

Submission to the Australian Competition and Consumer Commission

A91436-A91440 – Medicines Australia Limited

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Purpose

The Pharmaceutical Society of Australia (PSA) makes this submission to the Australian Competition and Consumer Commission with respect to Medicines Australia's request for re-authorisation of Edition 18 of the Code of Conduct (the 'Code'), a voluntary industry code of conduct for the prescription medicines industry in Australia.

About PSA

PSA is the peak national professional pharmacy organisation representing Australia's pharmacists working in all sectors and locations. There are over 28,000 registered pharmacists,¹ of which approximately 80% work in the community sector.

PSA's core functions relevant to pharmacists 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.

PSA is also a registered training organisation and offers qualifications including certificate and diploma-level courses tailored for pharmacists, pharmacy assistants and interns.

¹ Pharmacy Board of Australia. Pharmacy registrant data: March 2014. At: www.pharmacyboard.gov.au/About/Statistics.aspx

Key recommendations

- 1. PSA does not support the supply of product starter packs as it appears that this activity continues to give rise to occasions where medicines are inadvertently issued to consumers without appropriate labels or information which has the potential to impact unfavourably on patient safety and the quality use of medicines.*
- 2. PSA recommends the inclusion of a full pharmacist member in the Monitoring Committee to further enhance the quality use of medicines focus of the Committee's activities.*
- 3. PSA supports the implementation of a transparency model that allows for robust but pragmatic recording arrangements. This means processes for pharmacists and other health care practitioners are not administratively burdensome and the data captured and reported are meaningful for Australian consumers who choose to use the information to assist in their health care decision-making. It also requires a process to refine the model over time based on experience of use and evaluation.*
- 4. PSA strongly advocates for the implementation of education initiatives to inform pharmacists and other health care practitioners, as well as consumers on the transparency model.*

Specific comments on the Code of Conduct

Product Starter Packs (Section 7)

PSA understands the requirements outlined under Section 7 of the Code aim to provide for transparency and accountability of the distribution of product starter packs by authorised company representatives. Although Section 7.1 states that the manner by which starter packs are distributed must include compliance with 'quality use of medicines' principles, we note that the requirements articulated in Section 7 are, perhaps understandably, mostly around quality processes and accountability rather than a focus on patient outcomes.

PSA is aware that in some circumstances starter packs are regarded to offer advantages to consumers, for example, to assess the tolerability of a medicine, to provide immediate access to the medicine to allow prompt commencement of treatment or cost considerations. However, on balance, we believe there are many negatives which have the potential to pose unacceptable risks to patient care and/or disadvantages to the health care sector. These are further elaborated below.

Patient safety

PSA has expressed its concerns through previous submissions as a result of the feedback it receives from pharmacist members regarding starter packs of medicines. While the feedback is largely anecdotal, PSA believes that any reporting of negative experiences or outcomes suggest further efforts to address these concerns from a quality use of medicines perspective are warranted.

The two most common issues outlined to PSA are:

- the apparent supply of starter packs without an appropriate label stating doses or treatment duration; and
- the possible supply of multiple sample packs to an individual resulting in quantities which appear to exceed what would be envisaged for any of the reasons stated in the Code (Section 7.3) viz.
 - for immediate use in the surgery for relief of symptoms;
 - for the use of alternative treatments, prior to a prescription being written;
 - for after hours use; or
 - for gaining familiarisation with products.

The concerns of pharmacists expressed to PSA are usually a consequence of the experiences and confusion presented to them by consumers. Lack of written instructions has resulted in unsafe doses being consumed, inappropriate use of the medicines or duplication of therapy. Large quantities of starter packs can also add to inappropriate dosages or treatment periods. These incidents and experiences are examples of undesirable outcomes impacting on patient safety and quality use of medicines, often with the potential for further harm in the absence of intervention by pharmacists.

Although PSA is not aware of more recent data, our profession's concerns are consistent with previously published trends in calls received through the Adverse Medicine Events Line.² The authors of that study stated the need to be cognisant of disadvantages associated with the use of starter packs including, for example, the use of expensive medicines when effective and less expensive alternatives are available.

Labelling of starter packs

Section 7.8 of the Code includes relevant labelling requirements for all starter packs and includes the provision of pre-printed adhesive labels by companies to facilitate the entry of relevant details by the dispensing health care professional. Medicines Australia has also highlighted to PSA the changes that have been incorporated over the years to enhance the overall section on product starter packs.

However, the Code does not include any obligations for member companies to educate health professionals on the requirements associated with the dispensing of starter packs. Further we do not believe there are any plans by Medicines Australia to investigate other options to enable appropriate labelling of starter packs. We believe consideration of the true impact on quality use of medicines and ways to improve on any gaps is currently lacking in relation to the supply of product starter packs.

² Patounas MP., McGuire TM. Starter packs: a good start to therapy? Aust Prescr 2007; 30(1):14–16. At: www.australianprescriber.com/magazine/30/1/14/6

Although unrelated to the Medicines Australia Code, discussions are taking place with the aim of improving the safety and quality of pharmacy dispensing labels.³ In such an environment PSA strongly believes it is inappropriate to support a supply mechanism which, from time to time, results in the supply of medicines without dispensing labels or other appropriate consumer information.

Advertising through starter packs

There are reports to suggest that starter packs can play a role in the marketing of medicines despite the strict conditions attached to their procurement by health professionals. The provision of starter packs can influence the prescribing process potentially due to enhanced familiarity. That is, starter packs can influence the prescribing of one brand of product over another and this could generate a competitive advantage.

Other impacts

Several other concerns have been raised by pharmacists including the following.

- Pharmacists have reported consumer confusion or misunderstanding around the use of starter packs and whether or not ongoing treatment is needed or intended. In some instances, continuity of supply is required but the patient does not have an appropriate prescription resulting in disruption to treatment. Conversely there may be consumer expectation of continued therapeutic need when the prescriber has determined this is not necessary.
- It is reported that prescription medicine starter packs have been found to be predominantly newer and more expensive products. This has the potential to add to the cost of pharmaceuticals and the health sector or community.
- Starter packs are not sourced through standard pharmaceutical distribution channels and this may directly or indirectly add to costs in the health care system.

Membership of the Monitoring Committee (Section 32.1)

PSA notes that the purpose of the Monitoring Committee is to “promote compliance” with the Code and “thereby support the quality use of medicines”. The Code outlines that the Monitoring Committee reviews promotional materials and activities as well as information about educational meetings and symposia.

PSA re-iterates that pharmacists have a core role in all matters relating to the quality use of medicines. Despite this, the membership of the Monitoring Committee currently does not include a pharmacist member (Section 32.1).

³ Australian Commission on Safety and Quality in Health Care, NSW Clinical Excellence Commission. Improving the safety and quality of pharmacy dispensing labels. National round table report 25 Nov 2013. Sydney: ACSQHC; 2014. At: www.safetyandquality.gov.au/wp-content/uploads/2014/01/Pharmacy-Dispensing-Label-Workshop-25-Nov-2013-Report.pdf

Pharmacists can be subjected to promotional materials from Medicines Australia member companies or be the target of promotional activities at educational events. Pharmacists also receive queries from or requests for advice by consumers as a result of promotional activities that they have been exposed to.

The types of promotional activities which are not restricted to specific therapeutic areas (listed at the top of p. 68 under Section 31.2.1b) are virtually all directly relevant to pharmacists.

Given the focus of the Monitoring Committee is ultimately on the quality use of medicines and the types of activities within its scope are highly relevant to pharmacists, PSA supports and recommends the inclusion of a full pharmacist member. We believe this course of action would enhance the overall public benefit of these arrangements within the Code.

Transparency Reporting (Section 41)

General comments

PSA is in support of 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.

PSA was one of the stakeholders invited by Medicines Australia to participate in the Transparency Working Group (TWG) to provide input to the initial development of a transparency reporting model. During this process, open and robust discussions took place and agreement on many issues was achieved. However, members of the TWG were unable to reach consensus on every aspect of the model but understood that the options suggested by the group would be subjected to broader consultation.

The current application outlines Medicines Australia's decision to adopt an activity-based model of transparency which is currently being introduced across Europe. This model reportedly captures transfers of value that are significant while avoiding 'low level noise' (p. 17 of the application). PSA notes that this approach is somewhat different to the parameters discussed by the TWG particularly around thresholds of transfers of value for recording and reporting purposes for which consensus agreement could not be achieved at the time. PSA, as a member of the TWG, was not aware of Medicines Australia's decision to adopt the European model in preference to the outcomes of decisions made by the TWG.

PSA is aware that similar initiatives to enhance transparency of payments are being implemented internationally but through different models of data collection and reporting. However, whatever model is selected or adapted, PSA believes it is vital that the model implemented in Australia is appropriately tailored for the Australian health care sector and is meaningful and useful (e.g. a single web site in the public domain with robust search functionality) for Australian consumers. For this reason, we are somewhat surprised that the input of the TWG which included considerable Australian health care sector expertise appears to have been largely disregarded.

PSA therefore suggests that the implementation of the model must be closely monitored and regularly evaluated in the short term, and refined over time based on experience and feedback from health professionals and consumers. The evaluation must include consideration of

administrative workload on pharmacists and other health care practitioners and ensuring this is necessary and justified in order to deliver appropriate information to assist consumers with their health care decision-making if they wish to do so. It is also difficult to assess on paper at this stage, the true impact that a transparency model may have on industry, health professionals and consumers.

During the TWG discussions, a strongly expressed view was the inclusion of educational processes for health care practitioners and for consumers. PSA fully supports this suggestion as we believe education of all parties is fundamental to the transparency model being implemented to its fullest potential and delivering maximum benefit for consumers.

By way of example, the launch of the European transparency model is accompanied by a comprehensive public information campaign including:⁴

- online videos explaining the code and testimonials from healthcare professionals;
- a suite of helpful information leaflets and guides;
- stakeholder education events and webinars;
- best practice sharing opportunities via promotion of case studies; and
- a dedicated healthcare professionals/healthcare organisations social media campaign.

PSA is disappointed that there does not appear to be any mention in either the Code or the body of the application of plans to include or deliver educational initiatives on the Australian transparency model.

Identification of health care professionals

PSA appreciates the complexities around:

- the need to correctly identify individual health care professionals in transparency reporting;
- the inability to adopt or use government identifiers such as those issued by the Australian Health Practitioner Regulation Agency; and
- the requirement to comply with privacy legislation.

The fact that an individual health care practitioner may not consent to the publication of their personal information is clearly a barrier to the implementation of a comprehensive and detailed transparency model. However, this is one of the areas where PSA believes health professional education will be vital in communicating the purpose and benefits of transparency reporting and thereby encourage 'uptake' by individual health professionals. We re-iterate our support for the inclusion of such initiatives.

⁴ European Federation of Pharmaceutical Industries and Associations. Responsible transparency: getting ready for disclosure. Campaign launched to raise awareness of new financial disclosure rules. 2014; Apr, 14. At: www.efpia.eu/mediaroom/159/43/Responsible-Transparency-getting-ready-for-disclosure-Campaign-launched-to-raise-awareness-of-new-financial-disclosure-rules

Summary

The PSA appreciates the opportunity to provide comments on the application to re-authorise Edition 18 of the Medicines Australia Code of Conduct.

PSA continues to have concerns around the availability and use of product starter packs. We understand the rationale provided by Medicines Australia regarding the potential benefits of such packs, however, we firmly believe they do not facilitate the quality use of medicines and can potentially impact negatively on patient safety.

While acknowledging the considerable efforts invested by Medicines Australia and other affected stakeholders including PSA, we will continue to advocate for the implementation of a transparency model which is meaningful for consumers who wish to use the information as part of their health care decision-making and does not cause undue administrative burden for pharmacists and other health professionals.

PSA is happy to be involved in future work with Medicines Australia to help refine any details of a transparency model or to consider issues around product starter packs.

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PSA has no objections to this submission being made public.

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