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Secretary Code of Conduct Committee
Medicines Australia
16 Napier Close
Deakin ACT 2600

Submission - Medicines Australia Transparency Model – Consultation and Discussion Paper

Thank you for your invitation to provide a submission to the *Transparency Model – Consultation Discussion Paper ('Model').* Our submission is issued on behalf of CSL's businesses in Australia and includes bioCSL and CSL Behring.

CSL is committed to the responsible promotion and marketing of prescription medicines and view this responsibility as vital to maintaining consumer trust in the pharmaceutical sector and to ensuring patients receive the greatest benefits from pharmaceutical products and services. This is why we are a member of Medicines Australia and a signatory to the Code of Conduct.

We acknowledge there are a range of community views on the interactions between pharmaceutical companies and healthcare professionals and we fully support the efforts of Medicine Australia, via the Transparency Working Group, to deliver greater transparency. While the changes proposed will be a significant shift in practice for Medicines Australia members, we support the underlying premise of the Model which is in the most part consistent with regimes implemented or being considered in other regions around the world.

Our full submission follows. In summary, we believe that to minimise administrative burden, avoid unintended impacts on patient care, and ensure public information meets the needs of consumers: only material payments are captured and reported; a central cost-effective technology-based reporting platform that complies with privacy requirements is utilised; and that organisations be afforded adequate lead-time to develop and embed changes.

Should any aspect of our submission require clarification, please contact Patrick Castauro, Senior Manager Corporate Responsibility on (03) 9389 2514.

Sincerely

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bioCSL

Simon Green
Senior VP and General Manager
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CSL Comments on the Transparency Model Consultation and Discussion Paper

Glossary (page 2)

The transfer of value definition seems too broad and subjective. Consider adopting a description similar to The European Federation of Pharmaceutical Industries and Associations – *Direct and indirect payments, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of prescription-only medicinal products exclusively for human use.*

Definitions for the categories of payments and transfer of value should also be stated in the glossary.

2. Limitations (page 3)

Clarity is required on the reporting obligations of an organisation's international operations/affiliates. How does the model propose to ensure an Australian organisation's affiliate/parent office in another country report on payments and transfers of value to healthcare professionals (HCPs) residing in Australia, where those transfers of value pertain to an Australian prescription medicine? Therefore, we recommend payments and transfers of value to Australian HCPs from companies operating internationally be included in the reporting, consistent with the US Physician Payment Sunshine Act approach. In its absence, this could be perceived by consumers as a potential loop-hole.

General Requirement & Limitations: Scope of the transparency model (page 3)

We believe a cost effective technology-based solution provided by a third party to manage the receipt, review and publication of records is the optimal solution. This will serve to streamline reporting and reduce the administrative burden for organisations and HCPs. Engagement of a third party authority to oversee management of a central database would encourage the expansion of the model to all therapeutic companies and professions. Furthermore, for the broader community it will bring credibility and a level of assurance to the process. Medicines Australia could facilitate submissions on behalf of member companies, providing some oversight and ensuring consistency in the quality of information. Medicines Australia could also manage the relationship with the third party on behalf of member companies, helping to streamline processes and any contractual obligations. Similar arrangements could be overseen by other industries not governed by Medicines Australia.

Consideration must also be given to the planning and implementation tasks required to deliver a robust Model. Requirements to satisfy disclosure won't be fully known until the ACCC has authorised edition 18 of the Medicines Australia Code of Conduct (which can be anytime between July – December 2014). We recommend a minimum six-month lead time post ACCC authorisation for organisations to scope and build the appropriate internal systems to fully support delivery of a robust and effective Model.

3. Information to be reported (page 4)

Additional data items, such as those required for 3.8.1 should also be listed in 3.2.

3.3 Identifiers for healthcare professionals (page 4)

Other than an AHPRA number, we are unaware of any other unique identifiers, which are served by formal verification and registration processes. There is an option to only consider HCPs that are AHPRA members, which is likely to provide the greatest coverage.

There may be implications under the Privacy laws regarding use of the AHPRA number as it is prohibited for an organisation to collect a particular Commonwealth government assigned identifier and then use that identifier to organise and match other personal information organised by reference to that same identifier. This and other privacy related implications must be considered more broadly and with consultation with appropriate privacy stakeholders before determining a final model.

We note, access by companies to AHPRA numbers is limited, and the onus will rest with HCPs to provide their AHPRA number. Along with privacy concerns, this raises issues of data integrity/accuracy and may result in the misattribution of activities to HCPs, complicating the review process. Companies typically rely on service providers to provide up-to-date HCP contact lists. Privacy laws permitting, these service providers should be supplied with the unique identifier to aid integrity of the data.

3.7 Category of payment or transfer of value (page 5)

Most of the categories as stated are sufficient and appropriate. Should our proposed amendments to 5.3 not be included, we recommend royalties and licence fees for bona fide intellectual property, which do not relate to prescription medicines, be excluded from reporting obligations. In the event this category of payment is endorsed as originally proposed, only those royalty or licence fee arrangements that come into effect after approval of the model should apply. This is because applicable agreements entered into prior to the Model becoming effective may not contain the appropriate confidentiality waivers to allow for the disclosure.

In addition, we believe each reportable activity should capture a short description, as is currently required for the disclosure of payments to Health Consumer Organisations. For example, a description to describe the purpose of a consultancy engagement or grant would help provide context around the activity. Furthermore, a description will ensure a seamless and more efficient review process and will mitigate delays borne by disputes. We believe transparency is enhanced and fully achieved by complementing the category with a description.

For items 3.5.1 and 3.5.2 we recommend the option to report the total payment or other transfer of value using the last payment date as the reported date not the first. The last payment date, should the organisation chose this method of reporting, is a more accurate record of the complete value transferred. We believe it can be misleading to report the full value when it may not have been fully received.

Overall, we believe the categories are well enough defined. We also recommend one method for the reporting of HCP payments and transfers of value. This would require reworking of item 9.10 in version 17 of Medicines Australia Code of Conduct to ensure there is no duplication in reporting effort.

3.8. Payments to third parties, including registered charities (page 7)

The reasons for excluding the name of the recipient in 3.8.2 are unclear. Furthermore, we oppose the inclusion of item 3.8.3. We see no reason why the recipient of the activity should not be disclosed, however acknowledge that the HCP should not be named as the individual played no role in determining the benefactor. Item 3.8.3 could be incorporated into edition 18 of the MA Code of Conduct as an amendment to item 14, whereby payments made to charitable organisations and other applicable third party organisations in lieu of a transfer of value to a HCP are publicly disclosed along with contributions to Health Consumer Organisations.

4. Requirements for payments or other transfers of value related to continuing professional development programs (page 7 & 8)

Given the conditions stated, we support item 4.1.

5. Reporting threshold (page 9)

We note that varying community expectations exist for other forms of disclosure thresholds, such as for Local Council members, National Health and Medical Research Council panel members and members of the Australian Parliament. For the Parliament, all Members are required to register benefits from official sources valued at $750 or more and $300 or more from private sources[1]. For the Victorian Parliament, disclosures commence when activities typically exceed $500[2]. We are supportive of a model that discloses material interactions with healthcare professionals with a threshold of $100 (annual CPI increases rounded to the nearest dollar). Furthermore, we note The European Federation of Pharmaceutical Industries and Associations have chosen to exclude 'Meals and drinks' from the final version of the "EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations" (Disclosure Code).

Significant effort will be required by companies to deliver the necessary changes to achieve compliance with Alternative 1 & 2. We believe HCPs will be significantly burdened by requirements proposed in the model, which are likely to impact consulting time with patients and may impose additional cost for the HCP.

Regarding the application of function costs, it is neither practical nor appropriate to distribute costs amongst attendees or to those who provide an intention to attend (i.e. RSVP). As with many events, function/venue space is determined by the number of individuals who have indicated interest in attending. In circumstances where the HCP is unable to attend (for e.g. work commitments, illness, travel) attributing a component of the function cost to all who expressed interest is not accurate and unfair, and likewise for the remaining participants that do attend. In the latter, where the number of intended participants does not materialise, a higher cost is unfairly allocated to those who do attend.

We believe educational meetings are critically important to the professional development and ongoing education of HCPs. Attendance at such meetings provides opportunities to share and debate scientific data and build an essential body of knowledge to enable the best possible care for patients.

[1] http://www.apsc.gov.au/aps-employment-policy-and-advice/aps-values-and-code-of-conduct/aps-values-and-code-of-conduct-in-practice/gifts-and-benefits
[2] http://www.parliament.vic.gov.au/publications/fact-sheets/1021-fact-sheet-e2-members-code-of-conduct#register of members interests

5.3 Payments for product research & development (page 10)

For clarity we propose that payments associated with pre-clinical research would also not be required to be reported. Pre-clinical research should be excluded from the Model because pre-clinical research takes place a long time before a product is ready for market, and is being prescribed by the HCP. Please also see related comments in section 3.7. Our amendments to the stated item follow.

> 5.3 Payments made under ***a pre-clinical or clinical*** research or development agreement where there is a written agreement, a research protocol, or both between the company making the payment and the healthcare professional.

5.4 Starter packs (page 10 & 11)

We support excluding product starter packs which are not intended to be sold and intended for patient use. We also note that both the US (Physician Payment Sunshine Act) and European (European Federation of Pharmaceutical Industries and Associations Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations) Models exclude starter packs as a transfer of value.

5.9 Payments or other transfers of value made to a registered charity in lieu of payment to a healthcare professional (page 11)

Please see our response to 3.8. Item 5.9 should be included as a reportable activity.

5.11 Payments for Expert witness in legal or administrative proceedings (page 11 & 12)

We support the rationale provided for the exclusion of payments under this category.

6. Procedures for electronic submission of reports (page 12)

Please see our response above to General Requirement & Limitations: Scope of the transparency model

It is unclear why the reporting period has been specified as the calendar year. We believe that compliance with the transparency model will require significant involvement and interplay with company financial systems and their resulting reporting processes. In light of this, it seems practical and efficient to align processes where possible. Therefore, we recommend utilising the Australian financial year for the reporting period. We acknowledge that not all member companies report in accordance with the Australian financial year and are flexible in this regard.

7.2 Notification (page 13)

We believe the 45 day review period is inadequate and recommend a phased approach for the review timeframe. Our view is that the review period should ensure disputed records are able to be resolved with adequate time such that only confirmed records are published (see 7.4 for further information). Disclosure of records in dispute is contrary to the spirit of full transparency.

We recommend an initial 90 day review period, inclusive of the review and management of disputed records. While we support disclosure, we believe there is significant effort required to comply with the model and believe a phased approach should be adopted whereby companies, HCPs and applicable external stakeholders are able to learn from the first publication effort. Any gaps and opportunities identified should be considered in setting a new review timeframe for the

second publication event. This may be less than the initial 90 day period set for the first publication event.

7.3 Process (page 14)

We believe the effort required by HCPs to review applicable activities must be facilitated by a technology solution. This is the most efficient and effective way for ensuring consistency and quality in the information received by HCPs from applicable organisations. This is where a unique identifier is essential.

A technology platform that facilitates the review and dispute process, alongside publication, is critical for ensuring the integrity of data and reporting.

Member companies should be able to post records to the platform (as is the case in the US), a process which could be facilitated by Medicines Australia. Until such time that the review process is closed, a HCP will have access to only those records allocated to them. The technology solution should then facilitate the management of disputed records between the HCP and the organisation, perhaps via a web based front-end, and when resolved also manage the publication of the record.

Items 7.3.1 through to 7.3.5 would be managed by the proposed technology platform.

The transfer of multiple files in varying formats, relying on conventional methods of contact such as email and phone, will be time consuming, error prone and only serve to compromise the integrity of information.

7.4 Data disputes (page 14)

As stated, we do not believe a 45 day review period is sufficient. Furthermore, we do not support the publication of activities that remain in dispute. This view is compounded by the approach that resolved disputes will not be updated until the website data is 'refreshed'. How often will data be refreshed and how will this be managed?

We believe an extended review period supported by a technology solution will ensure high quality transparency.

Item 7.4.1 should be amended to reflect an extended review period such as 90 days. Item 7.4.3 should be amended to ensure only resolved records will be published. Appropriate controls could be deployed via the technology solution to ensure disputes are promptly resolved. For example, the technology solution could alert/report all outstanding disputed records (i.e. >30 days from the date the record was flagged by the HCP as in dispute) to the HCP and organisation, or an appropriate authority for escalation. Once resolved, the technology solution will either remove the record or publish it close to real-time.

7. Errors or omissions & updating the information (page 15)

As for prior items, we believe 7.5.1 and 7.5.2 should be facilitated by an appropriate technology platform. Only when disputed records are resolved should they be published (if applicable). In the absence of a technology solution, item 7.5.2 should be amended to reflect a close to real-time update of revised information. We support the removal of historical information after 5 years.