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Committee Secretary
Senate Finance and Public Administration Committees
Chair, Senator Helen Polley
PO Box 6100
Parliament House
CANBERRA ACT 2600

Dear Committee Secretary

Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013

Thank you for providing Pfizer Australia (Pfizer)¹ with the opportunity to comment on the *Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013* (the Bill).

Pfizer is a member of Medicines Australia (MA), the peak body representing innovative pharmaceutical manufacturers. Pfizer fully supports the views expressed by MA and we urge the Committee to carefully consider and review the evidence presented in MA's submission.

The integrity of Australia's health system is of paramount importance in maintaining the quality of healthcare. We commend the Bill's sponsors on their initiative to further the transparency provisions governing Australia's healthcare system. 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.

Pfizer agrees with the intent of the Bill with respect to increased transparency. We support transparency where it serves to add value and further contributes to fostering trust. However we have grave concerns with the Bill's ability to achieve this. This Bill is a piecemeal legislative mechanism that will have limited capacity in advancing the transparency agenda in any meaningful or systematic manner. The intent and eventual implications of the Bill (should it be passed) are drastically misaligned. **We strongly urge the Committee to recommend that the *Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013* is rejected.**

We are acutely aware of the community's desire for greater levels of transparency. It is essential to Pfizer that we continue to maintain the trust and confidence of *all* parties with whom we engage. We recognise the effectiveness of our ability to succeed in this, can only ever be assessed through the eyes of the community and those with whom we engage. With this goal in mind, we take great pride in the proactive

¹ This response has been prepared by Pfizer Australia, a wholly owned subsidiary of Pfizer Inc., New York.



efforts our industry has taken to date and the mechanisms we have put in place to ensure we are as transparent and answerable to the Australian public as any other industry.

Pfizer disagrees with the **prohibitions** included in the Bill. Prohibition is unnecessary as the *Medicines Australia Code of Conduct* (MA Code) includes robust provisions covering sponsorship of healthcare professionals to educational meetings and requires detailed publication of these sponsorships. Leaving aside the fact that the Bill prohibits sponsorship of a doctor to attend an educational event and then also requires this to be reported, prohibition of support that facilitates doctors to participate in educational meetings is unnecessary and would have an adverse impact on public health. The unintended consequences are elaborated upon further in this correspondence.

Pfizer is a strong supporter of the MA Code and its charter to provide a mechanism for the pharmaceutical industry to establish and maintain an ethical culture through a committed, self regulatory approach. We are proud that the MA Code is not static but rather responsive in its ability to reflect changes in community and professional standards. The MA Code undergoes extensive review on regular basis² and is authorised by the ACCC after rigorous scrutiny and an extensive public consultation process.

Pfizer has actively championed increased transparency by encouraging other industry members to support the inclusion of greater transparency measures in the MA Code. Pfizer has been voluntarily disclosing the actual amount we provided to health consumer organisations and other not for profit organisations for the last 6 years³. We were very pleased to see a positive vote by members to include these transparency provisions in the latest edition of the MA Code.

In addition to these and other measures introduced by Edition 17 of the MA Code, MA has established the *Medicines Australia Transparency Working Group* (MA 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 membership of this working group includes representatives from the Consumers Health Forum; Australian Medical Association; Generic Medicines Industry Association; Medical Technologies Association of Australia; Pharmaceutical Society of Australia; Pharmacy Guild of Australia; Royal Australian College of Physicians; Royal Australian College of Surgeons and CHOICE amongst others.

The MA Transparency Working Group will 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. They will also consult with all relevant stakeholders to ensure their perspectives are considered. It is anticipated that the working group will provide its final recommendations by June 2013.⁴

We are aware that there is widespread community expectation of increased transparency with respect to the relationships between pharmaceutical companies and healthcare professionals. We wish to assure the Committee individual disclosure of the nature of these relationships remains a high priority for our industry. However, we believe that industry and healthcare professionals must work together to ensure that any system introduced to report these transactions is accurate, effective and not overly onerous due to the limited resources of many organisations.

We must also be considerate of healthcare professionals' personal privacy and how the information will be used. It would be damaging to implement legislated regulation without garnering the views of all parties affected, as well as giving due consideration to the practicalities of this disclosure. We therefore support the work of the MA Transparency Working Group and the Pharmaceutical Industry to find resolution to this issue through broad collaboration with relevant parties.

² The Code of conduct requires Medicines Australia to carry out a review of the provisions of the Code, after seeking input from interested parties no later than every three years. The Code was last reviewed between August 2011 and June 2012, with Edition 17 of the Code authorised by the ACCC on 20 December 2012 and coming into effect on 11 January 2013. The current edition of the Code is expected to be reviewed again and submitted to the ACCC for authorisation in July 2014.

³ These reports are available at:

http://www.pfizer.com.au/sites/au/about_pfizer_Australia/our_partnerships/Pages/PartnershipswithHealthConsumerOrganisations.aspx

⁴ MA Transparency Working Group Communiqué, 13th March 2013. Available at:

<http://medicinesaustralia.com.au/files/2012/08/20130313-comm-Transparency-Working-Group-fourth-Meeting-final.pdf>

Pfizer is disappointed to see that the Bill has been drafted with little awareness or regard for the scope and detail of existing transparency standards the industry has imposed upon itself or the proactive measures taken to further enhance these standards. We have serious concerns with the scope of the Bill; its impact on Australian patients; the inadequate reporting requirements and that the Bill in some instances is actually weaker than the existing MA Code. Our concerns in relation to these specific matters are outlined below:

- **Narrow scope of the Bill:** The scope of the Bill only relates to interactions with “*registered medical practitioners*”. The MA Code on the other hand covers all healthcare professionals, health consumer organisational and patients. Further, the Bill only relates to “*regulated pharmaceutical products*” and fails to encompass medical devices.

We are disappointed to see the missed opportunity to harmonise transparency and create a level playing field across the sector. The narrowly defined scope of the Bill fails to bind all sponsors to a recognised ethical standard and it only deals with one aspect of pharmaceutical companies’ interactions with doctors. This has the danger of leading to a piecemeal, inconsistent combination of self-regulation and government regulation.

- **Unintended consequences of the Bill:** Section 42DS(1) of the Bill would prohibit an Australian company paying a doctor to attend an educational event or pay for their travel and/or accommodation costs to attend the event.

This will adversely impact doctors and Australian patients. Australia is not only large but geographically isolated. This presents both advantages and challenges on many fronts when it comes to delivering health care. Most major international medical conferences are held in North America and Europe, while most major domestic medical conferences are held on the Eastern seaboard. Australian patients have an expectation that medical professionals continue to further their education and are well versed in the medical advances in their fields.

Our industry provides valuable support by financially supporting healthcare professionals’ attendance at medical educational events. An outright ban on sponsorship can only have a detrimental impact. If doctors are not supported in this manner, many would not be able to attend. If the Bill is passed it will be placing Australian doctors at large and more specifically those in rural Australia and on the Western seaboard at a distinct disadvantage, which in turn will negatively impact their patients. In the event that any measure to limit annual tax deductions for self-educations were to come into effect (such as the intent announced by Wayne Swann to limit the annual tax deductions for self-education to \$2,000 from July 2013) this would add additional economic barriers for educational opportunities for doctors. The adverse impact again would disproportionately fall upon remote and rural doctors.

The MA Code currently requires transparency in reporting sponsorship of healthcare professionals to domestic and international educational meetings. It is expected that the MA Transparency Working Group’s recommendations will require reporting of such sponsorships (and other payments and transfers of values to healthcare professionals) by naming of the healthcare professional.

- **Inadequate reporting requirements:** The Bill requires each company publish on their own company website their interactions with healthcare professionals. Such a proposal is fundamentally at odds with consumer demands. Through the ongoing MA Code review process, consumers have expressed that they want to have access to transparent information about interactions between healthcare professionals and companies on one centrally located website in an accessible and searchable format. Pfizer understands that the model being developed by the MA Transparency Working Group intends a single web-based location for these detailed reports. The Bill also fails to provide a mechanism for doctors to check the validity of data to be published by a company about financial transactions with them. This is essential to protect the privacy and reputation of healthcare professionals. Our understanding is the MA Transparency Working Group’s model will include such a provision.



In addition to the issues highlighted above, we are disappointed to see the Bill is weaker in some instances than the existing MA Code. For example section 43DS (2) describes what is to be regarded as a form of payment to a doctor to attend an educational meeting. According to the Bill a gift of less than \$25 is acceptable and not reportable. This is *weaker* than the existing MA Code, which prohibits any form of gift, whatever the value. In such an instance Pfizer would adhere to the higher standard as outlined in MA Code.

We have expressed earlier that Pfizer agrees with the intent of the Bill with respect to increased transparency. We support transparency where it serves to add value and further contributes to fostering trust between government, industry, healthcare professionals and patients. However the Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013 is severely limited in its capacity to do so.

Pfizer is confident our industry is well positioned to continue to strengthen our self-regulatory mechanisms. The MA Transparency Working Group, MA, and MA Member Companies working with representative bodies will deliver the desired outcome of transparency more efficiently, more effectively, with consensus across stakeholders, and with due regard to the privacy interests of doctors and their patients. At a time when the Government is looking to cut costs, the additional burden that this Bill would place on the TGA is unnecessary and would not be in the best interests of patients, Government or industry. We therefore **strongly urge the Senate Committee reject the Bill as unnecessary, inequitable and flawed in its construct.**

Pfizer thanks the Committee for the opportunity to express its view and is available at any time to provide further information or briefings if this would assist Members.

Yours faithfully

David Gallagher