

Transparency Model- Company submission

Company's comments in blue font

Glossary – no comments

1. General Requirement: Payments or other transfers of value – no comments
2. Limitations

Companies are only required to report payments or other transfers of value that are related to prescription medicines.

Companies that have separate operating divisions that do not supply prescription medicines for human use (for example, animal health divisions) are only required to report payments to healthcare professionals related to prescription medicines.

Comments

This practice will put MA members at disadvantage compared to non-MA members or non-prescription products

Some companies may consider to drop out from MA membership for these reasons

Some companies may reduce the number of educational events, or stop running them

HCPs may feel invasion of privacy, which may lead to a big drop to educational meetings attendance

Transparency should be put in context of education received, not only monetary value perceived. For example, the total cost of an international KOL speaker (if spread across all attendees) will be significantly higher than, say, a territory-based, 'local' dinner meeting. How will the different levels/quality of medical education be communicated & understood by the public, etc?

General Requirement & Limitations: Scope of the transparency model

The transparency model has been developed with the intention that it will be included in the Medicines Australia Code of Conduct. It therefore is limited to payments or other transfers of value related to prescription medicines. However, the TWG believed that the Transparency Principles it developed are applicable to all therapeutic goods companies, not just members of Medicines Australia.

The transparency model gives the option of Medicines Australia receiving the reports of payments and transfers of value. Other options were discussed by the TWG, such as publication by a relevant third party organisation (for example, the Australian Health Practitioner Regulation Agency (AHPRA) the organisation responsible for the implementation of the National Registration and Accreditation Scheme across Australia, which regulates 14 health professions under the National Registration and Accreditation Scheme) or the establishment of a separate Foundation to manage the reports, as has occurred in The Netherlands. These options may facilitate expansion of the scheme beyond members of Medicines Australia. They may also raise concerns with some stakeholders, for example concern that a government regulatory agency might receive data about payments from commercial businesses to individual healthcare professionals.

What are the advantages and disadvantages of these different options for who should receive and publish the reports? **If MA member companies have to report, MA should be the reporting body**

Are there other options that should be considered?

What is your preferred option for management of the transparency reports? [Medicines Australia should be the body managing the transparency reports](#)

3.3 Identifiers for healthcare professional recipients. The Australian Health Practitioner Regulation Agency (AHPRA) Registration Number. If a Registration Number cannot be identified for a healthcare professional, the field may be left blank, indicating that the company could not determine one.

[Will have to carefully study this option, as privacy law does not allow use of identifiers by 3rd parties. Companies should not be responsible for gathering private information and checking this information. What happens if a HCP does not give permission for his/her information to be publicly available?](#)

3.5.1 For payments or other transfers of value made over multiple dates (rather than as a lump sum), companies may either report each payment or other transfer of value as separate line item using the dates the payments or other transfers of value were each made, or report the payment as a single line item for the total payment or other transfer of value using the first payment date as the reported date.

[Lump sum over a threshold should be reported rather than each individual transaction](#)

3.7 Category of payment or transfer of value.

The category of each payment or other transfer of value as described below. The company must categorize each payment or other transfer of value using one of the categories listed below, using the designation that best describes the category of the payment or other transfer of value. If a payment or other transfer of value could reasonably be considered as falling within more than one category, the company should select one category that it deems to most accurately describe the category of the payment or transfer of value.

- a) Consulting fee
- b) Payment or transfer of value for services other than consulting, including serving as faculty, a chairperson or a speaker at a Code compliant educational event
- c) Honorarium [for advisory board attendance.](#)
- d) Food and beverage
- e) Travel and accommodation (including the destination (town or city))
- f) Education = [registration fees?](#)
- g) Market research [Companies do not know who the HCPs are. Not reportable](#)
- h) Charitable contribution (see also Section 3.8)
- i) Royalty or licence fee
- j) Current or prospective ownership or investment interest
- k) Grant

Reporting threshold

There was considerable debate within the TWG regarding the monetary level below which companies would not be required to record a payment or transfer of value or to report them. [Companies should be recording transactions above \\$25 and reporting for sums above \\$250 for the year](#)

[Anything less will be posing an extreme administrative workload and systems to companies that will not translate the added benefit](#)

[Current practice is to report hospitality costs, etc based on RSVPs, rather than on actual attendees. Actual costs/head based on attendees rather than RSVPs may be significantly](#)

higher, and yet the 'value' received by each attendee remains unchanged irrespective of the number of attendees. Conversely, if the costs are based on RSVPs, we would be attributing a value transfer to customers who didn't attend & thus in reality received nothing. How will this be reconciled under the transparency model?

Should function costs (non-hospitality and non-travel costs) be distributed amongst the delegates or attendees at a meeting, and therefore included in the information about payments and transfers of value?

We believe this should not be reported to the individual, as companies will already report this costs in the educational events report

What are the practical implications of different thresholds for recording and reporting of payments and transfers of value, for both companies and healthcare professionals? What time period needs to be allowed for companies to implement mechanisms to record and report information?

Companies will have to add a lot of resources, monetary, technical and human, to be able to comply with these requirements. Smaller companies may not have the ability to comply with such high requirements

Does this differ depending on the thresholds set, or not? Yes, very much.

What are the risks associated with setting the threshold too high or too low? If the threshold is too low, it dilutes the message to the public and the associated costs of gathering all that information are too much

Do you agree that changing the threshold each year in line with the CPI is appropriate? Is there an alternative approach that you would recommend? May be every 3 years? If annual inflation is 3%, the proposed \$25 threshold would only move to \$25.75 – this could entail an additional administrative burden with little meaningful difference in outcome

Do you agree that starter packs should be excluded from the transparency reporting requirements? Yes

6. Procedures for electronic submission of reports

As noted above in relation to Sections 1 and 2 of the transparency model, the model gives the option of Medicines Australia receiving the reports of payments and transfers of value. Other options were discussed by the TWG.

What are the advantages and disadvantages of these different options for who should receive and publish the reports? Medicines Australia should be the body managing these, especially for member companies

Are there other options that should be considered?

What is your preferred option for management of the transparency reports? Medicines Australia.MA should provide assistance, troubleshooting and resources to companies to be able to comply

Is the timeframe for submitting the reports by 31 May each year appropriate, taking into account Section 7.3 which suggests a mechanism to allow each healthcare professional to review and verify payments and transfers of value attributed to them? This should be managed by MA (HCP is contacted once to verify and check, not by every single company)

The transparency model suggests a 45 day timeframe in which healthcare professionals would have the opportunity to review and correct (where required) information recorded about them. The suggested timeframe would give companies from 31 December until 1 March each year to compile the information; healthcare professionals would have from 1 March to 15 April to review the information.

Is the timeframe for reviewing the information appropriate? [Maybe the HCPs could review their report more frequently, rather than leaving this to once a year. It will add a burden to their already very busy time schedule](#)

Do you have any suggestions for how this process could be streamlined or facilitated?

[As stated above, if the HCP receives 1 report to check, this would streamline the process, as opposed to several reports.](#)

[Companies should make this available to MA who would contact the HCP on their behalf once information has been collated](#)

[For expenditures that have not been captured in agreements, HCPs should be informed by the company about the approximate cost that will be reported so they can verify at the time.](#)

Data disputes.

The transparency model suggests that data for publication must be submitted to Medicines Australia (or whoever it is finally determined will receive and publish the data) by 31 May each year, irrespective of whether there is an unresolved dispute about the data. Once the dispute is resolved, the corrected data may be submitted and the published data will be revised.

Is this procedure fair and appropriate?

Can you suggest an alternative procedure that would ensure that accurate data is published, but the publication of information is not unreasonably delayed whilst a dispute is resolved?

[Data under dispute should not be published until it has reached resolution](#)

[HCPs may not want to act as consultants when other HCPs or other companies will be able to learn what they have been paid.](#)

[Another option is for the Code to set acceptable monetary payments for ad board attendance, consultancy...etc so all companies are in a similar range](#)

Failure by a company to report accurately and completely or to report within the required time frame may be considered to be a breach of the Code

[With the amount of information required for reporting, it will be very difficult for companies to guarantee completeness or 100% accuracy. Different levels of completeness may have to be defined.](#)

Other sections of the code:

- E-detailing: companies are now embarking on the production of e-sales aids, which are very expensive to design and produce as well as make changes. Current guidelines for the formatting of these pieces are very scarce and don't cover all options. Ipsen suggests that a working group and a forum through the Medicines Australia website could be commenced to clarify questions from different companies