

1 August 2014

Australian Competition & Consumer Commission
adjudication@accc.gov.au

Re: A91436-A91440 – Medicines Australia Limited - submission

The Society of Hospital Pharmacists of Australia (SHPA) is the national professional organisation for over 3,000 pharmacists, pharmacists in training, pharmacy technicians and associates working across Australia's health system. SHPA is the only professional pharmacy organisation with a strong base of members practising in public and private hospitals and other health service facilities.

SHPA offers the following comments regarding Medicines Australia's submission to the Australian Competition & Consumer Commission (ACCC) for authorisation of Edition 18 of their Code of Conduct (the Code), particularly the proposed transparency model.

SHPA acknowledges that the Code is only applicable to members of Medicines Australia. **SHPA would strongly support the broader application of aspects of the Code, in particular the transparency model, across all companies that manufacture or sponsor any medicines registered or listed in Australia.**

We are cognisant that the Code seeks to offer consumers the ability to 'assess' the degree of influence pharmaceutical companies may have over the health professionals they consult. SHPA fully supports this approach and welcomes a move towards transparent reporting of 'payment or transfer of value'. However, we believe that the intent will only be realised if the reporting categories are contextualised and meaningful to consumers.

SHPA notes that the Code touches on, but **does not** specifically address, the relationship with healthcare organisations / employer organisations. We believe the Code should include a new section on the relationship between pharmaceutical companies and healthcare organisations / employer organisations which mirrors the section relating to the relationship with individual health professionals.

In considering Edition 18 of the Code, SHPA has focused on the impact of the proposed transparency model on individual health professionals and how the model may change or drive their interaction with pharmaceutical companies. Our thoughts on Edition 18 of the Code are detailed in Appendix 1.

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Comments on Edition 18 of the Code of Conduct: Promotional Material Directed at Healthcare Professionals and relationship with the general public

SHPA reiterates statements it has made in submissions to the Therapeutic Goods Administration regarding Product Information (PI) and Consumer Medicine Information (CMI) and regulating the advertising of therapeutic goods to the general public.

“All medicines have inherent risks; just because a medicine has been deemed as ‘low risk’ is not a reason for consumers to be denied access to appropriate and accurate information. In a recent submission to TGA regarding Mechanisms to maintain the currency of approved PI and CMI we made the following statement:

“SHPA strongly believes that to support the appropriate use of **all medicines (listed and registered)** the PI and CMI should be available for all registered medicines through the TGA and preferably all listed medicines.”

SHPA believes that if a PI was available for **all registered and listed medicines** this would dramatically improve and support the appropriate advertising of therapeutic goods. The PI would detail the basis for therapeutic claims that have been verified and would therefore identify the therapeutic claims that could be made in an advertisement.”

SHPA also raised concerns regarding advertising via the internet, email, SMS and MMS. SHPA acknowledges that there may be difficulties in regulating the content as the content may emanate from outside Australia, SHPA suggests that these media should be regulated when they are used as part of a multi-media campaign. That is, that content ‘approved’ for mainstream print media or broadcast is also suitable for electronic media used as part of a multi-media campaign. In addition, sponsors or advertisers should be responsible for electronic advertisements that originate from Australia as part of a multi-media campaign.

If you would like to discuss the issues raised in this submission or require further information please contact Jerry Yik (jjyk@shpa.org.au or 03 94860177).

Yours sincerely,



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Appendix 1: Comments on Edition 18 of Medicines Australia's Code of Conduct

SHPA's comments focus on identifying a practical and efficient process that ensures health professionals are fully informed about the information that will be recorded and reported before they agree to either accept a service, attend an activity, or provide a service.

1. Principles for transparency

SHPA supports the principles for transparency described in Edition 18 of the Code.

We note that the focus is the interaction between individual health professionals and their interactions with companies and how transparency is crucial to the trust consumers have with their health professionals.

However, SHPA believes that the principles should be equally applicable to the relationship between pharmaceutical companies and healthcare organisations / employer organisations.

2. Application of the model

SHPA agrees that all 'payments and transfers of value' pertaining to travel, accommodation, invoiced fees and financial sponsorship should be recorded and that reportable items should be identified and reported on a six-monthly basis..

We also agree that six weeks is an appropriate timeframe for the health professional to review and amend the reports if necessary.

SHPA does not support allowing health professionals to opt-out of disclosure. Giving the option for health professionals to opt-out is counter-productive and goes against the spirit of the Code. **Health professionals who opt-out should be precluded from dealing with pharmaceutical companies**, as it is not in public interest for them to receive financial support without disclosing their activity. There are many other avenues for health professionals to obtain continuing education without interacting with pharmaceutical companies.

SHPA understands the choice of categories for 'payment or transfer of value' is based on an overseas model but the terminology chosen may have specific connotations in the Australian context and may have a specific meaning within Australia's taxation system.

We would suggest that the categories should clearly distinguish between those that are related to education and professional development activities and that have tax implications for the individual health professional and categories. SHPA believes this high level classification would assist:

- consumers to interpret the information that will be reported on member companies' websites;
- individual health professionals with deciding to accept invitations offered by companies and their record keeping; and
- companies in developing the activities and funding they offer to individual health professionals.

SHPA supports the amendments in Edition 18 which state that travel, accommodation and hospitality costs **MUST** be in relation to an educational event or activity. However, SHPA believes hospitality must also be a reportable item and not be specifically excluded. For example, if a pharmaceutical company paid for a health professional to attend a social event at the conclusion of a conference which involved significant hospitality, this would be not captured under the proposed arrangements.

SHPA suggests that the total ‘payment or transfer of value’ (i.e. the anticipated total cost) of an education event or professional development activity should be calculated and advertised to invitees as part of a consent / acceptance process. Health professionals would then know the dollar value of the ‘payment or transfer of value’ and the category of that value as well as that the information will be recorded in the public repository as pertaining to professional development **prior** to accepting to receive the services / activity.

The individual health professional would then acknowledge their understanding of the category and total cost to be recorded through the provision of their identification details (e.g. Australian Health Practitioner Regulation Agency (AHPRA) identification number) with their acceptance.

Equally, where ‘payment or transfer of value’ relates to a non-educational / professional development activity the health professional will understand the dollar value and the category that will be recorded **prior** to accepting to receive the services / activity or delivering the service.

We believe that this approach will minimise the concern some health professionals have with receiving any benefit from company activities (e.g. eating a sandwich at a lunchtime meeting). We also believe that reporting a total cost rather than component costs of educational events will be more acceptable to health professionals and less confusing to consumers interpreting the reported information.

However, this approach will only meet the objectives of the proposed transparency model if all costs associated with these events are included (e.g. cost of venue, materials supplied, travel and accommodation). It is also dependent upon the Code’s definition of education events / professional development activities being identical to the AHPRA definition and aligned with definitions in Australia’s taxation system.

We believe that it should be sufficient for individual health professionals to provide an identifier number (such as their AHPRA identifying number) and contact details for confirmation of the information recorded rather than their full name, position, employer, address and electronic contact details.

SHPA would also like to emphasise that when a health professional provides their identification details that this DOES NOT equate to consent for their details to be used for marketing activities and the Code should clearly make this statement.

3. Business to business trading arrangements

We note that ‘business to business trading arrangements’ are generally excluded. SHPA believes that although most of these arrangements indirectly benefit individual health professionals, there are some circumstances that consumers would perceive as directly benefiting individual health professionals as they have a financial interest in the business.

SHPA believes that the same principles detailed in the section regarding individual health professionals would be equally applicable to the relationship between pharmaceutical companies and healthcare organisations / employer organisations. The Code should include a new section on the relationship between pharmaceutical companies and healthcare organisations/employer organisations which mirrors the section relating to the relationship with individual health professionals. That is, that pharmaceutical companies report on ‘payment or transfer of value’ to business entities.

Paralleling the reporting on ‘payment or transfer of value’ to individual companies, including professional organisations, (based on ABN) would report the total cost of these values in each category such as:

- supporting professional development (e.g. grand rounds at hospitals)

- contributions to third parties to support involvement in professional development (e.g. sponsorship of national / international conferences)
- supporting practices / hospitals (e.g. purchase of refrigerator to store product, gift of laptops to business, supporting the salary of a practice nurse within the business)
- devices that support the delivery of medicines (e.g. anaesthesia machines, medicine delivery devices)
- supporting practice based research (e.g. supporting the salary of researcher)
- all starter packs and all medicines provided as part of product familiarisation programs
- offering grants through third parties (e.g. practice based research grants offered through professional organisations)
- consulting fees, honorariums royalties or license fees (if paid to the organisation rather than an individual)
- travel and accommodation, food and beverage not related to educational activities (if provided to non health professional staff of the organisation)

The reported information should be aggregated at the level of the legal entity (i.e. ABN) and signed off by a nominated person within the business / organisation (e.g. medical director, chief financial officer). This information should be available through a centralised location and not only on individual companies' websites.

SHPA believes that discount arrangements for the purchase of pharmaceuticals and agree that the support of clinical trials should not be included in this reporting framework.

SHPA believes that this approach is required to improve transparency for consumers and prevent under-reporting by individual health professionals. We also believe it would assist health service managers / hospital executive and Boards of Management to understand the extent of support offered by pharmaceutical companies to their business / organisation.

We note that the Code could be read as stating that companies must report all consulting fees, honorariums, royalties or license fees not just those paid to health professionals or healthcare organisations.

4. Management of transparency reports

SHPA believes an independent body should manage transparency reports. This would also allow for expansion of the reporting system beyond health professionals not registered through AHPRA and all companies that manufacture or sponsor any medicines registered or listed in Australia.

5. Identifiers for healthcare professionals

At this time, while the AHPRA identifying number would be sufficient to identify an individual, we are aware that Medicines Australia state they are prohibited to use government related identifiers. SHPA notes that some healthcare professionals that are not registered through AHPRA may be involved in the selection of prescribed medicines, for example dieticians involved with the use of total parenteral nutrition solutions and related products. SHPA supports the establishment of unique identifiers managed by the independent body to identify individual health professionals.

As noted above SHPA suggests the use of ABNs to identify separate legal entities / businesses.

6. Category of payment or transfer of value

SHPA believes that the total 'payment or transfer of value' related to education activities and professional development activities (including travel accommodation, food, beverages, venue etc.)

should be clearly identified and reported. We believe that there is no need to record value when the individual health professional indirectly receives value (e.g. sponsorship of a conference they attend). That is 'payment or transfer of value' is only recorded when the individual / organisation directly receives support from the company.

The terminology chosen for the remaining categories may have specific connotations in the Australian context and may have a specific meaning within Australia's taxation system. We would suggest that the terminology clearly indicates where 'payment or transfer of value' is provided to support the individual / organisation or where it is provided as a payment for services provided by the individual / organisation.

7. Payments to third parties

SHPA believes there may be tax implications for individuals where a payment to a registered charity is made on their behalf, therefore the value of such payments needs to be disclosed.

8. Continuing professional development

As noted above SHPA believes that the total 'payment or transfer of value' related to education activities and professional development activities (including travel accommodation, food, beverages, venue etc.) should be clearly identified and reported. We believe that there is no need to record value when the individual health professional indirectly receives value (e.g. sponsorship of a conference they attend). That is 'payment or transfer of value' is only recorded when the individual / organisation directly receives support from the company.

SHPA believes that a definition for formal education / professional development events should be based on the AHPRA definition / guidelines and agrees that where the company either chooses the speaker, topic or attendees that the 'payment or transfer of value' should be recorded.

9. Reporting thresholds

SHPA agrees that not all values recorded need to be reported. We also agree with the concept of reporting based on either the total value or the number of interactions. SHPA suggests that to assist individual health professionals with managing their financial affairs the reporting should be based on the financial year rather than the proposed November – April / May – October reporting periods to align with taxation requirements.

SHPA supports the recording of all interactions irrespective of the value and that interactions would be reported in 2015 IF the value was greater than \$25 or that all interactions would be reported if there are ten or more interactions during a 12 month period.

This approach would mean that individual health professionals that attend lunch time educational events organised by a company would have their attendance recorded irrespective of the catering provided or the cost of the speaker etc. But it would only be reported if the total value was above \$25 or if the individual professional attended ten such events / interacted with company representatives ten times during a 12 month period.

Similarly we would support recording of all support offered to businesses / organisations and that they would be reported if the total value was above \$1,000 or if the business / organisation interacted with company representatives ten times during a 12 month period.

10. Starter packs and Product Familiarisation Programs

Amendments to Edition 18 of the Code stipulate that authorised health professionals must consent to and authorise receipt of starter packs, but do not need to be reported on. SHPA does not believe that starter packs and medicines provided through product familiarisation programs should be excluded from the transparency reporting requirements. The value of these medicines should be recorded either against individual health professionals or the business / organisation.

11. Data recording, reporting and publication

SHPA believes that the recording and reporting process will be more efficient and data disputes minimised if the total 'payment or transfer of value' of an activity/ event / service is calculated and advertised to individual health professionals as part of a consent / acceptance process.

We also believe that the proposed six weeks for the health professional to review the information record and reported against their name is sufficient, if individuals are fully informed at the time they consent to / accept the activity/ event / service.

If the Code is expanded to include 'payment or transfer of value' to individual companies, six weeks may not be sufficient to enable review the information recorded and to be reported.

SHPA believes that from the published date, transparency reports should remain on the company's website for a minimum of seven years.