Response to the Medicines Australia Transparency Model Consultation and Discussion Paper

The following response is provided from the perspective of the regulation of medicines and poisons. The World Health Organisation states that "Effective medicines regulation promotes and protects public health by ensuring that… health professionals and patients have the necessary information to enable them to use medicines rationally; and promotion and adverting is fair, balanced and aimed at rational drug use". The community expects that the advice given or treatments prescribed are rational, in the individual patient's best interests and free from undue interests of others. It would seem that the aim of the transparency model proposed is to provide the public with some confidence that the practices of health professionals who provide their care are indeed free of undue pecuniary influence. If this is the purpose of the model, then refinements to the model should consider whether changes improve transparency in an accessible and meaningful way to improve public confidence.

Responses to the specific questions in the paper and other specific comments.

Glossary

Are the explanations included in the Glossary sufficiently clear?

In the definition of Healthcare professional, the last sentence is confusing and requires further clarification. What is Section (MM)? Why is a healthcare professional 'who is a bona fide employee of the company that is reporting the payment' excluded from reporting? What if that healthcare professional also had a second job, and was being given incentive payments by the company as a result of this second job?

Are there other terms used in the model which should be included in the Glossary with an explanation?

None identified.

General requirement and Limitations: Scope of the transparency model

The scope of the model is limited to prescription medicines. While this would suggest a reasonable risk-based approach (i.e. that the highest risk medicines are the focus), the transparency model would equally apply to other therapeutic goods, particularly those high-cost items funded by the public purse e.g. devices.

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?

The Commonwealth government through its various agencies has responsibility for the rational advertising and promotion of medicines. At the present time, an industry self-regulation model has been adopted with more hands-off government oversight. As the self-regulation body, Medicines Australia seems logical but there may be a view that this is somewhat "in house" and not providing the transparency. Also, not every therapeutic goods company is a member of Medicines Australia, so not all are bound by their Code of Conduct. Since the government is ultimately responsible for the regulatory environment, a government website – Therapeutic Goods Administration, Department of Health and Ageing, or a delegated body such as Australian Health Practitioner Regulation Agency (AHPRA) may give the public greater confidence in the transparency of the payments and transfers of value.

AHPRA may well be an appropriate host for the information because the purpose of the National Boards is to protect the public from harm related to the practices of the registered health professional. It is argued that where transfers of value are excessive, not transparent and unduly influence the practice behaviours and treatment decisions

of the health professional, then this is unprofessional practice and a matter for the relevant Board. AHPRA already has processes to manage datasets about health professionals. The limitation of this option is that not all professions involved with prescription medicines used for the treatment of humans are nationally registered, however, the majority are.

Another potentially relevant recipient and publisher of transparency reports is NPS (formerly, the National Prescribing Service). This government funded agency is responsible for promoting rational use of medicines (and other health care services) and modifying prescribing behaviours to support rational use of medicines. Since therapeutic goods companies may make payments or other transfers of value to promote their products over competitors, it would seem reasonable that the agency charged with promoting rational use has oversight of the transparency reporting. However, collecting and maintaining this kind of dataset would possible be a new activity for NPS and would require appropriate resourcing.

What is your preferred option for management of the transparency reports?

What is important is where this information is reported to and then made available to the public. As long as the means used makes the information available, any of the options above would be acceptable.

3.3 Identifiers for healthcare professionals

Are there other options for uniquely identifying healthcare professionals for the purpose of the transparency model? What are they and what are their advantages?

While the Healthcare Provider Identifier (HPI) issued through Medicare may be another option to uniquely identify healthcare providers including those who are not registered through AHPRA, this identifier is not a public identifier.

If the purpose of the identifier is to clear link all transfers of value to a specific health professional, then a multi-channel identification methodology would be required e.g. use the AHPRA identifier first then if no AHPRA identifier, use name, organisation/address and information about the person's profession or practice type. The data collected should include the type of profession of the recipient or another description of how they are known professionally in the community or a professional affiliation e.g. 'sports scientist'.

Note that since this transparency model is about prescription medicines, another possible identifier is the Medicare issued prescriber or provider number. Use of this identifier would enable governments to more readily link prescribing behaviours to transfers of value, but may be unpopular with many stakeholders.

What are the practical requirements for pharmaceutical companies and healthcare professionals with respect to a unique identifier, in order to implement a transparency model?

Where an existing unique identifier is not available, i.e. non-AHPRA registered professional, then some kind of fuzzy-logic matching should be used to give the best available match of payments to a specific professional. If the attribution is incorrect the model does have a dispute mechanism.

3.7 Category of payment or transfer of value

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?

Where do gifts fit in? If a representative of a therapeutic goods company goes to a pharmacy or a doctor's surgery and gives the pharmacist or the doctor a few pens, a notebook and a calculator after presenting information on a new drug, and if the

individual values of these gifts when added up are more than the threshold reporting value, which category is that?

The information to be reported is not capturing "why" a payment was provided. For true transparency, the public should be able to understand why the payments were made.

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

Yes, they appear to be.

3.8 Payments to third parties, including registered charities

Section 3.8 suggests a way to achieve a balance between these options. 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?

Agree with the option not to report against a healthcare professional if the healthcare professional does not request the company to make a payment to a third party. However, if the healthcare professional requests a payment to be made to a selected third party, then that third party's name should be disclosed. The paper proposes naming the organisation only, but not disclosing the name of an individual in this case. In the interests of true transparency, the individual should also be named.

4. Requirements for payments or other transfers of value related to continuing professional development programs

Is it reasonable to exclude payments or transfers of value associated with formal, independent CPD from the transparency reporting requirements?

The scenario described sounds more like event sponsorship, rather than payment to an individual healthcare professional. In this case, exclusion seems reasonable assuming this sponsorship is reported elsewhere. Note that this part of the transparency model does not included auditing approaches to check on whether non-reported CPD-related transfers of value actually did comply with all of the conditions. If it has not been recorded, how can it be audited?

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, however it may be worthwhile using the explanation in the second paragraph inside the box related to this section as an example for further clarification in the final document.

Are there other relevant standards for CPD that the transparency model could reference in relation to Section 4?

Professions whose members are not registered by AHPRA may have some comments in this area.

Reporting threshold

What are the practical implications of different thresholds for recording and reporting of payments and transfers of value, for both companies and healthcare professionals?

As soon as you make the value to be reported aggregate-able over the course of a calendar year, you are by default imposing a recording burden, which can become complicated. From a practical perspective, a one-off threshold value (per occasion) may be simpler to administer.

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?

The greater the recording burden, the more time companies are likely to need to set up their recording and reporting mechanisms. Therefore, the lower the threshold, the heavier the burden and the more time companies are likely to need to set their systems in place.

What are the risks associated with setting the threshold too high or too low?

Too high, and transparency is lost. Too low, and the recording and reporting burden becomes more onerous. A threshold amount of up to $25 is supported, as in alternative 1. Why have exclusions been suggested for amounts over this value provided at conferences? Most conference "handouts" would be below the threshold value, but the more expensive "draw prizes" should be reportable.

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?

This would depend to a certain extent on the value of those costs. The threshold amount could be imposed in these situations.

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?

Changes in line with CPI would seem to be appropriate.

Clinical research

Does Section 5.3 adequately describe and define clinical research activities?

Payments related to clinical research where ethical approval has not been sought or granted should be reported in the interests of transparency. Ethics committees would provide the transparency for payments made related to the clinical research they have approved.

Starter packs

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

In Queensland, there is a requirement under the Health (Drugs and Poisons) Regulation 1996 for wholesale representatives to keep records of all samples of restricted drugs given to practitioners. Whether starter packs are reported for transparency purposes or not, this requirement will remain. As the starter packs are generally being provided to patients at no cost it would seem reasonable for them to be excluded from transparency reporting.

Payments related to direct education of patients

In the interests of transparency and to support compliance with the current regulatory model where direct-to-consumer advertising is precluded, then the payments described under 5.5 should be INCLUDED in the reporting model

Payments for Expert witness in legal or administrative proceedings

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?

Probably should be included. There are other occasions where the health professional is not acting as an advocate for the company and is paid (such as attendance at an educational event where food is provided), so for true transparency this should be reported.

In relation to 5.12, care should be taken in this instance, where an individual employee of a company is making payments to healthcare professionals at their own

expense. There could be a suggestion of bribery, if the employee could be seen to be giving these gifts in an effort to boost their personal sales figures.

6. Procedures for electronic submission of reports

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 previous comments. An additional option would be to separate the collation/receipt of data from the publication of aggregate data i.e. data aggregated per recipient health professional that shows the companies that are the source of payments to that health professional. Medicines Australia could be the custodian of the dataset and AHPRA the publisher.

What is your preferred option for the management of the transparency reports?

As above, AHPRA probably gives the most independent solution in the interests of the public, but would need to be enhanced, and given some mechanism to record and/or report payments to healthcare providers not on their register.

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 would seem to be appropriate. The reports must be as timely as possible, but still give adequate period for review.

7. Period for review and error correction

Is the timeframe for reviewing information appropriate?

Yes, see above.

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

7.4 Data disputes

Is this procedure fair and appropriate?

The data should be transparent, but natural justice also needs to be seen to be applied. Provided the payment is flagged as being in dispute, and the healthcare professional is given the right to initiate disputes even after the review period has ended, this would appear to cover these situations.

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

No

Updating the information

Do you think there should be a period after which historical information is removed from the website; for example, after five years?

As these are financial records, five years would seem to be appropriate.

Response prepared by Medicines Regulation and Quality,
Queensland Department of Health.
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