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Glossary

There is a short glossary of terms used in the Transparency Model. This includes a brief explanation for terms such as "transfer of value" and who is included in the descriptor "healthcare professional".

- Are the explanations included in the Glossary sufficiently clear?
  Yes the glossary terms used in the transparency model appear adequate.
- Are there other terms used in the model which should be included in the Glossary with an explanation?
  No additional terms appear to be required.

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? Are there other options that should be considered?
  There may be distinct advantages in having a third party received and publish reports. The Australian Health Practitioner Regulation Agency is primarily responsible for the management of registration and renewal of registration for health practitioners around Australia. Publication within Medicines Australia may be more appropriate than within APRHA.
- What is your preferred option for management of the transparency reports?
  The submission and publication of reports is not likely to affect medical practitioners to any large degree. Costs and the administrative burden for submission and publication of the reports should rest with pharmaceutical companies.

3.3 Identifiers for healthcare professionals

The TWG recognised that a transparency model that will collate and report information from many companies requires a uniform, unique identifier for each healthcare professional. The model suggests that one option is to use the Australian Health Practitioner Regulation Agency (AHPRA) registration number as the unique identifier.

The option of using the AHPRA registration number would not mean that all healthcare practitioners regulated by AHPRA would be subject to the transparency model. The model defines healthcare professionals in terms of their professional activities relating to prescription medicines. For example, practitioners of Chinese medicine would not be involved in professional activities relating to prescription medicines.

- Are there other options for uniquely identifying healthcare professionals for the purpose of the transparency model? What are they and what are their advantages?
  It is with some concern that healthcare professional details will be published linking individual healthcare practitioners to transfer of value items. Whilst the principles of transparency should include the ability to identify individuals, this could be exercised at a more generic level without the publication of unique identifying details with in the public domain. Until the principles of transparency are adopted within other community sectors it appears inequitable that healthcare professionals are expected to have unique identifying details published within the public domain. The medical staff Association would like to seek what justification there is for public release of identifying details before the concept of uniquely identifying healthcare professionals is linked to transfer of value items.

- What are the practical requirements for pharmaceutical companies and healthcare professionals with respect to a unique identifier, in order to implement a transparency model?
  There may be practical implications with the registration of unique identifying details being provided to pharmaceutical companies during certain educational events. It should not be expected that healthcare professionals provide registration details to pharmaceutical companies in order to attend an educational event. The onus of collecting information should be placed on pharmaceutical companies providing the transfer of value.

Category of payment or transfer of value.

The model suggests that a company would select a category of payment or other transfer of value from the list provided, using the designation that best describes the category. It is intended that these categories should be interpreted using the ordinary meaning attributed to each term. The following provides some examples of what could be covered by the different categories:

a) Consulting fee – payment for services provided as a consultant to a company.

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 – such as a sitting fee for attending an Advisory Board meeting

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d) Food and beverage – meals and drinks. Note that hospitality such as food and beverages may only be provided to a healthcare professional in association with, and be secondary to education (Code of Conduct Sections 9.4.3 and 9.5.5)
e) Travel and accommodation (including the destination (town or city) – includes all travel costs such as flights, taxis, parking, ground transfer costs
f) Education – such as a conference registration fee
g) Market research – any payment for participating in market research
h) Charitable contribution (see also Section 3.8) – payment to a charity made in lieu of a payment to a healthcare professional
i) Royalty or licence fee – This category includes, but is not limited to, the right to use patents, copyrights, other intellectual property and trade secrets, including methods and processes. Companies could report total aggregated payment amounts for payments made under a single agreement, in order to simplify reporting.
j) Current or prospective ownership or investment interest – payments made by a company in the form of an ownership or investment interest in a company. This includes ownership or investment interests currently held by a healthcare professional, as well as ownership interests or investment that the healthcare professional has not yet exercised. It would not include ownership or investment interests that a healthcare professional has purchased themselves on the open market.
k) Grant – payment made to an individual healthcare professional to enable them to undertake a specific activity.

- Do these categories sufficiently cover the types of payments and transfers of value that occur? Are there other categories that should be added, or can some categories be deleted?
  These categories seem a reasonable representation of the types of payments and transfers of value that occur.

- Are the categories well enough defined to enable companies to categorise payments or other transfers of value?
  Yes

3.8. Payments to third parties, including registered charities.
The TWG considered different options concerning whether a payment to a third party in lieu of a payment to a healthcare professional should be attributed to the healthcare professional in any circumstance. The TWG was concerned that payments made to a selected third party should not be used as a way of avoiding transparency. On the other hand, if a healthcare professional declines to receive a payment and does not request that the payment be made to another person or organisation instead, but such a payment is made by the company of its own volition, there is an argument that the payment should not be attributed to the healthcare professional.

- Section 3.8 suggests a way to achieve a balance between these options.
  Yes this balance appears adequate particularly if a healthcare professional declines to receive a payment and the pharmaceutical Organisation makes a payment of its own volition. This should not be registered as a transfer of value.

- Is the balance right? Does Section 3.8 sufficiently explain where the balance should lie between appropriate transparency and avoiding inappropriate attribution of a payment?
  Yes

4. Requirements for payments or other transfers of value related to continuing professional development programs.
Section 4 suggests that, in very narrowly defined circumstances, payments or other transfers of value for attending or speaking at a continuing professional development program would not be required to be reported.
Grants made to professional development program organisers or medical education providers where the program is a formal CPD event would not trigger transparency reporting requirements, even it part of the grant is used by the organisers to pay for travel and accommodation of invited attendees or speakers. If a company has any role in selecting the speakers or attendees or any other influence on the educational content then the transparency reporting requirements will apply to any healthcare professional receiving a transfer of value from the company's grant.
The TWG has suggested that the standard of CPD required for Section 4 to apply would be where the program meets the *Continuing professional development registration standard* for the relevant health profession. These CPD registration standards are published on the AHPRA website: (http://www.ahpra.gov.au/Education/Continuing-Professional-Development.aspx)

- Is it reasonable to exclude payments or transfers of value associated with formal, independent CPD from the transparency reporting requirements?
  On the basis of the strictly defined circumstances listed above it would seem appropriate that grants made to professional development program organisers or medical education providers do not need to be registered as a transfer of value against attendees.
- Are the circumstances in which a payment or transfer of value to a healthcare professional in association with a CPD activity would not be required to be reported sufficiently well described and defined?
  Yes
- Are there other relevant standards for CPD that the transparency model could reference in relation to Section 4?
  No

Reporting threshold

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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. Some members of the TWG considered that the proposed reporting model should have a $10 threshold for recording payments or transfers of value to healthcare professionals; reporting would be required for annual cumulative payments or transfers of $100 or more to an individual healthcare professional. A recording threshold of $10 would capture lunches provided in a medical practice, for example, where several healthcare professionals receive the hospitality in association with a sales representative's call. These members were concerned about the provision of hospitality which, although of a relatively low monetary value, has the potential to influence healthcare professionals and create a sense of reciprocity or obligation.
Other members of the TWG considered that the proposed reporting model should have a $25 threshold for recording and reporting payments or transfers of value to healthcare professionals. These members were concerned at the complexity of capturing low level hospitality provided by sales representatives at the individual healthcare professional level. Company Chief Financial Officers (CFOs) had advised the TWG that most companies would have to build new systems to capture these data, whereas their current systems could capture and report payments or transfers of value above $25. Systems being implemented in the US to comply with the US Sunshine Act are not easily "imported" into Australian companies because the same software platforms are not used universally by a company's country affiliates.
The transparency model for consultation therefore includes both options for consultation.

Another important issue for discussion is whether non-hospitality and non-travel function costs should be allocated as a transfer of value to the healthcare professionals who have attended an educational meeting. That is, audio-visual and room hire costs etc could be distributed between attending healthcare professional delegates. Whilst some TWG members thought that these costs should not be allocated to attendees, it was also strongly argued by some members that all costs of an educational meeting should be allocated to the attendees. This view was in part due to a concern that there could be 'cost shifting' of food and beverage costs to non-reportable function costs in order to stay below the threshold for recording and reporting hospitality and other costs.
These are important issues for discussion and debate during the consultation period on the transparency model.

- What are the practical implications of different thresholds for recording and reporting of payments and transfers of value, for both companies and healthcare professionals?
  A reasonable balance between what is regarded as potentially creating a sense of reciprocity or obligation to pharmaceutical companies is required against the administrative burden associated with collecting information on "low" transfer of value items. Considering the excessive administrative burden associated with collecting information with these low value items a threshold of $25 is likely to be acceptable in the community as potentially creating a sense of obligation. The MSA does not feel strongly

about this issue as long as the administrative burden is again placed on pharmaceutical companies rather than individual healthcare professionals.

- What time period needs to be allowed for companies to implement mechanisms to record and report information? Does this differ depending on the thresholds set, or not?
  No comment
- What are the risks associated with setting the threshold too high or too low?
  See above
- 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?
  The administrative burden associated with distributing these costs and allocating the transfer of value to individual healthcare professionals would seem burdensome. Although cost shifting may be a theoretical possibility is unlikely in the opinion of the MSA that this practice would be widespread and would be easily open to scrutiny.
- 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?
  No comment

Clinical research

The transparency model suggests that payments associated with clinical research would not be required to be reported.

- Does Section 5.3 adequately describe and define clinical research activities?
  Yes

Starter packs

The transparency model suggests that the provision of starter packs for patient use, which are not intended to be sold, would be excluded from any reporting requirement.

Some members of the TWG thought that the value of starter packs provided to healthcare professionals should be reported as a transfer of value to healthcare professionals. Other members thought that these should not be captured as a transfer of value to an individual healthcare professional because that person provides them at no cost to patients. Whilst starter packs of medicines obviously have a value, the healthcare professional is not personally receiving a transfer of value.

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

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Payments for Expert witness in legal or administrative proceedings
The transparency model suggests that payments to healthcare professionals where the healthcare professional is acting as an expert witness in legal or administrative proceedings would not be required to be reported. The reason is that the medical practitioner is not retained by a company for the purpose of presenting its view, but rather as an expert to advise the court (or other tribunal).
Each State and Territory has within its Procedure Rules for Courts within that State or Territory, a code of conduct for expert witnesses. These Rules make it clear that an expert witness has an overriding duty to assist the court impartially on matters relevant to the expert witness's area of expertise. Further, an expert witness's paramount duty is to the court and not to any party to the proceedings (including the person retaining the expert witness). An expert witness is not an advocate for a party.
The alternative point of view is that the payments to a healthcare professional, whatever their purpose, should be transparent and therefore should be reported.

- What is your view on whether payments to healthcare professionals when they are acting as an expert witness should be included in or excluded from reporting requirements?
  It would seem reasonable to exclude these transfers of value.

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? Are there other options that should be considered?
  See comment above regarding medicines Australia capitalise that receiving the reports of payments. It is the opinion of the medical staff Association that identifying details linking individual healthcare providers with transfer of value should be collected but should not be released into the public domain.
- What is your preferred option for management of the transparency reports?
  See comment above
- 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? 1
  it is critical that healthcare providers have the ability to review the information collected on them and that has the potential to be published in the public domain. Rather than have a 45 day timeframe an approval from the healthcare provider of the data to be published should be considered to be built into the reporting system before reports are published.

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?
  Data should not be published without the explicit approval of healthcare professionals. An approval facility should be built into the system.
- Do you have any suggestions for how this process could be streamlined or facilitated?
  See comment above

7.4 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?
  An approval system would avoid the need for data disputes occurring. The information collected by pharmaceutical companies has the capacity to significantly influence patient perception of clinicians which may have personal (and potentially commercial) repercussions. Data dispute should not place any administrative burden on healthcare professionals and so on approval system rather than a dispute system would seem more 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?
  See comment above

Updating the information
The transparency model suggests that the information on the website will be updated at least once a year with any corrected information. However, the model does not suggest a “sunset” period, after which data would be removed from public view.

- Do you think that there should be a period after which historical information is removed from the website; for example, after five years?
  No comment