SUBMISSION

In Response to

The Senate Finance and Public Administration Inquiry into the *Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013*

19 APRIL 2013

MEDICINES Australia

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Executive Summary

Medicines Australia strongly supports the policy objective of safeguarding the integrity of health care professionals' interactions with patients. This includes ensuring that treatment decisions are made in the interests of patients' wellbeing without improper influence from commercial entities and ensuring appropriate transparency mechanisms exist to provide the community with confidence in the integrity of their healthcare professionals.

With this in mind, Medicines Australia recommends that the *Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013* (the Bill) should not be passed for the following key reasons:

1. An effective system ensuring transparency is best achieved through existing industry self-regulation mechanisms that are being further strengthened through development of new transparency measures. The Medicines Australia Code of Conduct provides more comprehensive regulation, is efficient and effective, avoids unnecessary red tape and achieves a greater degree of stakeholder support than the measures proposed in the Bill. Self-regulation under the Code is self-funded, without requiring any tax-payer funded support or resources.
2. Through the Transparency Working Group the Industry has engaged with consulted key stakeholders, including clinicians whose interests are affected by the Bill but who do not appear to have been consulted in its formation. The Transparency Working Group, by developing an Australian transparency model for inclusion in the Medicines Australia Code, will deliver the desired outcome of transparency more efficiently, more effectively, and with consensus across stakeholders.
3. The Government and Industry have also cooperatively engaged in developing policy responses to these issues. The Working Group on the Promotion of Therapeutic Products (the 'Trimmer Review') has recommended to Government measures that will ensure that industry self-regulation is comprehensive and consistent. The new Government Advisory Group on Codes of Conduct has been tasked with implementing the Trimmer Review recommendations.

   If enacted, the Bill would undermine these initiatives which have multi-stakeholder support; duplicate existing effective industry regulation; undermine the significant progress in developing a transparency model; contribute to maintaining an inequitable playing field within the sector; and impose additional cost to Government and red tape.
4. The Bill would jeopardise the legitimate and appropriate educational and informational interactions between healthcare professionals and those who supply the medicines they prescribe. These interactions ensure Australian healthcare professionals are engaged and informed about medical developments. Further, company sponsorship enables healthcare professionals to engage and information-share with local and international peers, ultimately improving health outcomes for Australian patients. The Bill, by presupposing that these important and legitimate interactions are all inappropriate and should be unlawful, risks having a significant negative impact on public health outcomes.

Recommendations

1. The Bill should be opposed and not passed by the Senate;
2. In recognising that self-regulation is the most appropriate and efficient manner to enforce conduct across industry, the Australian Government should expedite implementation of the recommendations of the Working Group it convened on the Promotion of Therapeutic Products, particularly the recommendation that each company should to agree to abide by an applicable industry self-regulatory code in its entirety as part of registering a product on the Australian Register of Therapeutic Goods (ARTG); and
3. The Committee should support policy development by the Transparency Working Group initiated by Medicines Australia to implement measures to drive transparency and consistency across the sector, through consultation and cooperation with healthcare professionals.

This submission refers to several policy initiatives that have been undertaken or initiated in the last two years. For ease of reference, these are:

- The Working Group on the Promotion of Therapeutic Products, which was chaired by Ms Anne Trimmer (the 'Trimmer Review'). The Report of the Trimmer Review may be found at:

  http://www.health.gov.au/internet/main/publishing.nsf/Content/37D9B56C888EF27ECA2577D600081DDD/$File/Report%20of%20the%20Working%20Group%20on%20Promotion%20of%20Therapeutic%20Products.pdf
- The Advisory Group on Codes of Conduct, which is chaired by Emeritus Professor Lloyd Sansom. The Advisory Group was established in March 2013 has been charged with implementing the Trimmer Report recommendations.
- The Transparency Working Group was established by Medicines Australia in September 2012. Information about the work of the Transparency Working Group may be found at http://medicinesaustralia.com.au/issues-information/transparency-working-group/ and is discussed in detail below.

Effective self-regulation through the Code of Conduct

Medicines Australia strongly supports the policy objective of safeguarding the integrity of health care professionals' interactions with patients. This includes ensuring that treatment decisions are made in the interests of patients' wellbeing without improper influence from commercial entities and ensuring appropriate transparency mechanisms exist to provide the community with confidence in the integrity of their healthcare professionals.

These policy objectives are best achieved through the existing, efficient, self-regulation mechanisms of the Medicines Australia Code of Conduct (the 'Code'), as well as through the transparency mechanisms being developed by the Transparency Working Group. If enacted, the *Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013* would undermine the Code; duplicate existing, effective industry regulation; and undermine the significant progress of the Transparency Working Group. The following section outlines how the Code and the Transparency Working Group has been established and its progress towards achieving the aforementioned policy objectives.

Overview of the Code

Medicines Australia administers a self-regulatory Code of Conduct that was established in 1960 and which has since been regularly, systematically and comprehensively reviewed and revised ever since. The 17th Edition of the Code was authorised by the Australian Competition and Consumer Commission (ACCC) on 20 December 2012 and became effective in January 2013. It is highly detailed and prescriptive. The Code effectively and efficiently regulates interactions between pharmaceutical companies and healthcare professionals through:

- Overarching Guiding Principles (see **Attachment 1**)
- Detailed provisions covering all aspects of how companies interact with healthcare professionals (see **Attachment 2**, extract of the Contents of the Code, Section 9: *Relationships with healthcare professionals*)
- Monitoring of compliance
- A Complaints mechanism, adjudicated by independent committees
- Sanctions to deter non-compliance.

A copy of the Code may be found here: http://medicinesaustralia.com.au/code-of-conduct/code-of-conduct-current-edition/

Reform of the Code – continuous improvement to meet community standards

Medicines Australia and its 54 member companies agree that providing greater transparency about companies' interactions with healthcare professionals will give the community greater confidence that the independence of healthcare professionals in making recommendations and decisions about treatment is not compromised by those interactions. It has therefore implemented successive reforms in each Edition of the Code.

Edition 15 of the Code, which became effective in December 2006, introduced public reporting of educational events, meetings and symposia that are organised by or sponsored by member companies, in addition to

other improvements to the Code.[1] Educational event reports from each company are published on Medicines Australia's website every six months. The reports detail the:

- purpose and duration of the event
- venue and its location
- professional status of attendees
- nature and cost of any hospitality provided
- nature and cost of any accommodation or travel provided
- number of attendees, and
- total cost of the event, or the total sponsorship contribution for an event not organised by the company.

The most recent educational event reports are available at the following website: http://medicinesaustralia.com.au/code-of-conduct/education-events-reports/member-company-reports/, which also provides access to all past reports from 1 July 2007.

Edition 16 of the Code, which became effective in January 2010, significantly expanded on the specific provisions regulating the relationship between companies and healthcare professionals, and in particular on the conduct of educational events.

By way of example, Section 9.4 of Edition 16 of the Code, *Company educational events held in Australia*, introduced specific provisions on:

- educational content (requiring objective evidence of the educational value of the event)
- venue selection (including an explicit prohibition on choosing venues for their leisure, sporting or recreational facilities)
- meals and beverages (requiring that any hospitality must be secondary to the educational purpose, appropriate for the educational content and duration, and that it must not be excessive)
- travel (prohibition on providing any class of travel other than economy within Australia. Note that educational meetings for Australian healthcare professionals must be held within Australia)
- accommodation (permits reasonable accommodation for delegates to be provided if justified by the timing and duration of the meeting and the origin of the delegates)
- entertainment (an explicit prohibition on provision of entertainment in any form)
- remuneration (an explicit prohibition on paying a delegate to attend an educational meeting; any remuneration provided to faculty, speakers or chairpersons must be commensurate with work involved)
- partners, family or guests (an explicit prohibition on paying for or subsidising any expenses associated with an accompanying person associated with a delegate).

Edition 17 of the Code, which became effective on 11 January 2013, further expanded the scope of transparency of the interactions between companies and healthcare professionals and extended transparency of interactions with health consumer organisations. In addition to the educational event reports, which have continued to be required since July 2007, Edition 17 of the Code requires companies to provide three new reports to Medicines Australia for publication on its website:

- A report on all Advisory Board meetings held during each six month period, including details of the venue and location of the meeting, the professional status of members of the Advisory Board, the total honoraria or other fees paid to members, a description of any hospitality, travel or accommodation provided and the

[1] The educational event reporting requirements were implemented from 1 July 2007.

cost, the number of participants at the meeting and the total cost of the meeting (including venue hire, audio visual costs etc).

- A report on all healthcare professional consultancies engaged by companies over a one year period, including the total consulting fees paid, a description of any hospitality, travel or accommodation provided to a consultant and the cost, the total number of healthcare professional consultants engaged, and the total cost of the consulting services provided.
- A report listing all health consumer organisations to which a company has provided financial support and/or significant non-financial support over a twelve month period. The report must list the name of the health consumer organisation, a brief description of the nature of the support and the monetary value of the support, including assigning a value to significant non-financial support or clearly describing that non-financial support.

These new reports will be published on the Medicines Australia website. The six-monthly Advisory Board reports will be published by the end of June 2013, and the annual reports on consultancies and support for health consumer organisations will be published by the end of June 2014.

Benefits of the Code over legislation

Medicines Australia considers that effective industry self-regulation provides many benefits over imposing a regulatory regime under the *Therapeutic Goods Act 1989*, as proposed by the Bill.

The Australian Competition Tribunal accepted the significant public benefits of effective industry self-regulatory Codes in *Re Medicines Australia*.[2] The Government has also expressed its support for self-regulation of relationships between healthcare professionals and therapeutic goods companies.[3] The ACCC's own *Guidelines for developing effective voluntary industry codes of conduct* recognise the benefits of effective voluntary self-regulatory industry codes of conduct.

Medicines Australia believes that an effective voluntary code that complements and extends beyond the reach of statutory regulation is of significant public benefit. The Medicines Australia Code provides the benefits of a strong, voluntary industry code which is "best in class" both in Australia and internationally.

In relation to the scope of application of the Code:

- Medicines Australia's members supply at least 86% of the medicines supplied under the PBS and adherence to the Code is a requirement of membership of Medicines Australia.
- All prescription medicines must be registered on the Australian Register of Therapeutic Goods. As a condition of registration of prescription medicines the TGA requires that promotional materials relating to the registered goods must comply with the Medicines Australia Code.

Therefore, the Medicines Australia Code provides an effective mechanism for implementation of measures to provide transparency of interactions between healthcare professionals and companies. (See also comments in relation to a 'level playing field' below)

The Medicines Australia Code is efficiently and effectively enforced. Complaints under the Code are dealt with much more quickly by the independent complaint and appeals committees than would occur under a regulatory regime. For example, the average time to finalise a complaint from receipt to decision in 2011-2012, for all complaints, was 32 working days or approximately six and a half weeks.

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[2] Australian Competition Tribunal, *Re Medicines Australia Inc* [2007] ACompT 4 (27 June 2007), paragraph *308.*

[3] The Hon Catherine King MP, Parliamentary Secretary for Health and Ageing, Speech to the AusBiotech CEO Forum, Parliament House, Canberra, 14 March 2012.

Self-regulation is self-funded. The mechanisms that underpin the Medicines Australia Code, from education and training about the Code through to monitoring and enforcement are funded entirely by Industry and require no tax-payer funded support or enforcement resources.

By consulting with member companies and all stakeholders when revising the Code, which occurs at least every three years, broad support for the Code is promulgated. The regular review and updating of the Code ensures that the Code keeps pace with community expectations, as is reflected in the current development of a transparency model.

Support for broadening the application of the Code of Conduct

If the Senate Committee has concerns about the conduct of companies that are not Medicines Australia members and their potential impact on maintaining the integrity of the health system and safeguarding patient confidence in health care professionals, it should consider supporting mechanisms to ensure all companies involved in the sale or promotion of therapeutic products abide by a relevant industry Code of Conduct. This is consistent with the recommendations of the Trimmer Review, which specifically recommended that government implement a mechanism to ensure that all companies would be bound by a relevant industry self-regulatory code through the product registration process, whether or not the company was a member of an industry association. The Government has recently established the Codes of Conduct Advisory Group, chaired by Emeritus Professor Lloyd Sansom, to progress implementation of these initiatives and has allocated $1.4m to this work.

Implementing greater transparency through the Transparency Working Group

The *Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013* pre-empts the outcomes of the multi-stakeholder Transparency Working Group initiated by Medicines Australia, which is developing a model that will provide greater transparency over interactions between companies and all healthcare professionals.

Formation of the Transparency Working Group

When Medicines Australia members formally adopted Edition 17 of the Code at a General Meeting on 26 June 2012, members also formally resolved to develop options to provide greater transparency of relationships between industry and healthcare professionals. Members agreed to establish a working group with relevant stakeholders to develop recommendations for greater transparency.

Medicines Australia has formed the Transparency Working Group to develop measures and policies that will further enhance transparency of payments and other transfers of value between healthcare professionals and the pharmaceutical industry. The Working Group has made rapid progress to develop a recommended transparency model in a constructive and collaborative manner.

The terms of reference for the Transparency Working Group are to:

- develop principles to govern the further transparency of payments and other transfers of value between healthcare professionals and the pharmaceutical industry, with the interests of health consumers as the primary objective;
- evaluate different models for further transparency, with particular reference to initiatives associated with disclosure of payments to healthcare professionals under consideration in other countries, including the US, UK and other EU countries;
- consult with all relevant stakeholders to ensure that their perspectives are considered;

- identify efficient and effective mechanisms to promote further transparency of payments and transfers of value between industry and healthcare professionals; and
- provide a report with recommendations to each Working Group member organisation's governance board or committee. This report will also be publicly available.

The primary purpose of any further transparency measures will be to increase trust between consumers and healthcare professionals by enhancing the availability of information about payments and transfers of value between industry and healthcare professionals.

The membership of the Transparency Working Group is provided at **Attachment 3**.

Progress on transparency mechanisms

As noted above, the Transparency Working Group has made rapid progress towards developing a recommended model that will deliver transparency of payments and other transfers of value to individual healthcare professionals, by name. The draft model has been developed with consideration of the *US Physician Payments Sunshine Act* and Draft Rule, which was released for consultation in February 2013, as well as transparency initiatives under development or being implemented in other countries, including Japan, the Netherlands and the UK.

The final agreed transparency model is expected to be included in the revised edition of the Code (Edition 18) which will be submitted to the ACCC in July 2014 for authorisation. The timetable for the delivery and implementation of the Australian transparency model is provided at **Attachment 4**.

It should be noted that it has taken considerable time for the US *Physician Payments Sunshine Act* to be implemented. The legislation was signed by President Obama in March 2010 and was originally intended to be implemented by March 2013, reporting payments and transfers of value made in 2012. However, consultation about the proposed regulations which will describe the mechanisms for implementation was not initiated by the Centres for Medicare and Medicaid Services (CMS) until 19 December 2011. Following this consultation, the Draft Rule was released for final consultation on 8 February 2013. The Final Rule has not yet been published. CMS has stated that applicable manufacturers will be required to start collecting the required data from 1 August 2013, for submission to the CMS by 1 March 2014. The cost of implementing the Physician Payments Sunshine Act has been estimated by the CMS to be US$269 million in the first year and US$180 million annually thereafter, with the majority of this cost falling on manufacturers and other reporting organisations.

The Senate Committee would appreciate the significant complexity and high cost of implementing a transparency system for interactions between doctors (and other healthcare professionals) and pharmaceutical companies, as is evidenced by the implementation of the US *Physician Payments Sunshine Act*. However, the Transparency Working Group has almost completed its work, which may be implemented within the next year and a half with the support of all stakeholders.

The importance of consensus

Medicines Australia draws to the attention of the Committee to the importance of extensive and meaningful consultation with all interested stakeholders to gain consensus from stakeholders to support new transparency measures, as has been conducted by the CMS in the US and is proposed by the Transparency Working Group,.

In authorising Edition 17 of the Code, the ACCC recognised the importance of implementing further transparency measures through meaningful engagement with all stakeholders. It said:

> *The ACCC also recognises the need to consult widely with stakeholders to ensure that the framework for individual disclosure is widely supported and can be implemented in a workable and*

meaningful way. The ACCC notes that there are issues that need to be resolved to ensure its success.[4]

It should be noted that the implementation of the recommended transparency model will depend on all stakeholders (industry, healthcare professionals and consumers) agreeing to adopt and support the further transparency measures. Effective consultation with all affected parties is fundamental to the successful implementation of greater transparency measures relating to interactions between companies and healthcare professionals. Once the Transparency Working Group has finalised its recommendations for the Australian transparency model, extensive consultation with all stakeholders will be initiated. We expect this to commence in June 2013, coordinated by Medicines Australia with the assistance of the Working Group members undertaking consultation within their respective constituents.

The Transparency Working Group, by developing an Australian transparency model for inclusion in the Medicines Australia Code, will deliver the desired outcome of transparency more efficiently, more effectively, and with consensus across stakeholders.

The Bill undermines government and industry progress on transparency

In addition to undermining the substantial progress of the Transparency Working Group already discussed, the Bill also undermines efforts for industry harmonisation, and is contrary to the recommendations of the Trimmer Review.

In particular, the Bill targets medical practitioners to the exclusion of other healthcare practitioners. This is in stark contrast to the Code which covers all healthcare professionals.

Further, the Bill unjustifiably targets regulated pharmaceutical companies to the exclusion of other organisations involved in the development, sale or promotion of therapeutic products, including medical devices. The Bill perpetuates the uneven playing field, which is contrary to principles of harmonisation and is contrary to the recommendations of the Trimmer Review.

By seeking to regulate just one small aspect of industry's interactions with the health care professions, the Bill perversely carves out just one specific area of the Code. In this regard, implementation of the Bill would result in a piecemeal, inconsistent burden of government regulation overlaying self-regulation.

To ensure reform that achieves the desired policy objectives, without undermining government and industry progress, the Government should implement the recommendations of the Trimmer Review, which recommended that therapeutic product regulation should include a requirement for each sponsor to agree to abide by an applicable industry self-regulatory Code in its entirety.

The Bill also undermines the Government's own recent policy initiatives to ensure a level playing field across industry sectors and professional groups, as represented by its recently formed Code of Conduct Advisory Group. This process, chaired by Professor Lloyd Sansom, was established by the Government to, in part, work towards a common standard or level playing field across industry sectors.

As this demonstrates, there are a range of initiatives underway at the moment to achieve a more transparent and consistent regulatory framework and this Bill threatens to undermine these constructive, collaborative processes.

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[4] Determination, Applications for authorisation lodged by Medicines Australia Limited in respect of Medicines Australia Code of Conduct edition 17. ACCC, 20 December 2012, paragraph 160, page 31.

Ensuring legitimate, appropriate interactions between organisations and health care professionals

Although interactions between pharmaceutical companies and health care professionals should be subject to transparency mechanisms and industry regulation, it is important to acknowledge that these interactions are appropriate and indeed necessary to ensure patients have optimal access to new medicines.

These interactions can ensure Australian health care professionals are engaged and informed about medical developments. Further, in many instances, company sponsorship enables health care professionals to engage and information-share with international colleagues, ultimately improving health outcomes in Australia.

The Bill inappropriately presupposes that any financial transaction to a doctor is an "inducement". This is unjustified and pejorative. As a result of this unjustified and biased perspective, presupposing that these important and legitimate interactions are all inappropriate and should be unlawful, the Bill risks having a significant negative impact on public health outcomes.

The Bill is based on an outdated view

The Explanatory Memorandum to the *Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013* asserts that the Bill seeks to do several things:

- forbid payment (by pharmaceutical companies) for doctors to travel to attend educational meetings, whether held in Australia or overseas;
- ban the sponsorship (by pharmaceutical companies) of educational meetings for Australian doctors held overseas;
- "limit gifts and overly lavish hospitality"; and
- require reporting of any fees paid to a doctor or travel expenses that are paid for by a pharmaceutical company, with the reporting to be by name of the doctor.

However, the Bill is based on an outdated view of industry conduct.

The Medicines Australia Code already prohibits Australian pharmaceutical companies organising or holding their own educational meetings for Australian healthcare professionals offshore, or at exotic tropical locations (in Section 9.4 of the Code). Similarly, the professional code of conduct for doctors, administered by the Medical Board of Australia, would prohibit a doctor accepting such hospitality or travel benefits. The Explanatory Memorandum states "*In the past* (emphasis added) this has included flying doctors to events in tropical locations overseas". There is no evidence that companies are currently organising or sponsoring meetings at offshore or 'tropical locations' overseas. Medicines Australia challenges the Committee to uncover any evidence of such conduct by Australian pharmaceutical companies.

The Bill states that a gift of less than $25 in value would be acceptable and not reportable. This subsection is significantly weaker than the Code, which prohibits any form of gift to a healthcare professional, whatever the value. By way of example, the Bill would mean that the gift of a bottle of wine, a CD, a nice pen, some golf balls, a ticket to a football match or movie tickets is considered an acceptable "inducement" for doctors to attend an educational meeting. This however, is absolutely unacceptable to Medicines Australia. This is an example of the Bill potentially perpetuating and expanding the uneven playing field between members of an industry association and non-member companies.

Enshrining “inducements” in legislation is insulting to doctors and industry

The title of the proposed amendments to the *Therapeutic Goods Act* uses the word “inducements” to describe all financial transactions with doctors circumscribed by the proposed Part 5-1A. This is an extremely biased and insulting way to describe interactions between pharmaceutical companies and doctors.

In relation to companies paying for travel and/or accommodation for a doctor to attend an educational meeting, the word “inducement” improperly characterises legitimate educational experiences as resulting in an obligation on the doctor to the pharmaceutical company. To ensure appropriate patient outcomes, healthcare professionals need the opportunity to undertake reasonable levels of education and training on the use of prescription medicines. Patients want their doctors to know how prescription medicines work and how to prescribe them safely and effectively. Healthcare professionals need to have the most up-to-date information about the medicines Australians need, and it is in everyone’s interest to ensure these interactions are legitimate and transparent. If doctors and other healthcare professionals are banned from being supported to attend educational events, they won’t attend them and this will be a bad outcome for patients.

There is no “inducement” of doctors, and there is no obligation on any healthcare professional to prescribe or recommend a particular product if they attend a pharmaceutical company organised educational event. Healthcare professionals choose to attend educational meetings, and would only do so if they see value in the education being provided. These events occur mostly outside work hours. Healthcare professionals would not give up their discretionary time if they did not see the professional educational value in the meeting.

Given the distance from Australia to North America and Europe, where most major international medical conferences are held, pharmaceutical companies are providing valuable support for continuing medical education by financially supporting healthcare professionals’ attendance. There are similar issues with the distance that healthcare professionals may need to travel in Australia to attend domestic medical conferences (for example from Perth to the eastern States) – whether for company-organised conferences or third party conferences (e.g. a medical college conference). If doctors are not supported in this manner, many would not be able to attend. There is no obligation of healthcare professionals imposed or implied in return for sponsorship of their attendance at an educational meeting. The Medicines Australia Code requires transparency of reporting sponsorship of healthcare professionals to domestic and international educational meetings. It is expected that the Transparency Working Group’s recommendations will require reporting of such sponsorships (and other payments and transfers of values to healthcare professionals) by name of the healthcare professional.

Conclusion

The Bill should not be passed. It creates unnecessary regulation, red tape and cost in an area where industry, government and other community groups have already made considerable progress and it pre-empts the outcomes of the Transparency Working Group initiated by Medicines Australia. This work is aimed at achieving effective and efficient regulation without the problems and burdens created by this Bill. The Bill also seeks to ban sponsorship of activities that are important to industry-doctor interaction, the capabilities of Australian doctors and, ultimately, the welfare of Australian patients.

The Bill should be opposed and not passed by the Senate.

Attachment 1

Extract from the Introduction to the Medicines Australia Code of Conduct, Edition 17

The following **Guiding Principles** were developed and incorporated into the 2012 IFPMA Code of Practice and set out the basic standards which apply to the conduct of IFPMA Member Companies, which includes Medicines Australia Members, and their agents.

a) The healthcare and well-being of patients are the first priority for pharmaceutical companies.
b) Pharmaceutical companies will conform to high standards of quality, safety and efficacy as determined by regulatory authorities.
c) Pharmaceutical companies' interactions with stakeholders must at all times be ethical, appropriate and professional. Nothing should be offered or provided by a company in a manner or on conditions that would have an inappropriate influence.
d) Pharmaceutical companies are responsible for providing accurate, balanced, and scientifically valid data on products.
e) Promotion must be ethical, accurate, balanced and must not be misleading. Information in promotional materials must support proper assessment of the risks and benefits of the product and its appropriate use.
f) Pharmaceutical companies will respect the privacy and personal information of patients.
g) All clinical trials and scientific research sponsored or supported by companies will be conducted with the intent to develop knowledge that will benefit patients and advance science and medicine. Pharmaceutical companies are committed to the transparency of industry sponsored clinical trials in patients.
h) Pharmaceutical companies should adhere to both the spirit and the letter of applicable industry codes. To achieve this, pharmaceutical companies will ensure that all relevant personnel are appropriately trained.

In addition, the Code is consistent with the Principles described in the APEC *Principles for Voluntary Codes of Business Ethics in the Biopharmaceutical Sector (2011)*.

Attachment 2

Relationship with Healthcare Professionals

Code of Conduct Edition 17

Contents (extract)

Attachment 3

Membership of the Transparency Working Group

The Working Group is chaired by Dr Dominic Barnes, General Manager, Shire Australia on behalf of the Medicines Australia Board.

The members of the Working Group are:

Dr Justin Coleman	Royal Australian College of General Practitioners
Dr Elizabeth Feeney	Australian Medical Association
Dr Ken Harvey	CHOICE
Mr James Jones	Takeda
Professor Paul Komesaroff	Royal Australian College of Physicians
Ms Alison Marcus	Consumers Health Forum
Mr Geoff McDonald	GlaxoSmithKline Australia
Mr Roger Millichamp	Generic Medicines Industry Association
Professor Philip Morris	
Dr John Quinn	Royal Australian College of Surgeons
Ms Toni Riley	Pharmacy Guild of Australia
Dr Kay Sorimachi	Pharmaceutical Society of Australia
Ms Anne Trimmer	Medical Technology Association of Australia

Dr Brendan Shaw, Medicines Australia Chief Executive, attends as an observer.
Ms Deborah Monk, Medicines Australia, attends as the Secretariat.

Attachment 4