

AbbVie Pty Ltd Submission to Medicines Australia Regarding Proposed Transparency Model

AbbVie is committed to working closely with healthcare professionals to improve patient health across the globe. The information exchanged through these relationships has led to newer and better therapies and, most importantly, enhanced care for patients.

We believe interactions with healthcare professionals bring value to patient care. Our interactions with them are guided by openness and transparency. This is especially important when it comes to financial payments or other forms of value provided. Demonstrating the integrity of our relationships with healthcare professionals through transparency and disclosure is an important part of these relationships.

We encourage the engagement of trade associations in transparency discussions and request they reach out to all stakeholders that may be impacted, prior to making decisions on behalf of the industry.

Whilst AbbVie is supportive of greater transparency regarding transfers of value to healthcare professionals we do have some concerns regarding the need for any changes to conform with requirements of the Privacy Act and also the practicality of the proposed model. The current lack of consensus as to the exact scope of the transparency requirements or indeed the mechanisms for declaration raises serious concerns that the proposed timelines are unrealistic and will not allow sufficient time for companies to implement the systems and processes that will be required.

In addition, AbbVie wish to submit the following comments for consideration.

1. Full consideration of the impact of privacy law

AbbVie strongly recommend that Medicines Australia obtain legal advice in relation to the transparency proposals to ensure any storage and disclosure of personal information is done in compliance with privacy legislation.

2. Removing current disclosure requirements for Educational Event Report, Summary of Advisory Board Report and Summary of Health Professional Consultancy Report

The current reporting model based on i) educational event, ii) aggregated spend on consultancy and iii) aggregated spend on advisory board should be replaced by disclosing transfer of value to a healthcare professional. Retaining these requirements could be duplicative and unnecessarily increase costs for member companies.

The current disclosure requirements for any financial or significant non-financial support to a health consumer organisation will still be beneficial to the community and should be retained.

3. Requirement for disclosing all transfer of values to Australian healthcare professionals even if payment incurred outside Australia

AbbVie recommends MA's member companies make best efforts to report any payment or transfer of value to Australian healthcare professionals even if the costs are paid by their overseas affiliates or parent company.

AbbVie is of the view that transparency model will be incomplete if members only disclose payments made by Australian companies. Many medical meetings are organised and funded by parent companies normally headquartered in US or Europe. Australian healthcare professionals invited to attend these meetings should have their sponsored expenses reported by Australian companies regardless where the costs incurred.

This will also be in line with the US Sunshine Act and EFPIA transparency reporting requirements.

4. Identifiers for healthcare professionals

AbbVie agrees with using Australian Health Practitioner Regulation Agency Registration Number for identifying healthcare professionals. Also, we agree where the field is left blank it is indicating that the company could not determine one.

5. Financial amounts for reporting purpose

AbbVie acknowledges the two alternatives recommended by the Transparency Working Group. AbbVie favours alternative 1 (i) which states payments or other transfers of value less than \$25 do not need to be recorded or reported. Payments or transfers of value of greater than \$25 must be recorded and reported. The prescribed threshold should be GST inclusive.

There should not be exemption for payments or transfer of values provided at large scale conferences and similar large scale events, where such costs can be allocated to a named healthcare professional. The additional requirement for alternative 2 (ii) providing exemption for such events is not necessary.

AbbVie does not agree the increase in threshold each year in line with the CPI as the impact will not be significant and creates difficulty for training purpose. An alternative approach is to review the threshold during Code of Conduct Review process.

6. Function costs

AbbVie does not agree that function costs (non-hospitality and non-travel costs) such as audio-visual and room hire costs should be distributed between attending healthcare

professionals. It is AbbVie's view that such costs are not a transfer of value to healthcare professionals.

7. Starter packs

AbbVie agrees that starter packs should be excluded from the transparency reporting requirements.

8. Payments associated with Clinical Research

AbbVie agrees in principle that payments associated with clinical research are excluded. However, AbbVie requests clearer definition and guidance as to what constitutes clinical research to prevent payments being hidden for transparency purposes provided under this exclusion.

9. Payments for expert witness in legal or administrative proceedings

AbbVie agrees payment for expert witness in legal or administrative proceedings are excluded.

10. Procedure for electronic submission of reports

AbbVie recommends member companies submit their reports to Medicines Australia for publication.

AbbVie agrees with the proposed 31 May each year being deadline for submission to Medicines Australia for publication by 30 June.

11. Notification

AbbVie agrees with the 45 day timeframe for healthcare professionals to review and correct information prior to disclosure.

12. Data disputes

AbbVie agrees with the recommended procedure that data must be submitted to Medicines Australia irrespective of whether there is any unresolved dispute about the data. However, the record should be marked as being "in dispute". Once the dispute is resolved, the corrected data should be submitted.

13. Data updates

AbbVie recommends that Medicines Australia "refresh" the data as soon as possible.

14. Data removal

AbbVie agrees historical data should be removed from website after five years.