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19 April 2013

Committee Secretary  
Senate Standing Committee on Finance and Public Administration  
PO Box 6100  
Parliament House  
Canberra ACT 2600

Dear Secretary

Thank you for the invitation to comment on the Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013.

Janssen (the Pharmaceutical Companies of Johnson & Johnson) embraces research and science – bringing innovative ideas, products and services to advance the health and well-being of Australians. We are dedicated to addressing important unmet medical needs in areas such as oncology, immunology, neuroscience, and infectious diseases. Our company employs over 350 Australians and work conducted by Janssen has resulted in a number of critical medicines being made available to the Australian public.

Janssen is a member of Medicines Australia (MA), the peak body of the innovative medicines industry. We support and adhere to the standards set out in the MA Code of Conduct (the Code) for ethical interactions with healthcare professionals. Janssen has noted, contributed to and broadly supports MA's submission to this Inquiry.

The Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013 seeks to replace the Code with legislation that sets more stringent restrictions and reporting requirements on the interactions between pharmaceutical companies and physicians. Janssen opposes this Bill because we believe it is unnecessary, for the following reasons:

1. The innovative pharmaceutical sector is committed to continuous improvement in Industry conduct and sets the standard for other industries with respect to self-regulation;
2. The Code already contains stringent provisions to address the concerns raised in this Bill;
3. Industry supports the objective of greater transparency and is working with MA to deliver this in a timely and consultative manner; and,
4. The amendments proposed in this Bill will effectively prohibit pharmaceutical companies from providing medical education to physicians. We believe these proposals are unnecessary and may negatively impact the overall standard of health care in Australia.

## 1. Setting the standard in self-regulation

The supply and marketing of prescription medicines in Australia is governed both by statute and self-regulation. As the Committee is aware, statutory regulation applies to the approval, registration and reimbursement of medicines, as well as the prohibition of the promotion of prescription medicines to the general public. Self-regulation concerns itself with how the pharmaceutical industry interacts with healthcare professionals, consumers and the community.

A key strength of self-regulation is that it is undertaken by industry participants and therefore, likely to be well informed and responsive to innovations and changing community expectations<sup>1</sup>. The Medicines Australia Code of Conduct (the Code) was introduced in 1960 and has undergone several revisions since that time. Recent revisions of the Code, including Editions 14, 15, 16 and 17 (2003, 2006, 2009 and 2012 respectively) incorporated amendments designed to increase transparency around and further restrict member companies regarding their interactions with physicians.

Self-regulation is only credible if the code of conduct is published and available for inspection and if breaches of the code are penalised<sup>2</sup>. As the Committee may be aware, Medicines Australia promotes compliance with the Code through the following avenues:

- Conducting bi-annual reviews of educational meetings and symposia held or sponsored by member companies (requiring reports from member companies on all educational meetings);
- Publishing member company reports on the MA website;
- Issuing Annual and Quarterly Reports containing details of Code breaches and companies that have had complaints brought against them; and,
- Enforcing provisions through a package of disciplinary measures, including the imposition of monetary fines for Code breaches, from a minimum of \$50,000 to a maximum of \$250,000.

Further evidence that the Code is effective and that Industry is highly capable of self-regulation is found in the ACCC Determination authorising Edition 17 of the MA Code of Conduct. The report notes that innovative pharmaceutical company breaches of the Code do not appear to be common, nor is there any evidence of repeated breaches by any one company.

The ACCC also noted that the number of complaints received by the MA Code Committee has progressively decreased from 83 in 2007/08 to 14 in 2010/11. The number of complaints that required further investigation and therefore possible disciplinary measures has also decreased from eight in 2009/10 to two in 2010/11<sup>3</sup>.

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<sup>1</sup> Doyle, Chris (1997) Self regulation and statutory regulation. Business Strategy Review.  
<http://www.accessmylibrary.com/article-1G1-19737845/self-regulation-and-statutory.html> Accessed 8/4/2013

<sup>2</sup> Doyle, Chris (1997) Self regulation and statutory regulation. Business Strategy Review.  
<http://www.accessmylibrary.com/article-1G1-19737845/self-regulation-and-statutory.html> Accessed 8/4/2013

<sup>3</sup> Australian Competition & Consumer Commission Determination Applications for Authorisation lodged by Medicines Australia Ltd in respect of MA Code of Conduct Edition 17 Date: 20 December 2012 p. 38

Janssen believes that the level of Code compliance, as well as the Industry's demonstrable commitment to keeping pace with changing community expectations, confirms it is superfluous to enshrine the innovative Sector's interactions with physicians in legislation.

### **1.1 Self-regulation in the broader healthcare sector**

Looking beyond the research-based pharmaceutical industry and the Medicines Australia Code, Janssen understands there is broad acceptance within the sector of the need to reform the existing self-regulatory arrangements. In particular, we believe the Government supports the healthcare sector's efforts to harmonise codes of conduct and to incorporate the high level principles recommended by the 2010 Government Working Party on the Promotion of Therapeutic Products, released in March 2011.

In an effort to preserve self-regulation in the pharmaceutical industry and protect the high ethical standards set out in the Medicines Australia Code of Conduct, Janssen recommends the Government implement the Working Party's recommendations. In particular, **that therapeutic product regulation should include the requirement for each sponsor to agree to abide by an applicable industry self-regulatory code in its entirety.**

#### **Recommendation 1**

That the Committee recognises the effectiveness of the MA Code and acknowledges the innovative pharmaceutical industry's achievements in and commitment to self-regulation by opposing this Amendment

#### **Recommendation 2**

That the Government implements the recommendations of the 2010 Working Party on the Promotion of Therapeutic Products. In particular, that therapeutic product regulation should include the requirement for each sponsor to agree to abide by an applicable industry self-regulatory code in its entirety.

### **2. Existing Code provisions address the concerns of this Bill**

Janssen believes this Bill is superfluous partly because the Code already contains stringent provisions regarding the interactions between pharmaceutical companies and physicians. To illustrate this point, please see Table 1 (overleaf) which compares selected amendments proposed in this Bill with the existing standards set out in the Code.

**Table 1: Comparison of Amendment Bill and Medicines Australia Code of Conduct Edition 17**

<b>Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013</b>	<b>Existing MA Code Provisions</b>
The amendments relate to registered medical practitioners.	Provisions relate to all healthcare professionals, consumers and the general public.
The amendments seek to regulate just one aspect of pharmaceutical companies' interactions with physicians (that is, financial interactions).	Current code provisions relate to all interactions with healthcare professionals including the content of promotional materials.  Regulating just one aspect of this relationship will lead to a confusing and inconsistent combination of self-regulation (all other aspects of the Code would remain in place) and statutory regulation.
Amendment 42DR (1) is designed to curtail the possibility of a pharmaceutical company hosting an educational event in a tropical or otherwise exotic location.	Already prohibited. The Code stipulates the choice of venue must conform to professional standards of ethics and that it must not be chosen for its leisure, sporting or recreational facilities. (MA Code, Section 9.4)  Furthermore, there is no evidence that member companies are holding or sponsoring meetings within Australia or offshore at tropical locations or otherwise exotic locations <sup>4</sup> .

<sup>4</sup> Australian Competition & Consumer Commission Determination Applications for Authorisation lodged by Medicines Australia Ltd in respect of MA Code of Conduct Edition 17 Date: 20 December 2012 p.38

<p>Amendment 42DR (2) is intended to place limits on 'overly lavish hospitality'.</p>	<p>Already prohibited. The Code stipulates hospitality provided at educational events must be secondary to educational content and should not be excessive. (MA Code, Section 9.4)</p>
<p>Amendment 42DT introduces new requirements for reporting payments made to medical practitioners.</p>	<p>MA already monitors and reports on payments made to physicians with respect to educational events. Member companies provide MA with a report on all educational meetings and symposia, including details of sponsorships of physicians to attend any educational event, and details of payments to speakers to give a presentation at an educational meeting. This information is made public on the MA website bi-annually. (MA Code, Section 37)</p> <p>Please note: In its authorization for Edition 17 of the Code, the ACCC called for an increase in the level of transparency with respect to payments made to physicians. MA is addressing this issue. Please refer to the following section of this submission for further information.</p>

### 3. Working towards increased transparency

Janssen recognizes that a key objective of this Bill is to increase transparency around payments made to physicians. We are pleased to report that Industry is already working with MA to deliver greater transparency.

In 2012 Medicine's Australia Code of Conduct Edition 17 was authorised by the ACCC after rigorous scrutiny and an extensive public consultation process. The new Code of Conduct raised the level of transparency of member companies' interactions with healthcare professionals to disclose aggregate payments to doctors and consumer groups.

However, the ACCC reported that a number of stakeholders identified that the Code could be further improved by requiring pharmaceutical companies to disclose, on an individual level, payments made to healthcare professionals (consistent with developments in the United States)<sup>5</sup>. In response, Medicines Australia initiated a Transparency Working Group to develop a preeminent transparency model, working with a range of stakeholders including the AMA, CHOICE and CHF. The Group is working to swiftly address the remaining concerns raised by the ACCC on behalf of consumers. The proposed transparency model will provide essential input to the early revision of the Code (Edition 18) to be submitted to the ACCC for authorisation in June 2014.

History shows that self-regulation is the best and most efficient way of delivering transparency. This Bill and Senate Inquiry pre-empt the findings of the Working Group and the early revision of the Code. Industry will continue to work closely with healthcare professionals, patient groups and the sector to achieve the same transparency outcome as intended by the proposed Amendment Bill.

Janssen is concerned that the transparency model proposed in this Bill does not include a mechanism for physicians to check the validity of data to be published by a company about financial transactions with them. The Transparency Working Group's model will include such a provision. This measure is essential to protect the privacy and reputation of physicians and to avoid causing significant damage to relationships between physicians and Industry.

Janssen is unable to support the transparency model proposed in this Bill for the reasons explained above. We recommend the Committee advise the Government to maintain an emphasis on self-regulation by supporting the work being done by Medicines Australia.

#### **Recommendation 3**

That the Committee advises the Government to maintain an emphasis on self-regulation by supporting the work being done by Medicines Australia.

<sup>5</sup> Australian Competition & Consumer Commission Determination Applications for Authorisation lodged by Medicines Australia Ltd in respect of MA Code of Conduct Edition 17 Date: 20 December 2012 p.i

#### 4. The importance of continuing medical education

It is widely recognized that the pharmaceutical industry has a valuable and legitimate role in the healthcare sector<sup>6</sup>. Health care professionals and Industry work together when conducting research, within organisations, when providing healthcare to the community and in education and training<sup>7</sup>.

However, Janssen recognises that concerns exist within the Australian community regarding the provision of medical education and that this Bill has been drafted in an attempt to address these concerns.

Given the level of unease, we believe it is important to elucidate what medical education is and what it is not.

Medical education does not, as suggested in the Explanatory Memorandum of this Bill, involve flying doctors to events in tropical locations overseas or hosting lavish lunches or dinners for prescribers. This behavior is expressively prohibited by the Code. Nor does it involve the provision of gifts - this is also barred under the Code. Finally it does not, as suggested, threaten the integrity of prescribing medicines in Australia. Rather, we believe it improves the quality use of medicines. Medical education *is* the provision of specialized medicine information gained by pharmaceutical companies during the research and development process and from experience gained in clinical use<sup>8</sup>. This information allows healthcare professionals to make well-informed prescribing decisions.

Janssen believes it has a responsibility to provide physicians with current, accurate and balanced medical education in an ethical and professional manner<sup>9</sup>. To ensure appropriate patient outcomes, healthcare professionals need the opportunity to undertake reasonable levels of education and training on the use of prescription medicines. In turn, patients want their doctors to know how medicines work and how to use them.

This Amendment Bill prohibits pharmaceutical companies from sponsoring healthcare professionals to attend both international and domestic medical education events. Janssen believes this will make it difficult for certain healthcare professionals to attend, particularly those working in the public system or those in professions with a modest level of remuneration such as nurses. Janssen believes the resulting lack of continuing medical education will have a detrimental effect on patient outcomes.

Educational symposiums are not lavish affairs. They are held in appropriate venues such as conference centres or meeting facilities in hotels. Any meals and beverages must be appropriate for the educational content and duration of the meeting and are not excessive. Entertainment is strictly

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<sup>6</sup> The Royal Australian College of Physicians (2006), *Guidelines for ethical relationships between physicians and industry*, Third Edition, p.4

<sup>7</sup> Royal Australian College of Physicians (2006), *Guidelines for ethical relationships between physicians and industry*, Third Edition, p.4

<sup>8</sup> Medicines Australia Code of Conduct Edition 17 p. 7

<sup>9</sup> Medicines Australia Code of Conduct Edition 17 p. 42



prohibited and delegates must not be paid for their attendance at a company educational event, unless the physician is providing training<sup>10</sup>.

**Recommendation 4**

Janssen recommends the Committee oppose the amendments in this Bill disallowing pharmaceutical companies from sponsoring healthcare professionals to attend educational events as we believe this will adversely affect patient outcomes.

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<sup>10</sup> Medicines Australia Code of Conduct Edition 17 pp.36-38



## 5. Recommendations

### **Recommendation 1**

That the Committee recognises the effectiveness of the MA Code and acknowledges the innovative pharmaceutical industry's commitment to self-regulation by opposing this Amendment.

### **Recommendation 2**

That the Government implements the recommendations of the 2010 Working Party on the Promotion of Therapeutic Products. In particular, that therapeutic product regulation should include the requirement for each sponsor to agree to abide by an applicable industry self-regulatory code in its entirety.

### **Recommendation 3**

That the Committee advises the Government to maintain an emphasis on self-regulation by supporting the work being done by Medicines Australia.

### **Recommendation 4**

Janssen recommends the Committee oppose the amendments in this Bill disallowing pharmaceutical companies from sponsoring healthcare professionals to attend educational events as we believe this will adversely affect patient outcomes.

Once again, Janssen thanks the Committee for the opportunity to comment on this Amendment. Whilst we support the principle of increased transparency, Janssen opposes this Bill as we believe it is unnecessary for the reasons outlined above.

Janssen would welcome an opportunity to discuss these matters with the Committee at any future public hearings.

Please contact me if you require further information.

Yours sincerely

Chris Hourigan  
Managing Director  
Janssen Australia and New Zealand