

Medicines Australia Submission – Transparency Model Consultation and Discussion Paper

From: Novartis Pharmaceuticals Ltd

18th Code Edition: Transparency Model Feedback

Preamble:

In response to Medicines Australia’s (MA) Call for Submissions to the Review of the MA Code of Conduct & Invitation to participate in Stakeholder Forums, Novartis Pharmaceuticals Australia (Novartis) has prepared the below comments on the inclusions of further measures to provide transparency about payments or other transfers of value from pharmaceutical companies to healthcare professionals.

Novartis is generally supportive of the delivery of a model which introduces greater transparency to the interactions between the medicines industry and healthcare professionals and is in the best interest of the patient. However, careful consideration must be made for the resource and cost implications for increased recording and monitoring activities as outlined in the model for all involved parties, and weighed up against the intended outcomes.

Novartis is specifically supportive of some elements of the MA Transparency Model, however would suggest that in its entire current format cannot possibly be implemented in the proposed timeframe, and would therefore advocate a focus on the recording and reporting of all interactions under formal contractual arrangements with healthcare professionals irrespective of value.

Further implications of the Transparency Model highlighted by the MA Chief Financial Officer Group are supported by Novartis and accordingly are not reproduced here.

Scope

Novartis agrees that this should apply to all therapeutic goods companies, not just members of Medicines Australia. Novartis recommends that a third party is responsible for managing the transparency reporting, which provides all doctors with equal standing and circumvents the perception of biased behaviour by any one participant.

Reportable Information

Healthcare professional identifiers

In consideration of the *Privacy Amendment (Enhancing Privacy Protection) Act 2012 (Cth)*, Novartis suggests that all publicly disclosed interactions between the medicines industry and healthcare professionals must be subject to a signed contractual agreement between the pharmaceutical company and the healthcare professional.

Novartis also suggests that this Model be reviewed and ratified in its entirety by legal experts, as well as the Australian Privacy Commissioner, to ensure compliance with Australian legislation and Privacy requirements.

The Transparency Model suggests that healthcare professionals may be identified through use of the Australian Health Practitioner Regulation Agency (AHPRA) registration number. The legality of this must also be assessed in the context of the *Privacy Amendment (Enhancing Privacy Protection) Act 2012 (Cth)*. Additional consideration should be given to the recording and reporting of interactions with overseas healthcare professionals to whom an Australian-based identifier does not apply.

Categorisation of Payments

The level of reporting suggested will likely require a major change in internal IT infrastructure for a number of pharmaceutical companies. Additional resources will be necessary to maintain the new information for recording and reporting, and alignment must be sought across a number of different operating systems, making these changes logistically challenging.

Novartis believes that the imposition upon healthcare professionals, the medicines industry and a third party responsible for overview a model which utilises monetary thresholds to make accountable involved parties, will result in an administrative burden so onerous, that it will be unfeasible to implement in the proposed timeframe, and will be most challenging to sustain in the longer term.

Novartis suggests reportable information to include only the following categories:

- The provision/reimbursement of Air travel, Registration Fees and Accommodation in association with sponsoring Healthcare Professionals to attend Educational events (Australian and International);
- All Speaking fees; and Consultancies
- All Medical Practice Activities supported by the Company including Grants and other Financial Support
- Agreement of a Healthcare Professional to Act as an Expert Witness on Behalf of a Company

Given this proposed reporting substantially overlaps with existing reporting requirements; “the Medicines Australia Educational Event Reporting” Novartis proposes these new reporting requirements replace the existing requirements. Concurrent reporting would place an undue burden on each company and the different bases of calculation for the reports could be confusing to users of the reports.

Payments to third parties, including registered charities

The proposed Redirection of income as a gift, or transferring income to a third party requires formal tax review under the current tax legislation. For Novartis, any payments for services must be paid to the provider of the service.

Timeframe for Implementation

If the Transparency proposal were to be adopted as proposed, Novartis considers that a minimum time period of 18-24 months is required in order to implement mechanisms to first record

information in accordance with the Transparency model. The 18-24 month implementation timeframe arises as this will require extensive local and regional system changes, which are very expensive to introduce, and such changes are only implemented when a legal change is mandated. Thus, if the Transparency Model definition is endorsed by the Australian Competition and Consumer Commission (ACCC) in late 2014, endorsing the final design and collection of the data, first collection of data would only be appropriate for Novartis in January 2017 and first reporting in mid-2018. This timeline also assumes there is a full definition for the central collation repository available at the time of endorsement by the ACCC.

If the Novartis recommendations were to be adopted, the timelines for adoption would be significantly reduced (by possibly 12 months) from those outlined above.

Procedures for electronic submission of reports

The proposed dates for submissions follow a calendar year cycle. Novartis would prefer not to use calendar year cycles for collation to avoid resourcing issues with their financial reporting cycles.

Period for review and error correction

Novartis recommends that the time allocated to healthcare professionals to confirm or dispute company identified errors in data should be extended to 45 days in accordance with the broader review timeframes suggested, and to allow for some flexibility for those who may be on leave or otherwise temporarily detained.

Novartis also recommends educating healthcare professionals on this process (including how to dispute data and the relevant timeframes) in the lead-up to the release of the Transparency Model. This would preferably be conducted by a third party which makes it clear that active participation is required by all healthcare professionals. Individual companies undertaking this type of education may cause an inconsistent roll-out, and could reflect poorly on individual companies.

Conclusion:

Novartis is prepared and willing to undertake the necessary measures to deliver an ethical means of increasing transparency in our interactions with healthcare professionals in the interest of Australian patients and their health.

Novartis believes that the greatest challenge to successful implementation of this model is the undue administrative burden placed upon companies, healthcare professionals and other impacted third parties by the high level of reporting required for low value transactions. In the interest of increasing transparency effectively, the medicines industry must ensure that the proposed model is both workable in the short term and sustainable in the long-term.