SERVIER AUSTRALIA

19th September 2013

Deborah Monk
Secretary Code of Conduct Committee
Medicines Australia
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Dear Deborah

Submission to the Review of the Medicines Australia Code of Conduct Edition 17

Thank you for the opportunity to provide comments on the proposed model for introducing greater transparency about payments and transfers of value between companies and healthcare professionals into the Medicines Australia Code of Conduct (the Code).

This submission provides our feedback on the specific issues identified in the Transparency Model – Consultation and Discussion Paper. In addition we have provided comments on selected provisions and sections of Edition 17 of the Code and the associated Guidelines, for consideration for inclusion in Edition 18.

Servier agree to our comments being published on the Medicines Australia website.

Yours sincerely

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Submission from Servier

Review of the Medicines Australia Code of Conduct Edition 17

1. Transparency Model – Consultation and Discussion Paper

Before addressing the specific issues raised in the Discussion paper, Servier wishes to raise some general points.

1. Servier would like to stress the importance of Medicines Australia seeking legal advice on the Transparency Model. This is particularly relevant for issues such as obtaining consent from healthcare professionals for their details to be published and ensuring compliance with the *Privacy Amendment (Enhancing Privacy Protection) Act 2012* (Cth) which comes into effect on 12 March 2014. Financial advice on taxation issues related to payments and transfers of value should also be sought.
2. Servier is concerned that there is an expectation that companies will have systems in place to commence reporting on 1 January 2015, possibly down to the level of recording transactions of $10 or more. While Servier accepts the need for introducing greater transparency, it will require a complex process to capture the low level hospitality provided by sales representatives at the individual healthcare professional level. As with most companies, Servier would have to build new systems to capture these data, and construction of these databases cannot commence until the specifics of the reporting requirements are confirmed. As a result Servier suggests that the implementation of the transparency reporting is delayed until 12 months following the authorisation by the ACCC.
3. Given the huge amount of data that will be recorded in the report, Servier would like to suggest that reporting be six monthly rather than annually, as per educational events, which we believe will make the report and the verification of entries more manageable.

Point 2 Limitations

The Transparency Model limits transparency of payments and transfers of value to those related to prescription medicines. Servier feels strongly the transparency principles must also apply to generics and devices companies, and to non-Medicines Australia member companies. Not to do so will result in an anti-competitive environment for the prescription medicine industry.

Of the options considered for management of the transparency reports, Servier's preference is for AHPRA to receive and publish the data for the following reasons:

- AHPRA already has the systems and infrastructure in place for the collection and public review of data.
- All healthcare professionals are registered with AHPRA and have a unique ID number.

- The establishment of a separate Foundation would be very labour intensive and would add a substantial additional expense to the already considerable financial burden imposed by the transparency requirements. It is also questionable if this option is feasible given that final approval by ACCC will not occur until towards the end of 2014 and there is a need for the infrastructure to be functional by 1 January 2015.
- If Medicines Australia were to receive the reports the transparency requirements would have to be restricted to member companies only. As noted above, it is important that the scheme is expanded beyond the prescription medicine industry.

Point 3.3 Identifiers for healthcare professional recipients

Servier agrees that the AHPRA registration number is an appropriate identifier as this would be consistent, given ID numbers for healthcare professionals and their location vary with different vendors of data. If a different ID number was required it would extremely onerous to cross-reference to the AHPRA number.

However, it would need to be confirmed that adoption of the AHPRA number as an identifier complies with Australian Privacy Principle 9 (adoption, use or disclosure of government related identifiers) which becomes effective on 12 March 2014.

Servier would like to seek clarification on how AHPRA numbers would be obtained – would it be via the individual healthcare professional or would companies be required to purchase them from AHPRA?

Pont 3.7 Category of payment or transfer of value

(b) and (c) Speaker or chairperson fees, honorarium etc

In many cases the payment made to a healthcare professional for services rendered during a working day is intended to cover loss of income or the cost of employing a locum. Therefore the report should also record the opportunity cost lost eg if a specialist was paid to speak at a meeting interstate, the cost of the travel and speaker fee should be set against the specialist's loss of income for that day.

(d) Food and beverage

Servier foresees several practical difficulties in recording the cost of hospitality provided to healthcare professionals. As the final cost is often not known up front, how will healthcare professional give consent to an unknown cost? How will costs be apportioned for 'no shows', or for attendees who, for example, don't want dessert or to drink alcohol? Or for a sandwich lunch at a meeting where one delegate eats three sandwiches and another only eats one?

Servier suggests that there should be a standardised format for recording the cost of hospitality and gaining consent. This will make it for doctors to gain familiarity with the concept.

(f) Education

Currently the only example given for education is conference registration. Would this category also include the value of journals or textbooks provided as medical education?

(g) Market research

It should be made clear that payments for market research are only reportable if the research is being organised by the member company and the identity of the participants is known. Payments are not reportable when the market research is organised by a third party, even if by chance a company becomes aware of the identity of a participant undertaking the research.

(h) Charitable contributions

Servier does not agree that donations made to charities in lieu of payment should be reported as the healthcare professional has not gained personally. However, if a receipt was issued in the name of the healthcare professional, then it would be reasonable to report the payment.

Other categories

Servier propose a new category of Sponsorships. This would include:

- sponsorships for a healthcare professional to attend a conference where a lump sum is given and the breakdown of travel/accommodation and registration fee is unknown.
- Journal Clubs and Grand Rounds where is not possible to obtain the identity of attendees.

Do loans of equipment need to be reported and if so under which category?

Servier would also like to seek clarification regarding reporting of payments made by overseas companies to Australian healthcare professionals, if for instance an international Head Office paid an Australian healthcare professional to provide consultancy services or sit on an International Advisory Board.

Point 5 Exclusions from reporting

5.2 Reporting threshold

Servier strongly favours the adoption of Alternative 1, i.e. payments or transfers of value less than $25 need not be reported.

We believe Alternative 2 would be very difficult to implement and onerous to record and report. A threshold of $10 would capture lunches provided in a medical practice where it would be difficult to apportion costs as doctors come in and out and not all partake of the refreshments provided.

Payments of $25 and over would be more easily captured by existing infrastructure designed to record educational events and consultancy fees. Given the likelihood that the final transparency requirements will only be known at the end of 2014, it would be a huge impost to build a completely new database of the complexity required to capture items of minimal value, for example a few cups

of coffee. Companies will be very reluctant to invest in systems in advance of knowing the actual requirements.

5.2 Non-hospitality and non-travel costs

We do not agree that all function costs such as audio-visual hire, invitations and conference organisers should be allocated to individual delegates (with the possible exception of room hire). These costs are outside of the control of the healthcare professionals and do not constitute a transfer of value. As invoices are required for all expenditure it is not likely that there would be any untoward transfer of costs. Furthermore, these costs are already reported in the educational event reports.

5.3 Clinical research

Payments associated with clinical research should be exempt as the payment usually goes to an institution, not an individual. In addition reporting has the potential to dissuade participation in research and there could be issues of confidentiality if a company was required to disclose which investigators were participating in research.

The definition for clinical research needs to be more specific, does it include audits and Phase IV studies?

5.4 Starter packs

Starter packs provide no actual value to the healthcare professional and therefore should be exempt from reporting. We note starter packs are exempt under the US Sunshine Act.

Point 6 Procedures for electronic submission of reports & Point 7.2 Notification

The proposed timeframe for the reporting period is a calendar year i.e. January to December, commencing 1 January 2015, with reports to be completed by 1 March 2016 for verification by individual healthcare professionals. Servier is concerned with this deadline on two counts:

- The specific reporting requirements will not be finalised until Medicines Australia has received endorsement by the ACCC. This will most likely not occur until late 2014 which leaves insufficient time to develop a database and conduct the necessary testing and validation.
- Having the verification period commence on 1 March only allows January and February to compile the report. As many company staff take leave in January, we believe this timeframe is unworkable as a minimum of two months is required.

Servier proposes therefore that implementation of the transparency reporting is deferred until 12 months post the ACCC authorisation to allow sufficient time to build the database. In addition the reporting timeline should be extended by one month, i.e. verification takes places from 1 April to 15 May, and companies submit to Medicines Australia by 30 June.

As there is the potential for each healthcare professional to receive multiple reports for review, it would be more appropriate for the report to be made available on-line and the onus placed on the healthcare professional to review and approve.

As a final comment, Servier seeks confirmation that transparency reporting will replace existing Advisory Board and Consultancy reporting requirements.

2. Review of the Code of Conduct

Servier would like to provide the following comments on Edition 17 of the Code for review and consideration for Edition 18.

Suggested addition to the Code

It would be useful to include guidance around the promotion of a positive PBAC recommendation prior to PBS listing. For example can a positive recommendation be promoted prior to there being a confirmation of PBS listing with a specific date?

Section 1 Nature and Availability of Information and Claims

Section 1.1 of the Guidelines gives guidance on providing adequate balance for promotional claims. Servier believe this wording should be incorporated into Section 1 of the Code.

Section 2 Promotional Materials – Electronic Detailing

- Section on Electronic detailing in the Guidelines (page 47) should be incorporated into the Code as a new section, and a summary included in Table 3 (Summary of Requirements for Other Media) in the Code
- Page 47 of the Guidelines, paragraph 5: what is the definition of 'directly accessible' and 'immediately accessible' and are the same:

  The requirement for the Minimum Product Information is no longer mandatory if the full Product Information is directly accessible from within the eDetail aid. This is in line with the latest changes to the Code in Section 2, Table 3 for audiovisual material and the internet, where the need for the Minimum Product Information is no longer mandatory if the full Product Information is immediately accessible.

- Page 47, typo in paragraph 6 – delete 'not':

  Content must not be constructed in such a way that there is no loss of context by obscuring critical elements, for instance, a claim remains visible but a related qualifier statement, or other descriptive text that provides context, is hidden by a popup screen.

- Page 47, paragraph 8 should include that the Product Information must also be no more than 2 clicks away from any one screen via a hyperlink or URL. This should also be incorporated into Table 3.

Section 3.2 (e), Table 4, Section 13.8.1 and Glossary: Adverse effects

The Code refers to 'adverse effects' in Section 3.2 (e), Table 4 under Minimum Product Information, and in the Glossary under "Changes of Clinical Significance' and "Phase III Clinical trial'. No definition of adverse effects is provided.

Servier believe 'adverse effects' should be changed to 'adverse events' in line with CIOMS nomenclature.

Section 3.3 Changes of Clinical Significance

- This section gives the options for communicating changes of clinical significance to healthcare professionals. The first option is highlighting the change in the Product Information (PI) with an asterisk. Frequently asterisks have already been utilised in the PI (such as in graphs and figures), so to avoid confusion we suggest using the terminology of "a readily identifiable symbol" rather than specifying that it must be an asterisk.
- Servier notes that TGA regulations forbid alteration of the Approved Product Information. How does this fit with the requirement to highlight the changes of clinical significance?

Section 7 Starter Packs

The Code requires that records of the request, supply, return and disposal of starter packs are kept for 3 years, whereas State Regulations only require records to be kept for 2 years. Is there a reason for this discrepancy?