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Ms Sophie Hibburd  
Secretary, Code of Conduct Committee  
Medicines Australia  
16 Napier Close  
DAKIN ACT 2600

20 September 2013

Dear Ms. Hibburd:

**RE: SUBMISSION FOR THE CODE OF CONDUCT REVIEW**

Abbott is pleased for the opportunity to provide comment on the review of the Transparency Model and Edition 18 of The Code. Abbott supports the objectives of increasing transparency and safeguarding the interest of patients.

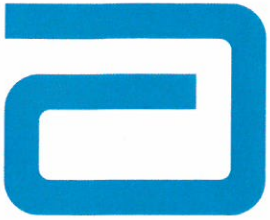
**Transparency Model**

Abbott believes that a number of issues have not yet received adequate consideration by Medicines Australia and the Transparency Working Group, and that these issues will significantly impede implementation of the Transparency Model put forth. Most significantly, it does not appear that any consideration has been given to the requirements of the Privacy Amendment Act 2012 (Cth) which comes into effect in March 2014, which could prevent companies from disclosing personal information that would be required under the Transparency Model. Additionally, the proposed timing for implementation is infeasible, as it would force companies to attempt to develop systems in the absence of final requirements, or to risk being unable to effectively track the required data on the planned start date.

***1. Timing considerations***

The proposed timeframe for implementation is impractical. Medicines Australia should consider that the ACCC will most likely endorse the 18<sup>th</sup> Edition of the Code in December 2014, yet Medicines Australia would require data collection to start on January 1, 2015. The lack of an implementation period after final requirements have been established is inconsistent with similar reporting programs. The U.S. Sunshine Act, which appears to have been the basis for much of the Transparency Model, provided for a 180 day implementation period, and the European Federation of Pharmaceutical Industries and





Association (EFPIA) HCP/HCO Disclosure Code provided for 1 full year after member associations integrate the Disclosure Code into their local country codes before data collection commenced. The Transparency Model appears to contemplate a very similar disclosure program to the Sunshine Act, with the added complication of data privacy laws, yet provides for no implementation period.

## **2. Privacy Laws**

Australia's new privacy law will go into effect in March 2014. Substantively, the obligations on companies collecting and disclosing the types of data that are contemplated under the Transparency Model are similar to the privacy laws in Europe. Due to these legal requirements, EFPIA provided for alternate mechanisms of disclosure for companies that were unable to gain consent from health care practitioners (HCPs) to disclose data. To ensure that the Transparency Model does not require companies to violate applicable law, Medicines Australia should take time to review the EFPIA Disclosure Code and consult with legal counsel to assess options.

## **3. Unique Identifier**

Medicines Australia should ensure that a unique identifier for each HCP is available for use by disclosing companies, by working with HCP associations and the government. The only current Australia-wide identifier is the AHPRA number; the use of this identification number may not be permissible under the applicable privacy laws, as it links to the HCPs' personal information

## **4. Reporting threshold**

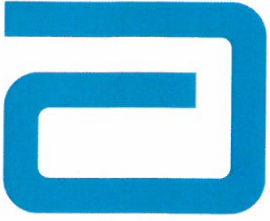
Abbott has reviewed both alternatives for Section 5.2 of the Transparency Model, and recommends adopting Alternative 1, a \$25 threshold for recording and reporting payments or transfers of value to HCPs. This option balances the burden of data collection and review by companies and HCPs with the goals of the Transparency Model.

## **5. Starter Packs**

Starter packs should be excluded from the transparency reporting as they do not represent a transfer of value to the HCP in his or her personal or professional capacity; rather, they are provided to patients to enhance treatment.

## **6. Period for Reviewing and Error Correction**

The data review process has not been clearly defined. Abbott recommends that further consultation with HCPs and other stakeholders take place to ensure an efficient and effective system of review. This process should take into account the requirements of



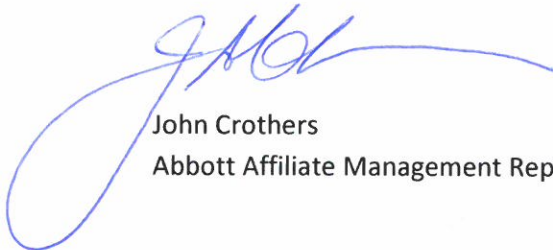
the IT system that will host the data, the time frame for reviewing and correcting the data, and whether a threshold for dispute eligibility should be imposed.

In addition, the data dispute procedure proposed has not taken the Australian Privacy Principles 12 and 13 into account, which stipulate that an individual has the right to access their personal information and request corrections of personal information at any time period and as a company we must respond to the request in a reasonable to period. Disclosing data information that is in dispute might expose companies to litigation as well as breach of law.

### **Conclusion**

Abbott recommendation that Medicines Australia takes additional time to consider a number of issues that have been raised during the consultation period, specifically the timing for implementation, privacy requirements, and the data review process. Should you have any questions please do not hesitate to contact me.

Yours sincerely,



John Crothers  
Abbott Affiliate Management Representative