterpreted in ways that assimilate them into established practices' ([74], p. 5). In the Australian pharmaceutical regulatory regime, the compliance risks associated with listed medicines are subsumed by their overall product risk, irrespective of the level of actuarial compliance risk. Compliance risks are also normalized, rather than treated as a sign of regime failure, because of the low-risk classification applied to listed medicines.

Characterizing risk on a product risk basis has allowed a diffusion of state responsibility and privatization of compliance risk. The mentality that the TGA is

the regulator of product (not compliance) risk is evident in written statements by TGA staff:

> [The] 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. […] [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*.[17]

In 2011, the then Secretary for Health, Catherine King, echoed these sentiments, stating that the TGA's role was to act as 'the regulator of safe, effective and quality products […] not the regulator of industry in essence' ([75], para. 26). The adoption of risk-based techniques is therefore about the self-limitation of government; markets are to be respected and state agency 'must only be exercised where it is positively and exactly useful' ([8], p. 44). Such examples demonstrate the extent to which the state is neoliberalized and governs for the market.

These governmental techniques also have a disciplinary, truth-creating effect; neoliberal governmentality 'create[s] a social reality that it suggests already exists' so that the exercise of these techniques is deemed rational ([76], p. 203). In the case of compliance reviews, the TGA's non-detection of non-compliance when a medicine is cancelled by the sponsor prior to the completion of a review reinforces the mentality that non-compliance has not occurred, as it was never detected. Of those reviews that can be completed, sponsors appearing cooperative by rectifying their non-compliance voluntarily reinforces the mentality that they are responsibilized and capable of self-regulation. However, this ignores the reality that sponsors only rectify non-compliance once they have been prompted to do so by a cancellation notice. In each case, the mentality that state intervention should be minimal is further supported; '[n]othing proves that the market … is intrinsically defective since everything attributed to it as a defect and as the effect of its defectiveness should really be attributed to the state' ([8], p. 116).

The regime 'reformed'

Following public acknowledgement by the TGA ([77], p. 8) that there had been 'a poor rate of compliance' in the listed medicine space, the TGA and the Department conducted a series of consultations seeking public comment on listed medicine reforms between 2010 and 2014. Four consistent themes arose from the consultations. These were: 1) that the TGA should evaluate applications prior to approval; 2) that sponsors should be required to submit further documentation, including evidence of efficacy, at the time of their application; 3) that the rate of compliance reviews should be increased; and 4) that civil and criminal penalties should be introduced. Enhancements to the regime, such as the evaluation of listed medicine

[17] Personal communication. Response to a follow-up question to an interview on 29 May 2013. Emphasis added.

applications prior to their approval, would decrease consumers' exposure to non-compliant products. Obtaining the level of documentation usually required for a compliance review from sponsors at the point of application would enable the TGA to detect non-compliance prior to approval. It would also allow the TGA to initiate a review at any time without first having to request that sponsors supply the documentation voluntarily. Since the TGA could initiate a review at any time and the likelihood of sponsors being subject to a compliance review would have increased, this would also have a greater overall effect in deterring sponsors from making applications for medicines that do not comply with the requirements.

The TGA's initial response to this feedback was to introduce a proposal in a two-part consultation paper entitled *Evidence Required to Support Indications for Listed Medicines* requiring sponsors to produce, but not submit, an expert report summarizing the evidence of the medicine's efficacy. As outlined in Part 1 of the consultation paper, this report had to be prepared by an expert who was 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' ([78], p. 10). This proposal was evaluated, and dismissed, by industry according to a risk and calculative rationale. Industry employed risk rationality to argue against an increase in evidence requirements:

> 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 […] [this is] inappropriate for listed medicines which are low risk by definition. ([79], p. 4)
>
> [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. ([80], 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 […] the level of evidence and analysis required is beyond the scope of the types of indications allowed to be made. ([Sponsor] [81], p. 5)

Industry also argued against the proposal in cost-benefit terms; an increase in evidentiary requirements would not only lead to increased time and financial costs for sponsors (in terms of compiling a report for each ingredient, hiring an expert, and running clinical trials), but would also have a negligible effect on deterrence as sponsors would not be required to supply the expert report.

In Part 2 of the consultation paper, the TGA removed several of the original requirements pertaining to the expert report, including that reports be based on the outcomes of new or unpublished clinical trials—reviews of existing literature would suffice—and be written by an independent expert ([82], p. 14–15). Sponsors were also offered the option of using established sources of evidence to support an indication, rather than producing an expert report ([82], p. 12–13). However, industry maintained that many of the requirements remained disproportionate to product risk. It further argued that the list of established sources of evidence was not sufficiently comprehensive to substantiate claims.

The inability of such proposals to withstand risk and cost–benefit rationality effectively enabled these 'sources of opposition to, and mere modulation of, capitalist rationality [to] disappear' ([37], p. 46). The TGA has since abandoned the idea of an expert report and has instead endorsed a list of established sources of evidence and pre-approved (coded) indications the TGA developed in conjunction with industry. 14% (143 out of 1021) of these coded indications require substantiation by scientific evidence ([53], p. 85); traditional evidence suffices for most of the indications approved, even when scientific evidence suggests a lack of efficacy. Following an amendment to the Therapeutic Goods Act in 2018, an additional approval pathway was introduced to allow applications for new listed medicines to be assessed by the TGA (designated by an 'AUST L(A)' number). However, this assessment is available for new listings only and it carries an additional cost. This approach is also problematic because it assumes that consumers are omnicompetent. Historically, research has found that few consumers are aware of the 'listed' designation or its meaning in risk terms [83]. Further, consumers' health literacy is bounded; the evidence used by sponsors to substantiate an indication is not often disclosed and this limits consumers' agency to independently evaluate claims.

Infringement notices and civil and criminal penalties have been introduced under the Therapeutic Goods Act.[18] However, data reported on the TGA's website indicate that such penalties have yet to be used and that the TGA continues to rely on product suspension and cancellation.[19] The penalties introduced also do not address the loophole that enables sponsors to avoid a compliance review without penalty through de-listing the medicine.

The TGA doubled the number of compliance reviews it completed between 2014 and 2017 (from 222 to 551 reviews), but this increase 'has not driven any improvement in compliance rates' ([5], p. 6). In the 2016–17 financial year, 79% (330 out of 417 reviews) of listed medicines reviewed were found to be non-compliant ([5], p. 24). The number of reviews completed by the TGA has since decreased to 243 and 181 in the 2017–18 and 2018–19 financial years, respectively ([7], p. 31). The Australian Government has also reaffirmed its preference to maintain industry cost recovery and has not allocated any additional funding.

In each case of attempted reform listed previously, public protections could not work against and compensate for the market; government had to 'recognize and observe economic laws' ([8], p. 146).

Conclusion

The ability of market forces to articulate market decentralization and deregulation as in the public health interest has enabled these forces to elicit support for regulatory techniques that have a limited impact on capital accumulation. Articulating

[18] For failing to provide information or documentation as requested by the Secretary within a specified period, to comply with a direction with a direction of the Secretary, and supplying a medicine not labelled in accordance with a direction of the Secretary.

[19] At the time of writing, one infringement notice had been issued for falsely purporting to hold evidence to support indications.

medicine access in public health terms enabled non-market forces to identify with the 'mutual' need to reduce approval times for listed medicines. Such reductions warrant the implementation of specific techniques that increase the TGA's efficiency in processing listed medicine applications.

This shift towards a neoliberal governmentality has been conducive to the emergence and development of risk governmentality. The low risk classification of listed medicines allows TGA activity to be reprioritized so that it no longer intervenes prior to approval to determine whether a medicine meets statutory listing requirements. This prioritization, in turn, has allowed greater responsibility to be delegated to sponsors to regulate their compliance risk to consumers. Although this self-regulation places pressure on sponsors to act in socially responsible ways, these 'counterpressures only constrain, and certainly do not remove, the pressure to maximize profits' ([84], p. 83–84) and 'entail ignoring the very rationale of the corporation' ([85], p. 425). Consequently, the Australian market consists of a high number of non-compliant listed medicines.

This governmentality continues to shape the Australian pharmaceutical regulatory regime in line with neoliberal hegemony. The notion that compliance risks ought to be outside the remit of the TGA and that sponsors should self-regulate is reinforced by the failure of the regime to achieve compliance. Yet this failure is a direct consequence of the risk-based techniques it promotes, which in turn reinforce the rationale that sponsors are cooperative and responsibilized. Risk classification and cost–benefit analysis have acted as the primary means through which to restrict reform and keep regulation to a minimum. This disciplinary control has contributed to the maintenance of the regime by rationalizing the exercise of these techniques.

The extent to which neoliberal governmentality has shaped the regime in the interests of the market is not only indicative of the pervasiveness of neoliberal market hegemony, but also of the extent to which the state is neoliberalized and conditioned to operate in ways that facilitate market interests. The legitimacy of the TGA is predicated upon its ability to sustain the market (that is, to process applications) and cost–benefit calculations have become the measure of all TGA practices. This implies that true change to the Australian pharmaceutical regulatory regime can only be achieved through a much larger transformational agenda. Otherwise, any positive advance to reform the regime to best serve the needs of the public will continue to be shaped by, and subordinated to, market interests.

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