Australian Government

Department of Health and Ageing

Submission to the Senate Finance and Public Administration Legislation Committee

Inquiry into the Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013

23 April 2013

Contents

1. Introduction

On 28 February 2013, Senator Di Natale introduced the Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill (the Bill) in the Senate. The Bill amends the *Therapeutic Goods Act 1989* (the Act) to create civil penalties related to the provision of payments, services or certain other inducements to medical practitioners by pharmaceutical companies. The Bill also provides for penalties for breaching reporting requirements about certain payments made to or in relation to medical practitioners.

On 21 March 2013, the Senate referred the Bill for inquiry and report. The terms of reference for the inquiry are 'to receive evidence on the need for regulation of pharmaceutical industry conduct with regards to interactions with the medical profession, and the appropriateness of the provisions in the bill that place restrictions on these interactions'.

The Department's submission provides information on current Government policy in relation to the promotion of therapeutic goods, national policy on pharmaceuticals, the regulation of the medical profession and the interaction of the proposed amendments with the Act.

2. Promotion of Therapeutic Goods: Government Policy

2.1 Position Paper on the Promotion of Therapeutic Goods

On 30 June 2010, following consultations with stakeholders, the Government released a Position Paper on the Promotion of Therapeutic Goods (the Position Paper **Attachment 1**).

The Position Paper noted continuing public concern about the promotion of therapeutic goods to health care professionals and stated the Government's aim as: 'to ensure that decisions on management (including treatment) options for health needs are based on sound clinical evidence, not driven by incentives or other influences, and that self-regulatory codes of conduct are effective in minimising the potential for any promotional activities to compromise the quality use of medicines and to increase cost pressures on the health system'.

The Position Paper supported self-regulation of industry conduct including promotional activities undertaken by therapeutic goods companies, and proposed strengthening and standardising self-regulation through the development of a common set of high level principles. The Position Paper stated that the Government's endorsement of the high level principles would rely on them being consistent with the objectives and principles of:

- The National Medicines Policy (NMP) (see section 3.1 below);
- The World Health Organisation's 1988 *Ethical Criteria for Medicinal Drug Promotion*; and
- The Australian Competition and Consumer Commission's *Guidelines for Developing Effective Voluntary Industry Codes of Conduct*.

The Position Paper indicated that if consistent arrangements could not be realised, then legislative options consistent with the Government's policy objectives could be put in place in 2012.

The Government also noted the need to ensure that the ethical standards in codes of practice for healthcare professionals align with the standards expected of the therapeutic goods industry (section 4.2 below refers).

2.2 Working Group on Promotion of Therapeutic Products

An industry-led Working Group on Promotion of Therapeutic Products was established in July 2010 to respond to the Position Paper (the Working Group). The Working Group was chaired by Ms Anne Trimmer, Chief Executive Officer of the Medical Technology Association of Australia (MTAA) and included representatives of industry associations, healthcare professionals and consumers.

On 18 March 2011, the Working Group Chair provided the Group's report to the then Parliamentary Secretary for Health and Ageing, the Hon Catherine King MP. The report incorporated a high level statement of principles developed by the Working Group and made 18 recommendations relating to: achieving consistency across industry codes of conduct; capturing and ensuring compliance by both members and non members of industry associations; ensuring consistency with ethical requirements for healthcare professionals; improving access to information and complaints mechanisms; and assessing the effectiveness of the implementation of the Working Group's recommendations (a copy of the report of the Working Group is at **Attachment 2**).

2.3 Government Response to the Working Group's Report

The Government's response to recommendations made by the Working Group form part of *TGA Reforms: A Blueprint for TGA's future* (the Blueprint) released by then Parliamentary Secretary King, on 8 December 2011. The Blueprint states the Government's preference to maintain an emphasis on self-regulation and strongly supports industry's initiative to harmonise their codes of conduct to incorporate the Working Group's high level principles.

The Government supported recommendations 1-3, 8 and 14 relating to industry initiatives to revise codes; develop industry training programs on codes requirements and improve access to information about industry complaints mechanisms. It noted recommendations 4, 9-13 and 15-17 relating to establishing an advisory group; developing a common complaints mechanism; improving communication and access to information; and evaluating the effectiveness of the implementation of the Working Group's recommendations. The response to these recommendations included referral of recommendations 10-12, on engaging the healthcare professional sector, to the appropriate organisations. The Government did not support recommendations 5-7 which would have required new regulation and hence departed from the self-regulatory model. The Government also did not support recommendation 18 relating to a review of the NMP (a copy of the Blueprint is at **Attachment 3**).

2.4 Implementation of the Working Group's recommendations

In the 2012-13 Budget, the Government announced funding of $1.4 million over four years to assist industry to respond to those recommendations of the Working Group that the Government had previously noted and which would benefit from some support from Government to achieve: supporting stronger self-regulation, better communication and shared systems for complaints reporting, and establishing an implementation advisory group to guide further work on implementing the recommendations (recommendations 4, 9-13 and 15-17). A high level overview of implementation of the Working Group's recommendations, including reference to the Budget measure, is set out in *Delivering reforms – Implementation plan for TGA Reforms: A blueprint for TGA's future*, July 2012 **(Attachment 4).**

In January-February 2013 a Codes of Conduct Advisory Group (the Advisory Group) was established by then Parliamentary Secretary King. The Advisory Group includes

representatives from industry associations, health professional and consumer organisations. The Advisory Group is responsible for overseeing a number of projects including an independent review of the uptake of the high level principles set out by the Working Group in industry's codes of conduct; development of shared information systems and a common complaints portal; liaison and discussion with health professional organisations in relation to alignment of industry and health professional codes; mechanisms to improve the coverage of codes of conduct and an independent evaluation of the effectiveness of the overall self-regulatory framework. The Advisory Group met for the first time on 5 March 2013. (A list of members of the Advisory Group is at **Attachment 5**.)

2.5 Response to the Medical Devices Inquiry

On 13 September 2012, the Government tabled its response to the Senate Inquiry into the Regulatory Standards for the Approval of Medical Devices in Australia (the Inquiry).

Recommendation 18 of the Inquiry report was that: 'the Department of Health and Ageing undertake further work to address the issue of inducements paid by pharmaceutical companies and medical device manufacturers to doctors and teaching hospitals, in line with the Physician Payment Sunshine provisions of the *Patient Protection and Affordable Care Act* of 2009 in the United States. The definition of inducements should include a commercial interest in a company or device; any cash payments or discounts offered to medical practitioners; and any other gifts provided to medical practitioners'.

In the response, the Government agreed with the recommendation in principle but noted that 'a legislative framework for ethical conduct of industry in the promotion of therapeutic goods to healthcare professions is not warranted in the Australian context at this time'.

3. National Medicines Policy

The Explanatory Memorandum for the Bill states that it is being introduced 'in order to safeguard the integrity of prescribing medicines in Australia' and that 'the integrity of Australia's health system is of paramount importance in maintaining quality of care and the sustainability of health expenditure'. The Government has national policy and programs in place which are relevant to these issues.

3.1 Outline - National Medicines Policy

Australia's National Medicines Policy (NMP) is designed to ensure that all Australians have timely access to high quality medicines at a cost individuals and the community can afford while maintaining a responsible and viable medicines industry. The NMP framework is at: http://www.health.gov.au/internet/main/publishing.nsf/content/National+Medicines+Policy-2.

3.2 Implementation - National Prescribing Service

The National Prescribing Service Limited (NPS) is the implementation arm of Australia's NMP to assist prescribers and patients in the quality use of medicines. The NPS has been funded by the Australian Government since 1998.

Along with delivery of consumer education programs, the NPS provides support for all health professionals to assist their clinical management decisions and to improve quality use of medicines through activities which include:

- embedding independent, evidenced-based decision support tools in prescribing and dispensing software;

- delivering independent and evidenced-based online and face to face programs to GPs, pharmacists and other health professionals;
- producing the journal Australian Prescriber which targets prescribers;
- providing independent information to prescribers and consumers on new and revised listings on the Pharmaceutical Benefits Scheme (PBS), through the Rational Assessment of Drugs and Research (RADAR) publication;
- implementing programs designed to improve the quality use of diagnostic and pathology services, aimed at reducing Medicare Benefits Scheme expenditure; and
- evaluating the education needs of nurse practitioners and midwives in relation to prescribing of PBS medicines.

The NPS has also established an online learning website, which includes learning modules for students and new health professionals; www.nps.org.au/health-professionals/professional-development/online-learning.

More information about the work of the NPS can be found on their website at www.nps.org.au.

4. Regulation of the medical profession

The outline in the Explanatory Memorandum for the Bill states that the proposed Act is intended to set 'more stringent restrictions on the interactions between pharmaceutical companies and physicians that minimises the opportunity to provide inducements and thereby unduly influence prescribing behaviours'. Current arrangements for the regulation of the medical profession include a code of conduct which makes reference to these interactions.

4.1 The National Registration and Accreditation Scheme

Under the National Registration and Accreditation Scheme, the Medical Board of Australia (MBA) is responsible for the regulation of the medical profession in Australia. It is supported in this role by the Australian Health Practitioner Regulation Agency (AHPRA). The *Health Practitioner Regulation National Law Act 2009* (the National Law), enacted in all states and territories, provides for the full operation of the Scheme. The Scheme is overseen by the Australian Health Workforce Ministerial Council (AHWMC), which comprises Health Ministers from all states and territories and the Commonwealth.

4.2 Code of Conduct for Doctors in Australia

The National Law prescribes a number of mandatory registration standards with which all practitioners wishing to practise in Australia must comply. In addition, registered practitioners must comply with any codes and guidelines approved by the national Board. The MBA has approved a code of practice for the medical profession – *Good Medical Practice: a Code of Conduct for Doctors in Australia* (the Code). The Code sets out what is expected of all medical practitioners registered to practice in Australia and is available from the MBA website www.medicalboard.gov.au.

The Code contains explicit reference to conflicts of interest (section 8.11). In relation to dealings with the pharmaceutical industry, the Code states that good medical practice involves:

> '…8.11.4 Recognising that pharmaceutical and other medical marketing influences doctors, and being aware of ways in which your practice may be being influenced.
>
> …8.11.6 Not asking for or accepting any inducement, gift or hospitality of more than trivial value, from companies that sell or market drugs or appliances that may affect, or be seen to affect, the way you prescribe for, treat or refer patients.
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> …8.11.8 Not offering inducements to colleagues, or entering into arrangements that could be perceived to provide inducements'. (p15).

4.3 Management of Breaches

Where a practitioner behaves in a way that may constitute unprofessional conduct, professional misconduct or notifiable conduct (as defined in the National Law), a notification can be made to AHPRA. Such conduct might include a breach of the Code.[1] Members of the public can make notifications to AHPRA about the conduct of a practitioner. Health practitioners and employers are required by law to make notifications in relation to notifiable conduct. Where a practitioner is found, on investigation of the complaint, to have behaved inappropriately, disciplinary action can be taken against the practitioner.

5. Proposed amendments to the *Therapeutic Goods Act 1989*

5.1 Objects of the *Therapeutic Goods Act 1989*

The objects of the *Therapeutic Goods Act 1989* (the Act) include that it is to provide for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy[2] and timely availability of therapeutic goods that are used in Australia, whether produced in Australia or elsewhere or exported from Australia.[3]

5.1.1 Focus of amendments

It is noted that the amendments apply only to 'regulated corporations' that import, manufacture or supply 'regulated pharmaceutical products'. It is also noted that the definition of 'regulated pharmaceutical products' is confined to a listed or registered medicine, that is, those medicines that are included on the Australian Register of Therapeutic Goods under Part 3-2 of the Act. It does not include medical devices or biologicals on the Register, thus excluding promotional activity undertaken by companies that import, manufacture or supply these therapeutic goods.

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1 Unprofessional conduct of a registered health practitioner is defined as 'professional conduct that is of a lesser standard than that which might reasonably be expected of the health practitioner by the public or the practitioner's professional peers'. The definition includes a number of specific contraventions. Professional misconduct includes 'unprofessional conduct … that amounts to conduct that is substantially below the standard reasonably expected of a registered health practitioner…; and more than one instance of unprofessional conduct ….; and conduct of the practitioner …. that is inconsistent with the practitioner being a fit and proper person to hold registration in the profession.' (s5 of the *Health Practitioner Regulation National Law Act 2009)*.

2 In the case of medical devices, the reference to 'efficacy' is to be read as a reference to performance of the devices as the manufacturer intended – see subsection 4(1A) of the Act.

3 See subsection 4(1) of the Act.

5.1.2 Scope of civil penalty provisions

Proposed sections 42DR and 42DT of the Bill list conduct ('prohibited inducements') by regulated corporations that is subject to civil penalties as:

- provision of overseas[4] conferences, conventions, educational seminars or other events where the majority of those attending are registered medical practitioners;
- providing hospitality to registered medical practitioners while they are attending an educational seminar or other event (worth more than $100 'on average');[5]
- paying a registered medical practitioner to attend such a conference, convention, educational seminar or other event or paying the travel or accommodation costs, or both, of a registered medical practitioner who is attending the event.

Although the civil penalty provisions are in respect of a regulated organisation (ie one which imports, manufactures of supplies registered or listed pharmaceutical products), the civil offences in the Bill do not have a direct relationship with the listed or registered medicines imported, manufactured or supplied by the 'regulated corporation'. The provisions would prohibit conduct even if that conduct was unrelated to the promotion of pharmaceutical products by the relevant company.

5.2 Reporting Requirements and Enforcement

The reporting requirements in proposed section 42DT consist of an annual report providing specified details of all 'reportable payments' which include a range of monetary and 'in kind' payments made to and in relation to registered medical practitioners.[6] There is an obligation to make the report available on the corporation's website within a specified time period and for a specified length of time.[7] Breach of the reporting requirements is subject to a civil penalty under proposed section 42DU. It is not clear, however, who would be required to determine whether there was a breach of the statutory reporting obligations and what enforcement arrangements would apply. The assumption may be that the TGA would have a supervisory role in enforcement. The 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.

While the TGA could ascertain whether the required report had been published on the company's website within the statutory timeframe, it would not be within the current powers of the Secretary of the Department of Health and Ageing under the Act (and therefore the TGA) to require the company to provide information that might demonstrate the accuracy of the report or whether it had been prepared 'in accordance with' proposed section 42DT (as required by proposed subsection 42DU).

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4 The meaning of 'overseas' is undefined and unclear.

5 It is not clear how this provision would be applied.

6 See proposed subsection 42DT(4) of the Bill.

7 See proposed subsection 42DT(3) of the Bill.

The Secretary's current powers under the Act to require sponsors to provide information to the TGA are generally limited to information about particular therapeutic goods[8] or in the case of manufacturers, their suitability to continue to hold a manufacturing licence.[9] In some instances, the Secretary can ask for information from a third party (not the 'wrongdoer') in connection with the application of a civil penalty.[10] However, it is unlikely that this power could be used unless the Secretary already had information which indicated a breach of the company's obligations, that is it could not be used to ascertain whether or not there was a breach of the reporting provisions but only to confirm the existence (from a third party) of such a breach.

6. Summary

In the context of concerns about the promotion of therapeutic goods to health care professionals, the Government's objective is to ensure health needs decisions are based on sound clinical evidence rather than incentives, promotions or other influences that might compromise the quality use of therapeutic products as well as increasing costs to the health system.

The Government supports self-regulation of industry conduct and provided funding in the 2012-2013 Budget to strengthen the self-regulatory framework. An Advisory Group with representatives from industry associations, health professional and consumer organisations has responsibility for progressing this work.

National policy and programs in relation to pharmaceuticals (the NMP and NPS respectively) are designed to ensure timely and affordable access to high quality medicines and assist prescribers and patients in their quality use.

The conduct of medical practitioners, including in respect of relationships with the pharmaceutical industry, is regulated through the Medical Board of Australia and the Australian Health Practitioner Regulation Agency under the National Registration and Accreditation Scheme and associated standards and codes.

The proposed amendments appear to raise issues in relation to their scope and enforcement, and alignment with the current scheme of the *Therapeutic Goods Act 1989*.

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8 See for instance section 31 of the Act in relation to registered and listed medicines.

9 See subsection 40(6) of the Act.

10 See section 42YE of the Act.