Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013

Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013

Introduction

1.1 On 21 March 2013, on the recommendation of the Senate Selection of Bills Committee, the Senate referred the Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013 (the Bill) to the Senate Finance and Public Administration Legislation Committee for inquiry and report by 17 June 2013. The reason for referral was 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.[1]

Conduct of the inquiry

1.2 The committee advertised the inquiry in *The Australian* newspaper on 27 March 2013, and invited submissions by 19 April 2013. Details of the inquiry, the Bill and associated documents were placed on the committee's website.

1.3 The committee received 25 submissions, which are listed in Appendix 1. A public hearing was held in Melbourne on 29 April 2013. A list of witnesses who appeared at the hearing is at Appendix 2. Submissions and the Hansard transcript are available on the committee's website at www.aph.gov.au/senate_fpa.

Overview of the Bill

1.4 The Bill is a private Senator's bill and proposes to amend the *Therapeutic Goods Act 1989* to place restrictions on the interactions between pharmaceutical companies and medical practitioners with the aim to minimising the opportunity to provide inducements and therefore unduly influence prescribing behaviours.[2] The Bill's Explanatory Memorandum (EM) outlines the current deficiencies in the level of regulation of, and lack of transparency in, relationships between the pharmaceutical industry and medical practitioners which the Bill proposes to address:

> Currently the marketing of regulated pharmaceuticals to consumers is banned under the *Therapeutic Goods Act 1989*. However, drug companies are free to communicate with the doctors that prescribe medicines. While doctors need up-to-date information on new therapies, drug companies have the added incentive of maximising the number of prescriptions written for some medicines. This can lead to aggressive marketing and lobbying of doctors under the guise of education.
>
> In the past this has included flying doctors to events in tropical locations overseas, paying for them to attend congresses and seminars held at 5-star resorts next to golf courses and hosting lavish lunches and dinners for prescribers. Other pharmaceutical company largesse includes appointing influential doctors to advisory boards and lucrative speaking engagements, including at overseas events.[3]

1.5 The EM summarises the Bill's intended effect on the interactions between pharmaceutical companies and medical practitioners as:

- forbidding payment for doctors to travel or attend education seminars and scientific conferences domestically and overseas;
- banning the sponsorship of educational meetings intended for Australian doctors outside Australia;
- limiting gifts and lavish hospitality; and
- requiring full reporting of any fees paid to prescribers outside the company.[4]

1.6 The pharmaceutical industry has acknowledged that there are perceptions of undue influence on the prescribing behaviour of medical practitioners. In response, self-regulated industry codes have been established by the pharmaceutical industry representative bodies. The Medicines Australia code of conduct (MA Code) sets the standards for the ethical marketing and promotion of prescription pharmaceutical products by pharmaceutical companies in Australia. The MA Code includes provisions

Petitions

Opening of the 44th Parliament

which address the behaviour of medical representatives and relationships with healthcare professionals. The EM notes that the measures contained in the Bill are intended to replace the MA Code.[5]

Provisions of the Bill

1.7 Item 1 of the Bill amends the title of Chapter 5 of the Therapeutic Goods Act to include the reference to 'inducements', amending the heading to 'Advertising, inducements, counterfeit therapeutic goods and product tampering'.

1.8 Item 2 of the Bill inserts new sections into the Act which place restrictions on interactions between pharmaceutical companies and medical practitioners and define new offences in relation to the provision of money, services, or other possible inducements.[6]

Civil penalties for prohibition of certain inducements

1.9 Proposed subsection 42DR(1) makes it an offence for a pharmaceutical company to arrange or sponsor a conference, convention, educational seminar or other event to be held overseas, where it would be expected that the majority of the people attending the event are registered medical practitioners. The EM elaborates on the application of this proposed subsection:

> It does not prohibit companies from hosting events within Australia, or for hosting events overseas that are not aimed primarily at Australian prescribers (doctors), nor does it prohibit Australian doctors from attending events outside Australia. This is intended to curtail the possibility of hosting an educational event in a tropical or otherwise exotic location which may act as an inducement.[7]

1.10 Under this subsection, a pharmaceutical company found to contravene this subsection would be penalised a maximum civil penalty of 600 penalty units.

1.11 Proposed subsection 42DR(2) intends to limit overly lavish hospitality by pharmaceutical companies which may be seen as a possible inducement.[8] This subsection would make it an offence for a pharmaceutical company to provide hospitality, including paying for meals or entertainment, to registered medical practitioners while they are attending an educational seminar or event where the value of the hospitality provided is more than $100 per head, or if a higher amount is prescribed in regulations, that amount. A maximum civil penalty of 1200 penalty units is prescribed for contravening this subsection.

Civil penalties for unreported inducements

1.12 Proposed subsection 42DS(1) specifies that a pharmaceutical company cannot pay a medical practitioner to attend a conference, convention, educational seminar or other event, including paying for travel or accommodation costs, if the medical practitioner is not representing the company or a sponsor of the event. Pursuant to proposed subsection 42DS(2), a company is taken to have made a payment to a medical practitioner if it does one or more of the following in exchange for the practitioner to attend an event:

- pays a fee to the practitioner or the practitioner's employer;
- pays for medical research;
- makes a donation to a charity; or
- gives a gift of more than $25 in value to the practitioner or to the practitioner's employer.

1.13 Contravention of this subsection carries a maximum civil penalty of 1200 penalty units.

Reporting requirements

1.14 Under proposed new section 42DT, pharmaceutical companies are required to prepare and make public a report which provides details for each reportable payment made by the company for each financial year. The EM states that:

> The reporting requirements in section 42DT do not apply to payments made to any individual who is not a registered medical practitioner. These provisions are intended, in the public interest, to discourage payments and other incentives that may unduly influence prescribing behaviour, but not to otherwise place restrictions on commerce between drug companies and individuals in the normal course of affairs.[9]

1.15 For each reportable payment made by the company, the report is required to provide detail of the amount or value, the name of the recipient, the date the payment was made, and the nature of and reasons for making the payment. Under subsection 42DT(2)(b), if a company does not make a reportable payment during the financial year, it is still required to prepare a report with a statement to that effect.

1.16 Under proposed subsection 42DT(3), the report must be made available on the company's website within one month after the end of the financial year to which it relates, and remain available for five years. Reportable payments by a pharmaceutical company to a medical practitioner, who is not an employee or consultant of the pharmaceutical company, are specified in subsection 42DT(4):

- payment for attending a conference, convention, educational seminar or other event on behalf of the corporation;
- payment of to a medical practitioner or the practitioner's employer;
- provision of a service to a medical practitioner or to the practitioner's employer;
- payment for the travel or accommodation costs or related services for a medical practitioner or to the practitioner's employer;
- payment used for medical research;
- a donation to a charity on behalf or in relation to the medical practitioner; or
- a gift of more than $25 in value to the medical practitioner or the practitioner's employer.

1.17 The failure of pharmaceutical companies to prepare and make public a report under section 42DT attracts a maximum civil penalty of 3000 penalty units.

Drafting errors in the Bill

1.18 The committee notes two errors in the Bill. To avoid any ambiguity in the intention of the Bill, the word 'or' should be

inserted at the end of clauses 42DT(4)(a) and 42DT(5)(b).

Statement of compatibility with human rights

1.19 In accordance with Part 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*, the EM includes a statement of the Bill's compatibility with human rights and freedoms recognised or declared in relevant international instruments, declaring that the Bill does not negatively impact on any human rights. The statement further acknowledges that:

> Although it places some small constraints on how pharmaceutical companies my compensate doctors, most interactions continue to be allowed under new transparency rules and there are no restrictions on the actions of individuals. These restrictions do not conflict with any of the rights enumerated in the applicable treaties.[10]

Background

1.20 The professional relationship between healthcare professionals and therapeutic goods companies is currently governed by industry and professional codes of conduct, not by government regulation.[11] Over recent years, the Government has acknowledged public concern about the promotion of therapeutic goods to healthcare professionals and the potential to influence medical practitioners' management of health needs of patients. In response, the Government has instigated consultation processes on these matters to seek the views of relevant stakeholders and the public.

Position paper on the Promotion of Therapeutic Goods

1.21 On 30 June 2010, the then Parliamentary Secretary for Health, the Hon Mark Butler MP, released the Government's *Position Paper on the Promotion of Therapeutic Goods*. The paper addressed public concern about the promotion of therapeutic goods to healthcare professionals and the level of coverage of, and inconsistency between, self-regulatory codes of conduct across the therapeutic goods sector. The paper stated the Government's policy objective as aiming:

> ...to ensure that decisions on management (including treatment) options for health needs are based on sound clinical advice 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.[12]

1.22 Government consultation with stakeholders from industry, health profession organisations and consumer groups revealed the following key issues:

- the need for high level principles underpinning sector specific codes;
- ensuring compliance of both member and non-member companies of industry bodies with relevant codes of conduct; and
- the structure of the complaints system.

1.23 While the paper stated that it was the Government's position to continue to support self-regulation of industry conduct, including promotional activities, it was found that reform of the existing arrangements was needed. This was broadly accepted by the industry.[13] The paper proposed that, in the first instance, 'industry strengthen and standardise self-regulation through developing an industry framework for universal adherence to consistent industry-wide codes based on a common set of high level principles'. If these reforms were not implemented, a legislative option would be considered by Government. The paper also noted the need to ensure that the codes of conduct which apply to healthcare professionals align with the standards expected of the therapeutic goods industry.[14]

Working group on promotion of therapeutic products – Report to Parliamentary Secretary Catherine King

1.24 A working group comprising industry stakeholders, representatives of health professional organisations and consumers was established to consider responses to the position paper. The working group was also tasked with developing a set of high level principles as a basis for strengthening and aligning industry codes of conduct.[15] The subsequent report, entitled *Working group on promotion of therapeutic products – Report to Parliamentary Secretary Catherine King*, was released on 18 March 2011.

1.25 The working group considered the coverage of the industry codes, the mechanisms for extending code compliance to non-members of associations, and the need for alignment of the codes of conduct governing healthcare professionals with industry codes, recognising the mutuality of these relationships. The working group made 18 recommendations for government, industry and professional health organisations.

1.26 The working group developed a high level statement of principles to be incorporated into each industry code, as well as a statement of the obligations on companies operating in the industry covered by the code. The statement of principles provides that:

> The Australian therapeutic products industry promotes the concept of good health incorporating the quality use of therapeutic products based on genuine consumer health needs and supported by the ethical conduct of all parties. In this context the quality use of therapeutic products means:
>
> - Selecting diagnostic and treatment options wisely based on the best available evidence and the consumers' needs;
> - Choosing suitable therapeutic products if this is considered necessary; and
> - Using therapeutic products safely and effectively.[16]

1.27 The working group specified the areas to be covered by the provisions of therapeutic industry codes, as well as the obligations of companies operating under the code. It was recommended that, as a condition of inclusion of a product on the Australian Register of Therapeutic Goods, all applicants, including those not a member of an industry association, be required to nominate the relevant code of practice to which it will subscribe.[17]

1.28 To address the issue of bringing professional codes of conduct into alignment with industry codes, the working group recommended ongoing engagement with health professional organisations. The working group also recommended the establishment of an advisory body comprised of representatives from industry, healthcare professional organisations and consumer groups to oversee the implementation of the recommendations of the working group report.[18]

TGA Reforms: A blueprint for TGA's future

1.29 The Government incorporated its response to the working group's report in the publication, *TGA Reforms: A blueprint for*

TGA's future, which was released in December 2011. Of the 18 recommendations made by the working group, the Government supported five, did not support three, noted seven, and referred three recommendations to relevant external bodies. The Government did not support recommendations 5 to 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 National Medicines Policy.[19]

1.30 The TGA Reforms report acknowledged that the promotion of therapeutic goods, including pharmaceutical products, to medical practitioners through offering inducements, has the potential to influence clinical decisions on grounds other than the best interest of the patient. It further noted that industry codes of conduct are effective in limiting unethical behaviour on the part of companies, but that currently there is inconsistency across codes and that companies which are not members of associations are not bound by these codes.[20]

1.31 The report stated that the Government's preferred position was to maintain the self-regulatory framework and that it strongly supported the harmonisation of codes across sectors through the incorporation of the high-level principles developed by the working group on promotion of therapeutic products.

> The inclusion of these high-level principles into industry specific codes of conduct is a continuing process and the Government will consider the feasibility of establishing a committee to evaluate the work of industry bodies. Further changes will 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 the TGA seeking notification of a sponsor's nominated code of conduct at the point of including a product on the ARTG [Australian Register of Therapeutic Goods].[21]

Implementation of the working group's recommendations

1.32 The Government allocated $1.4 million in funding over four years to support the implementation of the working group's recommendations which the Government had previously noted would benefit from some support. These included:

> ...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.[22]

1.33 In July 2012, the Government released the paper, *Delivering reforms – Implementation plan for TGA Reforms: A blueprint for TGA's future*, which provided a high-level overview of the implementation of the working group's recommendations.

1.34 The Government established a Codes of Conduct Advisory Group in January-February 2013. The Advisory Group has 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.[23]

National Medicines Policy

1.35 The Government's National Medicines Policy was launched in 1999 to bring about better health outcomes for all Australians, particularly in regard to people's access to, and wise use of, prescription and non-prescription medicines. Its framework is based on partnerships between Governments, health educators, health practitioners, and other healthcare providers and suppliers, the medicines industry, healthcare consumers, and the media, working together to promote the objectives of the policy.

1.36 The National Prescribing Service is described as the implementation arm of the National Medicines Policy to assist prescribers and patients in the quality use of medicines through education and prescriber feedback.[24]

Pharmaceutical industry self-regulation

1.37 Two main industry groups represent the pharmaceutical industry in Australia: Medicines Australia and the Generic Medicines Industry Association (GMiA). Medicines Australia has 54 member companies which supply 86 per cent of the medicines that are available to Australians through the Pharmaceutical Benefits Scheme.[25] GMiA is a representative body of generic medicine suppliers in Australia. GMiA member companies predominantly manufacture and/or sell generic medicines in the Australian market and/or manufacture generic medicines for export.[26] GMiA has 18 members, including five full members who supply approximately 90 per cent of the non-original generic medicines to the Australian market.[27]

1.38 The following outlines the codes of conduct for both Medicines Australia and GMiA.

Medicines Australia

1.39 Medicines Australia has established a code of conduct (MA Code) which sets out the standards of conduct for the activities of companies when engaged in the promotion of prescription pharmaceutical products used under medical supervision as permitted by Australian legislation. Established in 1960, the MA Code has undergone regular review by Medicines Australia 'to ensure it continues to reflect current community and professional standards and current government legislation.'[28]

1.40 The most recent update of the MA Code, Edition 17, was authorised by the Australian Competition and Consumer Commission (ACCC) for two years on 20 December 2012 and came into effect on 11 January 2013.[29] During the authorisation consultation process, the ACCC noted that the MA Code provides public benefits by providing greater transparency on the relationships between pharmaceutical companies and healthcare professionals. The ACCC stated that the MA Code could go further in ensuring that community expectations now, and in the future are met. The ACCC further noted that:

> The ACCC encourages Medicines Australia to look for ways to address the concerns that have been raised during the ACCC's consultation process. These include improving the accessibility of reports and the complaints process and considering disclosure of payments made to individual healthcare professionals.[30]

1.41 To ensure the MA Code is amended in a timely manner, the ACCC only granted authorisation of the Code for two years, and not the five year period sought by Medicines Australia. On authorising[31] the code, the ACCC stated that it had given member companies of Medicines Australia two years to improve transparency of payments and sponsorship made by pharmaceutical companies to individual healthcare professionals. Commissioner Sarah Court further advised that:

> Improving transparency around payments to individual doctors will play an important role in promoting community confidence in the integrity of these payments to healthcare professionals.[32]

1.42 Significant changes to Edition 17 of the MA Code include the requirement that companies are now to provide:

- aggregate amounts of all payments made to healthcare professionals for advisory boards and consultancy arrangements;
- attendance and speaking at medical conferences and educational events; and
- sponsorships for consumer organisations including the value of non-monetary support.[33]

1.43 Complaints and appeals under the MA code are overseen by the Code of Conduct Committee and the Code Appeals Committee which are responsible to the Medicines Australia Board.[34] The monitoring of member companies is undertaken by the Medicines Australia Monitoring Committee. This committee proactively monitors selected promotional material and conduct of companies on a regular and ongoing basis. At the end of each financial year, the Monitoring Committee also reviews the educational meetings and symposia provided by member companies. Medicines Australia makes the companies' completed reports available on its website within three months of the end of each six month period.[35]

1.44 The MA Code only covers members of Medicines Australia and membership of the organisation is voluntary.

Transparency Working Group

1.45 Following its adoption of Edition 17 of the MA Code, Medicines Australia established the Transparency Working Group comprising representatives of industry, professional medical bodies and consumers groups, to develop measures and policies to further enhance transparency of payments and other transfers of value between healthcare professionals and the pharmaceutical industry.[36] The Transparency Working Group expects to present its final recommendations by June 2013.[37]

1.46 Dr Ken Harvey, the CHOICE representative on the Transparency Working Group, provided an update on the group's progress:

> It has developed principles applicable to all therapeutic goods companies and all health professions, not just doctors. These include providing access to information in a single, public repository, enabling the information to be audited and validated by healthcare professionals and companies, and supported by an educational process to assist all parties to interpret the information in context. It is envisaged that member companies could commence recording payments made to individual health care professionals from Jan 1, 2015 with public reporting in 2016.[38]

Generic Medicines Industry Association (GMiA)

1.47 GMiA introduced its Code of Practice on 1 March 2010 and was granted authorisation by the ACCC on 3 November 2010. GMiA stated that:

> The Code formalises the commitment to GMiA members to a system of best practice self-regulation and ethical supply of generic medicines to the Australian community in compliance with applicable laws and standards.[39]

1.48 In addition to covering relationships with stakeholders and promotional and marketing activities, the GMiA Code also covers the manufacture, supply and distribution, safety, product availability, research and regulatory activities, and corporate governance. Under section 15 of the Code, the Code Administration Committee prepares an annual report which reviews the operation of the Code.

1.49 In comparison to the MA Code, GMiA further advised on the effectiveness of the Code:

> GMiA rejects any suggestion that its Code is any less rigorous or capable of self-regulation than the Medicines Australia Code. The GMiA Code specifically reflects the unique operating environment of suppliers of generic medicines and sets out the best practice standards, aligned with that unique operating environment required of all members...during the three years that GMiA has administered the Code, GMiA has received only five complaints.[40]

Medical practitioners' professional standards

1.50 The medical profession is currently regulated by the Medical Board of Australia, supported by the Australian Health Practitioner Regulation Agency (AHPRA). AHPRA supports 14 national health professional boards in their primary role of protecting the public and managing the registration processes for health practitioners and students. On behalf of the Boards, AHPRA also manages investigations into the professional conduct, performance or health of registered health practitioners, except in NSW where this is undertaken by the Health Professional Councils Authority and the Health Care Complaints Commission.

1.51 The professional conduct of health practitioners and students is guided by the Codes and Guidelines and Registration Standards of their relevant health profession. The conduct of medical practitioners is governed by the Medical Board of Australia's *Good Medical Practice: A Code of Conduct for Doctors in Australia*. Section 8.11 of the code deals with conflicts of interest. In relation to interactions with pharmaceutical companies, it specifies 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.
>
> 8.11.7 Not asking for or accepting fees for meeting sales representatives.
>
> 8.11.8 Not offering inducements to colleagues, or entering into arrangements that could be perceived to provide inducements.

1.52 Any person can notify AHPRA with concerns relating to the conduct of a registered health practitioner or student on the Medical Board of Australia's Code.

1.53 A number of professional medical bodies have also established guidance for members on ethical relationships with industry.

Overseas experience

1.54 The committee was provided with examples of recent developments overseas where the interactions between therapeutic goods companies and healthcare professionals have undergone reform.

1.55 In the United States, the Physician Payment Sunshine Act was passed in 2010 by the US Congress as part of the Patient Protection and Affordable Care Act and became operational earlier this year. It requires pharmaceutical and device companies to report to the Centers for Medicare and Medicaid Services all payments, or other transfers of value, made to individual doctors and teaching hospitals that total more than US$100 per year. The first instalment of transparency reports will be published by the Centers to a public website on 30 September 2014.[41]

1.56 The Dutch have established a central register (managed by an independent foundation) to record the financial relationships between healthcare professional, healthcare institutions and the pharmaceutical industry. All financial relationships exceeding €500 are entered in the register and this will be open to the public on 25 April 2013.[42] In Denmark, companies have been required to declare their payments to doctors since 2008, while doctors in Scotland have to declare payments received from companies themselves.[43]

Issues raised during the inquiry

1.57 While supporting the broad intent of the Bill, most submitters did not support its passage through the Parliament in its current form. The Department of Health and Ageing (DoHA), pharmaceutical companies, industry and health professional bodies were generally opposed to the Bill and advocated for continuing with the self-regulation model. However, it was conceded by some opposed to the Bill, that the current self-regulation model could be strengthened by some legislative reform, for example, to require companies to adhere to an industry code through the product registration process.

1.58 Some submitters also indicated that consideration of the Bill provided an opportunity to canvass a number of issues in regard to the current arrangements and possible models to govern the interactions between health professionals and pharmaceutical companies which may impact on prescribing behaviour.[44]

Importance of ethical relationships between pharmaceutical companies and medical practitioners

1.59 The potential effects of inducements from pharmaceutical companies, such as funding for travel and conference attendance, payment for consultancies, and sponsored lectures, on the behaviour of medical practitioners was outlined by Dr Ken Harvey. The effects included uncritical uptake of newer, expensive and less-well evaluated products and underutilisation of more cost-effective drugs and medical devices; distortion of published medical evidence by influencing how clinical studies are designed and conducted and which studies are published. Dr Harvey concluded that:

> This can have the overall result of "stacking the deck" in favour of new and expensive treatments and has been shown to lead "key opinion leader" doctors to advocate such treatments despite the lack of robust evidence about their safety. These influences can cause rapid take-up of new treatments with disastrous consequences when adverse effects (followed by product withdrawal) become apparent on much larger scale than would have occurred by more prudent use. The cost and safety implications of these distortions for our health system, which are under ever-increasing pressure to continue to meet the aspirations and expectations of an ageing population, are significant.[45]

1.60 The importance of transparency about relationships between pharmaceutical companies and medical practitioners for patients was noted by the Australian Medical Association (AMA) which commented:

> Patients need to make well-informed decisions about their healthcare that includes taking account of their healthcare provider's involvement with pharmaceutical companies. This is enshrined in medical practitioner regulation in Australia.[46]

1.61 The committee also received evidence from a number of pharmaceutical companies and industry bodies which also acknowledged the importance of transparency in their relationships with parties they engage with and the community expectation for increased transparency.[47] For example, Pfizer Australia advised:

> We recognise that transparency and the trust it cultivates is essential in both the development and delivery of healthcare and is the cornerstone which fosters trust between government, industry, healthcare professionals and patients.[48]

1.62 Medicines Australia stated that it strongly supported the policy objective of safeguarding the integrity of health care professionals' interaction with patients. It further stated that providing greater transparency about companies' interactions with healthcare professionals 'will give the community greater confidence that the independence of health professionals in making recommendations and decisions about treatment is not compromised by those interactions'.[49]

1.63 Consumers Health Forum of Australia (CHF) advised that there was strong support for the objectives of the Bill among its members and that it had long held concern with regard to the promotion of therapeutic goods to health professionals by industry. CHF noted that:

> ...the ethical promotion of therapeutic goods is essential if consumers are to be confident that their health professionals' decisions are based only on the consumers' best interests, rather than on inappropriate incentives or marketing strategies.[50]

1.64 The Government has acknowledged public concern about the promotion of therapeutic goods and DoHA commented that 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'.[51]

1.65 Although there was generally consensus among submitters to the inquiry on the need to safeguard the prescribing practices of medical practitioners by ensuring that pharmaceutical companies do not impose undue influence through their interactions with practitioners, there was some divergence of views on the most effective way to achieve this. A number of submissions raised concerns with the regulatory approach proposed by the Bill. Most submissions supported continuation of the self-regulation model which was considered to be effective, and particularly pointed to current reforms processes underway to further strengthen the current model. There was also some support for moves toward a co-regulation approach to deal with some weaknesses identified with the current model.

Concerns about the Bill

1.66 Evidence received addressed concerns with the timing of the legislation, its limited application, possible restrictions of appropriate interaction between companies and medical practitioners and lessening of existing requirements under the MA Code.

Timing of the legislation

1.67 A number of submitters argued that the timing of the Bill is not appropriate as there are reform processes currently underway. These processes are aimed at addressing some of the concerns which have been raised with the current self-regulation model and include reforms arising from reviews sponsored by the Government, and the expected reforms to the MA Code arising from the work of its Transparency Working Group.

1.68 Following recent consultation processes, the Government has confirmed its approach to continue with the self-regulation model at this stage. Considerable progress has been made following the release of the report of the Working Group on Promotion of Therapeutic Products. As noted earlier, the Government supported a number of recommendations from this report and has allocated funding to assist industry in the implementation of these reforms to support stronger self-regulation, better communication and shared systems for complaints reporting. Further support has been provided by the establishment of the Codes of Conduct Advisory Group, as noted earlier, to oversee the implementation of a number of the reforms.

1.69 Following its most recent code authorisation process through the ACCC, Medicines Australia has been responsive to suggestions that its Code needs to provide for more transparency. It formed the Transparency Working Group to undertake a consultative process to further implement changes to provide for greater transparency. The committee was advised that this Group's work is well advanced and is expected to report by June 2013. Group member, Dr Ken Harvey provided a copy of the principles drafted which, if adopted in the final report, will apply to reporting transfers of value between all therapeutic industry groups and all health professionals, which include:

- reporting the monetary transactions and transfers of value by individual, identified healthcare professional and company in a form that is readily accessible and meaningful to the public;
- providing access to the information in a single, public repository, that is readily searchable;
- enabling the information to be audited and validated by healthcare professionals and companies; and
- support through an educational process to assist all parties to interpret the information in context.[52]

1.70 Medicines Australia advised that the final transparency model is expected to be incorporated into Edition 18 of the MA Code which will be submitted to the ACCC in July 2014 for authorisation. Medicines Australia also noted that implementing a transparency model was complex, but progress was well advanced and the agreed model should be implemented within the next year and a half.[53]

1.71 The AMA highlighted the importance of the Transparency Working Group processes in the design and implementation of a public register. It asserted that the Transparency Working Group's recommendations, which will feed into the ACCC authorisation process, should continue unimpeded to:

- Ensure that any public register is designed to provide patients with access to useful information that is relevant to their healthcare decisions;
- Evaluate how patients access and use the information;
- Measure the cost of public reporting against the benefits to patients; and
- Revise the reporting arrangements if required.[54]

1.72 While acknowledging the importance ensuring public confidence in the prescribing practices of medical practitioners, the DoHA argued that the Government did not consider that there is substantial evidence to demonstrate that interactions between parties are negatively impacting on prescribing practices and patient care in Australia at present. Mr Peter Woodley, DoHA, commented:

> I guess we are aware of anecdotal evidence. I am not sure that it amounts to a substantial body of coherent evidence. Nevertheless, the government has chosen to respond. It recognises that this is an issue that needs to be addressed and at this point has chosen to go down a self-regulatory route with the prospect, if you like, that if by 2015-16 it does not work it will consider other options. So, on that basis, I guess there are some concerns that the consequences may, ultimately, be to the detriment of the consumer.[55]

1.73 Dr Steven Hambleton, Federal President, AMA, confirmed that the AMA was not aware of particular instances of pharmaceutical companies having undue influence over medical practitioners at present. However, he went on to comment that because of reports of overseas instances, the AMA supported increased transparency around that relationship to ensure confidence is maintained.[56]

Limited application of the Bill

1.74 Submitters commented that the application is limited to interactions between pharmaceutical companies and registered medical practitioners. DoHA noted that the amendments would apply to 'regulated corporations' that import, manufacture or supply 'regulated pharmaceutical products'. Under Part 3-2 of the Therapeutic Goods Act these are listed or registered medicines included on the Australian Register of Therapeutic Goods. This means that the relationships between other therapeutic goods companies and health professionals are excluded from coverage:

> 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.[57]

1.75 A number of submitters were of the view that other companies in the therapeutics sector should also be subject to similar disclosure.[58] It was suggested that other industries, such as medical device companies, should be subject to similar restrictions and disclosure requirements to those imposed on pharmaceutical companies in regard to their interactions with healthcare professionals. Similarly, the Bill fails to recognise the importance of a regulatory model which applies to other healthcare professionals who may be subject to possible inducement through relationships with therapeutic companies. These included, for example, pharmacists, laboratory scientists, theatre nurses, and radiographers.[59]

1.76 Pfizer Australia noted that, if passed, the narrow focus of the Bill 'has the danger of leading to a piecemeal, inconsistent

combination of self-regulation and government regulation', where some therapeutic goods sectors and healthcare professions would not be covered under the proposed regulations.[60]

1.77 The AMA also commented on the limited application of the Bill and stated that if it was a 'genuine attempt to safeguard patients and maintain the integrity of Australia's health system and the sustainability of health expenditure', then the Bill should apply to all health practitioners and all industry organisations involved in the sale or promotion of health related products.[61] Dr Hambleton explained the importance of a broad application further:

> There are lots of other relationships that warrant transparency. Thinking about pharmacy, for example, the Department of Health and Ageing, in 2006, advised the AMA that only three per cent of PBS prescriptions had the 'do not substitute' box ticked by the doctor on the prescription, yet there are a lot of products going into particular brands. So it is true; the pharmacist does make the most decisions about which brand of medicine is to be dispensed...It may well be that brand decisions are not made by the practitioner, and we do need to make sure that we are spending appropriately. If there is a reason a particular brand needs to be prescribed, the medical practitioners are not indicating that except in very small circumstances.
>
> So, yes, transparency would be important on a broader basis.[62]

1.78 The University of Sydney suggested that definitions of the parties to which the Bill applies may be problematic and unintentionally exclude or include certain groups. It was explained that the definition of 'registered medical practitioner' does not necessarily cover all prescribing professionals:

> The bill as drafted is not aligned with the current relationship between medical registration and the authority to prescribed. Not all "registered medical practitioners" have that authority; and not all prescribers are "register medical practitioners" – for example, dentists also prescribe.[63]

1.79 The University of Sydney also raised concern with the definition of 'regulated corporation' in the Bill suggesting that it may capture universities that import regulated pharmaceuticals for medical research or to conduct clinical trials on behalf of international pharmaceutical companies, exposing them to the penalties and regulatory requirements intended for that industry. If the Bill is not intended to apply to universities in this way, it was recommended in the submission that consideration be given to specifically exclude these parties.[64]

Publication of transaction details

1.80 Some submitters who supported improved transparency suggested that the requirement under proposed section 42DT for publication of reports on company websites was unhelpful to consumers. While having this additional information available to the public would be an improvement to transparency, a far more helpful mechanism for consumers would be for all information to be available in a single public repository.[65]

1.81 The proposal for a single repository was also supported by pharmaceutical companies. For example, Pfizer noted that through the current Medicines Australia review process of the MA Code, consumers had expressed a preference for access to information about interactions between healthcare professionals and companies on one centrally located website in an accessible and searchable format.[66]

1.82 Ms Deborah Monk, Medicines Australia, commented that a single repository was being considered:

> Certainly one of the principles that the transparency working group has developed is the concept that the repository of the data needs to be centralised...that could be on the Medicines Australia website, the TGA website or APRA's website. The concept is that it needs to be centralised, so that it is the one place that you go to find that information.[67]

1.83 Pfizer also noted that the Bill failed to provide a mechanism for doctors to check the validity of the details of reports which are required to be provided on company websites under section 42DT of the Bill.[68]

1.84 DoHA also raised concern with the lack of detail in the Bill with regard to the monitoring and enforcement of section 42DT:

> 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).[69]

Appropriate interaction between companies and medical practitioners

1.85 Submitters argued that the Bill would preclude appropriate interaction between companies and medical practitioners with Ms Maguire, GlaxoSmithKline stating that:

> The measures outlined in the bill will have a detrimental impact on the pharmaceutical company's ability to support valuable medical education for healthcare professionals. Medical education is critical to ensure quality use of medicines in the best interests of patients. Patients want to their doctors to know how medicines work and how to use them.[70]

1.86 As a consequence, it was argued that medical education provided by pharmaceutical companies should be continued.[71] The Australian Medical Association endorsed this position:

> It is equally important to recognise that interactions between medical practitioners and pharmaceutical and medical companies are a necessary and legitimate part of ensuring that patients have access to new and improved medicines, treatments and medical devices that save lives and improve the quality of life for Australians with illness.
>
> Australians enjoy world class health care because medical practitioners are actively engaged in the development of, and fully informed about, new or improved medicines, treatments and devices. Australian medical practitioners' engagement with international colleagues and experiences improve patient outcomes in Australia.[72]

1.87 It was further noted by some submitters that the current MA Code already provides a number of restrictions on the hospitality provided at these events to ensure they are conducted in an ethical and professional manner. Mr McDonald commented, for example, 'when a new medicine is being launched or there is an update on the medicine there is a proper educational process that follows the code and meets the requirements of the code'.[73]

1.88 A number of pharmaceutical companies also noted their belief that healthcare professionals who they work with should be fairly compensated for the service and expertise they provide.[74] Ms Maguire commented further:

> We believe it is appropriate to fairly compensate healthcare professionals for the legitimate and important insights and expertise into the medical care that they provide. While some might argue that healthcare professionals should fund their own education, it is not realistic in practice. Doctors come from all walks of life and it is appropriate that we support them to continue to gain new knowledge in an incredibly complex and evolving field.[75]

1.89 Two other areas where it was considered that the Bill may impact on appropriate interactions were in relation to clinical trials and university partnerships. Mr Geoff McDonald, GlaxoSmithKine, noted that clinical trials involve meetings with participants that usually do not take place in Australia. Mr McDonald added:

> The ability for them to interact and talk about where the research is going, what modifications they have to make et cetera is important. Out of that, as a medicine progresses, because we are not able to do any promotion until we have approval, those individuals who have been involved and working closely with those drugs over x number of years are the people we would use for education locally.[76]

1.90 While the University of Sydney supported the broad intent of the Bill, it raised concern that, in its current form, it will impact on the legitimate activities of Australian universities in partnership with pharmaceutical companies. It was noted that the quality of Australia's health and medical research relies on the engagement and collaboration between universities, medical research institutes, clinicians, and industry partners. However, the Bill may effect this engagement:

> We are concerned that the Bill will unintentionally diminish industry's capacity and willingness to collaborate with Australian universities, and to sponsor legitimate university-led education and research initiatives. Ultimately this would affect the capacity of universities to disseminate the findings of their researchers and to provide training to health professionals.[77]

Comparison with the existing MA Code

1.91 A number of submitters observed that some aspects of the Bill imposed restrictions that were less stringent than those currently in place under the MA Code.[78] For example, Pfizer Australia noted that section 43DS(2) which relates to the forms of payment to a doctor had a higher threshold than the current MA Code. The Bill stipulates that a gift of less than $25 is acceptable and is not reported, however the existing MA prohibits any form of gift, whatever the value.[79]

1.92 The submission from Janssen-Cilag Pty Ltd presented a table comparing selected amendments proposed in the Bill with the existing standards set out in the MA Code which they believe already address a number of the concerns raised in the Bill. For example, the submission states that the existing provisions in the MA Code relate to the interactions with healthcare professionals, including the content of promotional materials; whereas the Bill seeks to regulate just one aspect of pharmaceutical companies' interactions with physicians, that is financial interactions.[80]

Efficiency and cost effectiveness of self-regulation

1.93 A number of submissions raised concern about the additional costs that would be imposed on companies to comply with, and the government to administer, the proposed regulations under the Bill. It was suggested to the committee that self-regulation is both more efficient and cost effective.[81]

1.94 Medicines Australia noted that self-regulation is self-funded. It pointed out that industry currently funds the education, training, monitoring and enforcement mechanisms that underpin the MA Code and no tax payer funds are required for support.[82]

1.95 The Medical Technology Association of Australia (MTAA) and IVD Australia submission also noted that an industry code is more efficient and effective than one dealt with under a regulatory regime:

> All compliance processes bring with them an added cost which, in the case of companies working in the health sector, will result in additional burdens to sponsors of therapeutic products. These costs will be passed on to health product purchasers, thereby adding cost to the health system with no perceivable additional benefit.[83]

1.96 This view was endorsed by Dr Hambleton who commented that the AMA did not support the introduction of any mechanism which increased costs:

> ...any extra regulation, if it increases red tape, is something the AMA has stood against in many fora. We have a first-rate health system. We have some of the best outcomes in the world. We do not want to tie up the doctors at the front line of care in red tape...There are other health professions which warrant transparency measures because at the end of the day if there are increased costs because of red tape or increased costs because of education expenses which are not covered by other avenues, as we have discussed earlier, there is going to be an input cost of the medical care and that input cost will ultimately be transferred to the patients.[84]

1.97 The University of Sydney also noted in its concern about the increased regulatory burden on affected parties if the Bill proceeds, including universities. It also raised whether a regulatory impact assessment had been conducted to assist in the consideration of the proposed reforms under the Bill.[85]

1.98 However, not all evidence supported self-regulation. It was noted that those companies which did not belong to an industry association were not subject to the relevant industry codes of conduct. Dr Harvey provided the committee with an example in the generic industry in relation to a new generic companies, particularly from India. Dr Harvey stated:

> ...the particular company concerned has not joined an industry association. They did not join the Generic Medicines Industry Association.
>
> They were offering a substantial inducement of free stocks to pharmacists to preferentially dispense their product, which is

against some of the principles—and, indeed, the letters of the law—in the Medicines Australia code and the GMiA code: thou shalt not induce a practitioner to influence their prescribing or dispensing of a particular drug. So a complaint was put in. The company concerned were asked if they would be happy with the GMiA adjudicating and, not surprisingly, they declined to have it heard. That is the problem with self-regulation of industry codes: those outside it are not touched at all.[86]

Support for co-regulation model to strengthen existing industry codes

1.99 The committee received evidence from a number of individuals and organisations which proposed a co-regulatory approach in some areas to strengthen the existing self-regulation model.[87] In particular, a number of submitters endorsed Recommendation 5 of the Working Group on the Promotion of Therapeutic Products:

The Working Group recommends that TGA include on its application forms (whether electronic or paper) a requirement for an applicant to nominate the relevant code of practice to which it will subscribe, as a condition of registration/listing on the ARTG.

1.100 In its response to the Working Group's report, the Government did not support this recommendation, noting the preference to maintain an emphasis on self-regulation. However, it further noted that:

If after codes have been updated, further encouragement is required for non-members to nominate a code, the Government will consider further legislative measures including the TGA seeking this information.[88]

1.101 Medicines Australia stated that it supported a hybrid model: that the Therapeutic Goods Act is amended to provide that it should be a condition of registration that a particular company follow a self-regulatory code. In addition, Medicines Australia further stated that all of these self-regulatory codes should come up to the standard of the Medicines Australia code of conduct.[89]

1.102 Dr Ken Harvey suggests there is a precedent for this approach with regard to the sponsors of prescription generic medicines must agree to comply with certain parts of the MA Code when they sign the TGA letter of marketing approval.[90]

Conclusion

1.103 The committee acknowledges that it is important that health consumers are confident that the medical practitioner, from whom they are seeking assistance and advice, maintains an ethical and transparent relationship with pharmaceutical companies. The committee notes that since 2010 this relationship has been the subject of examination and consideration. Recommendations have been made to the Government to improve transparency of this relationship. The Government has responded by funding the implementation of some of the recommendations including the strengthening of self-regulation through industry codes of conduct.

1.104 The committee considers that it is appropriate that the relationship between medical practitioners and pharmaceutical companies be regulated through industry codes. Further, the committee notes that some aspects of the Bill are weaker than the existing Medicines Australia code of conduct. The committee therefore does not support the Bill.

Recommendation 1

The committee recommends that the Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013 not be passed.

Senator Helen Polley
Chair

Navigation: Previous Page | Contents | Next Page