

# Submission

## *Medicines Australia Code of Conduct Review*

SEP  
2013

### About PSA

The Pharmaceutical Society of Australia (PSA) is the peak national professional pharmacy organisation representing Australia's pharmacists working in all sectors and locations. There are over 27,000 registered pharmacists,<sup>1</sup> of which approximately 80% work in the community sector.

PSA's core functions include: providing high quality continuing professional development, education and practice support to pharmacists; developing and advocating standards and guidelines to inform and enhance pharmacists' practice; and representing pharmacists' role as frontline health professionals.

### Purpose

This submission is provided by PSA to the Medicines Australia Code of Conduct Review. It includes comments on the *Transparency Model – Consultation and Discussion Paper*, prepared by the Transparency Working Group, as well as other aspects of Edition 17 of the Code of Conduct.

### Key recommendations

1. *PSA supports the implementation of a transparency model in a manner that includes or allows for:*
  - a. *implementation of education processes for pharmacists and other health care practitioners, and for consumers;*
  - b. *processes for pharmacists and other health care practitioners which are streamlined as much as possible thereby minimising any administrative workload;*
  - c. *robust but pragmatic recording arrangements;*
  - d. *data reporting which is meaningful for consumers who choose to use the information to assist in their health care decision-making;*
  - e. *refinement of the model over time based on experience and evaluation.*

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<sup>1</sup> Based on data published by the Pharmacy Board of Australia in April 2013.

*2. With regards to the inclusion of a pharmacist as a full member of the Code Committee and the Appeals Committee, PSA believes the condition of inclusion (i.e. only where a complaint relates to an activity or material directed to the practice of Pharmacy) is not appropriate given pharmacists' core role and expertise in medicines-related matters and therefore seeks to have the relevant condition removed.*

*3. PSA does not support the issuing of product starter packs as it appears that this activity continues to occur in a manner which does not fully support or promote quality use of medicines principles.*

## **Comments on the Transparency Model**

### **General comment**

PSA was involved during the development of the proposed Transparency Model and preparation of the consultation paper. PSA acknowledges the open and robust discussions which took place during this process and that the consultation paper reflects the final outcomes of the discussions of the Transparency Working Group. In particular, we believe it is important to re-iterate the statement in the consultation paper that members of the Working Group did not reach a consensus on every aspect of the model and this is apparent where options have been provided for wider discussion and comment.

PSA strongly supports greater transparency around payments and other transfers of value from pharmaceutical companies to pharmacists and other health care professionals. For pharmacists, we believe this is one important component of demonstrating professional accountability to individuals and the community and thereby being committed to upholding the reputation and public trust of the profession.

We note that similar initiatives to enhance transparency of payments are being implemented internationally but through different structures and models of data collection and reporting. Thus there is a need and desire globally for these measures to be implemented although a model which is appropriate for the Australian setting must be determined by local stakeholders.

In order to implement a model which is appropriate for the Australian health care sector and meaningful for Australian consumers, PSA believes stakeholders must be willing to be able to refine the model over time with experience and feedback. The additional administrative workload on pharmacists, other health care practitioners and industry must be able to be justified by the appropriate delivery of information which can be used by the average consumer to help inform their health care decision-making if they wish to do so. PSA is concerned that there are already reports in the US that their transparency reporting arrangements introduced through legislation may not provide the appropriate information or awareness for US consumers.

PSA therefore believes the transparency reporting arrangements must be robust but pragmatic and strongly supports inclusion of educational processes for health care practitioners and for consumers.

## Comments on specific sections

**Scope of the transparency model.** PSA understands the scope of the current proposal relates to prescription medicine companies and through the implementation of the Medicines Australia Code of Conduct. However, consistent with discussions of the Transparency Working Group, PSA re-iterates its support for transparency principles to apply to all therapeutic goods companies.

**Identifiers for health care professionals (section 3.3).** While the proposal in the consultation paper suggests the use of a health care practitioner's professional registration number (through the Australian Health Practitioner Regulation Agency) as a unique identifier for the Transparency Model, PSA notes that this arrangement may not be permissible under the Health Practitioner Regulation National Law (the 'National Law'), as in force in each state and territory.

PSA notes other identifiers are being established for use in personally controlled electronic health records and other healthcare identifiers services (e.g. through Medicare Australia or the National E-Health Transition Authority), however the use of these identifiers for other purposes may also be limited.

**Category of payment (section 3.7).** PSA would question whether royalties or licence fees (category i) would be commonly paid to individual health care practitioners by pharmaceutical companies.

**Continuing professional development (CPD) programs (section 4.1).** PSA fully supports the proposal to exempt CPD programs which have been accredited under the National Law requirements.

Importantly, we would suggest that with this exemption in place, pharmaceutical companies have significant future opportunities to partner with organisations such as PSA to contribute to formal CPD programs or activities at arms length and reduce the burden of recording and reporting requirements.

**Thresholds for exclusion from recording (section 5.2).** As discussed earlier in this submission under *General comment*, PSA supports a transparency model which consolidates payment data in an accurate and robust manner without overburdening health care practitioners. It is also paramount that the information to be made available to consumers is meaningful.

At the present time, PSA is supportive of the \$25 threshold for both recording and reporting payments or transfers of value. PSA is aware of concerns expressed by some consumer organisations that lesser dollar amounts can still potentially influence health care practitioner behaviour and data should therefore be captured from the lower threshold. However we are also aware of counter views expressed by other consumers which suggested that, rather than the low dollar value reporting, they would be satisfied if they could access information on the aggregated total amount of payment, provided they could also see the types of payments (e.g. honorarium or education).

PSA believes the lower threshold suggested in the consultation paper would be administratively onerous on industry in capturing the information and also a burden for pharmacists and other health care practitioners who will verify those records.

As stated earlier, PSA believes there should be scope to refine the transparency model over time based on experience and evaluation. We would suggest that the threshold of recording and reporting might be a key aspect of the transparency model where a commitment to review the appropriateness and relevance of the thresholds and adjust in consultation with stakeholders is made.

**Product starter packs (section 5.4).** As explained below in our comments on the current Code of Conduct, PSA does not support the use of product starter packs. It follows that we do not believe the provision of starter packs should be excluded from transparency reporting requirements.

The consultation paper states that the reasons for excluding starter packs include that the health care professional “provides them at no cost to patients” and “is not personally receiving a transfer of value”. PSA would contend that the provision of starter packs does contribute to a transfer of value from a professional perspective and can potentially impact on health care practitioner behaviour. We therefore believe this information should be included in reporting requirements so that consumers can access the information as part of their health care decision-making process.

**Publication date (section 6.2).** PSA notes it is proposed that published reports are to cover information for the preceding calendar year. We would suggest that it may be more efficient and practical for health care practitioners to be able to verify payment information in line with financial year periods.

## Comments on the Code of Conduct

### Membership of the Code Committee and the Appeals Committee

PSA notes that the membership of the Code Committee (section 22.1) and the Appeals Committee (section 28.1) was expanded in the current edition of the Code of Conduct to include one pharmacist representative, “where a complaint relates to an activity or material directed to the practice of Pharmacy”. PSA had, in the past, continually advocated for the inclusion of a PSA representative on these committees to be able to provide pharmacist views and expertise, and therefore this was a welcome amendment.

However, we remain committed to our view that a pharmacist should be included as a full member of both committees without any ‘conditions’ given that medicines are a core component of pharmacy practice. We believe pharmacist expertise would be a valuable addition in the deliberations of both committees and therefore seek consideration for modification of the relevant sections of the Code of Conduct.

### Product Starter Packs

As mentioned in previous submissions, PSA receives anecdotal feedback from pharmacist members regarding concerns with starter packs of medicines which have apparently been provided to consumers without complying with relevant labelling requirements.

We note that section 7.8 of the Code of Conduct states that “the representative should supply adhesive labels” which have been pre-printed with specific fields. However the relevant section of the accompanying Code of Conduct Guidelines (version 3; April 2013) states that this is “not a

mandatory requirement". The experience of pharmacists reported to PSA would suggest that company representatives may be following the 'non-mandatory' interpretation contained in those Guidelines more often. It is disappointing for PSA to observe that the statement in the Code of Conduct that distribution of starter packs should be conducted in accordance "with QUM principles" (section 7.1) is apparently not a core commitment of Medicines Australia's member companies.

This type of feedback from pharmacists clearly influences PSA's views. As an organisation which supports a profession whose core remit includes the 'quality use of medicines', we are therefore not supportive of the issuing of starter packs. While we understand there may be some advantages offered to consumers by the use of starter packs, on balance, we believe there are many disadvantages (by not supporting QUM) including evidence which suggests that product samples influence prescribing behaviour and increase prescribing of a particular product. There may also be other concerns such as continuity of supply (as starter packs are not sourced through standard pharmaceutical distribution channels), or inadvertently raising consumer expectation of continued therapeutic need.

## **Summary**

In summary, PSA supports the implementation of a transparency model which is feasible and not overburdened with administrative workload for pharmacists, and which is accessible and meaningful for consumers who wish to use the information as part of their health care decision-making.

PSA would be willing to work in partnership with Medicines Australia or individual companies for the delivery of consistent messages to pharmacists and to ensure processes are as streamlined as possible.

PSA would also like to continue to be involved in any evaluation or refinement of a Transparency Model.

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