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Government of South Australia
SA Health

South Australian Medicines Advisory Committee (SAMAC)

Medicines & Technology Policy & Programs Branch (MTPP)

Public Health & Clinical Systems Division

SA Department for Health and Ageing

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July 2014

Dear Adjudication Branch of the ACCC

RE: A91436-A91440 – Medicines Australia Limited – submission

Thank-you for the opportunity to contribute to the Review of the Medicines Australia Code of Conduct edition 18.

The South Australian Medicines Advisory Committee (SAMAC) is the peak expert committee to SA Health in the area of medicines governance and includes multidisciplinary representation from across South Australian Local Health Networks and the Department for Health and Ageing.

SAMAC and the Quality Use of Medicines South Australia working group (QUMSA) have considered the revised code of conduct. Specific comments in relation to the Code of Conduct are provided in Attachment 1. SAMAC supports the introduction of transparency reporting for interactions between healthcare professionals and the pharmaceutical industry. This is seen as a positive step towards improving the impact of industry interactions with health professionals for the general public.

SA Health has a number of policies which outline the expectations for SA Health staff when interacting with the therapeutic goods industry (www.sahealth.sa.gov.au/medicinesanddrugs go to '*Interactions with pharmaceutical, medical device and other therapeutic goods companies'*). SAMAC requests Medicines Australia give consideration to adopting the principles of these policies in their Medicines Australia Code of Conduct 18.

SAMAC would support the expansion of this code of conduct to all companies involved in the manufacture, marketing and/or supply of therapeutic goods in Australia.

If you would like to further discuss the issues raised in this submission please contact Ashley Symonds, Executive Officer, SAMAC on (08) 8204 1941 or SAMAC@health.sa.gov.au.

Yours sincerely

Emeritus Professor Lloyd Sansom AO
CHAIR
SOUTH AUSTRALIAN MEDICINES ADVISORY COMMITTEE

Attachment 1: Response to ACCC regarding the Medicines Australia Code of Conduct (18th edition) Review

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Response to ACCC regarding the Medicines Australia Code of Conduct (18th edition) Review

SAMAC and QUMSA were disappointed to see that recommendations made during earlier consultation phases have not been included in the revised Medicines Australia Code of Conduct (18th Edition).

7. Product Starter Packs:

SA Health does not encourage the use of starter packs (samples). As provided in the SA Health Policy Directive, '*Samples (Product Starter Packs)*', SA Health does not permit the acceptance of starter packs/samples by prescribers within SA Health.

SAMAC recommends that Medicines Australia give consideration to prohibiting the provision of starter packs directly to healthcare professionals in the revised Code. This recommendation aligns with the SA Health stance on product starter packs and is important for a number of reasons including:

- Patient information, including education on adverse effects, interactions, and how to take the medication (and providing a printed consumer medicines information sheet) is less likely to occur with provision of a product starter pack.
- Adequate labelling of product starter packs rarely occurs.
    - As a result the correct quantity and date of dispensing recorded may not be on the pack; if a patient overdoses this information is essential to their care/treatment.
- Dispensing of product starter packs is less likely to include a check of the adequacy of storage of the medications prior to dispensing, a check of the product's expiry date and clear labelling of the product.
- Distribution of product starter packs is inadequately documented in patient records, therefore patients may not be notified or told to discontinue if there is a product recall or new complications discovered.
- If a patient is unable to afford a medication and therefore given a product starter pack they are unlikely to get a prescription filled for continuing therapy, therefore can have abrupt discontinuation of treatment.
- Medications dispensed in a pharmacy help to identify potentially harmful drug interaction and medication errors.

Whilst discouraged, if product starter packs are still to be provided to health professionals outside of SA Health, then they must be by appropriately managed by those health professionals. SAMAC acknowledges the labelling requirements outlined in the revised Code; however there should also be a requirement that samples provided to patients are subject to the same recording requirements placed on items dispensed via a prescription. There may be a role for AHPRA to track the volume of starter packs provided to practices by a company and to audit storage, supply and labelling of those packs.

If starter packs are provided directly to healthcare professionals, then the value transfer should not be excluded from the transparency reporting requirements. Inclusion should be considered under section 41. Transparency Reporting.

8. Product Familiarisation Programs (PFPs):

All patients who are commenced on a medication through a PFP should be guaranteed continuity of supply until the patient is able to access the product through an alternative funding mechanism. SAMAC does not think that section 8.4 which outlines that patients must be provided with a '…patient information document which explains that the product will be provided under a PFP for a fixed period, after which it may only be

available on a private prescription…' adequately protects patients from inappropriate discontinuation of therapy or an unanticipated level of cost at the cessation of a PFP. Patients may not be adequately made aware of the actual costs associated with a 'private prescription'.

SAMAC has concerns that this clause may set a precedent where patients who have benefited from a PFP initiated medication and who can no longer afford to access this medication at private prices following PFP discontinuation are seeking to obtain these medications through the public hospital system.

SA Health requires any PFPs conducted within the public hospital system to be supplied under the original funding arrangements for as long as the patient's treating doctor judges that there is clinical benefit

> *MAPs [Medicines Access Programs (including PFPs)] should be subject to a formal agreement …which ensures uninterrupted supply, free of charge from the Company (or as otherwise approved …), for as long as the patient's treating doctor judges that there is a clinical benefit…The sponsor company should acknowledge that supply, as indicated above, will continue until the medicine is available to those patients through a formal funding mechanism.*

SAMAC would encourage Medicines Australia to consider a similar clause as part of the Code of Conduct to protect patients who are initiated on PFP's in other settings.

SAMAC note Medicines Australia has highlighted the requirement to report suspected adverse drug reactions to the TGA in section 8.10. We would also recommend that Medicines Australia dictates that patients who are commenced on a PFP are informed about the potential risks and benefits of the medication and that they are provided with information which highlights that the treatment is newly registered for the indication and therefore there may be unknown adverse events associated with its use.

41. Transparency Reporting

SAMAC note that under section 41, companies are only required to report payments or other transfers of value that are related to prescription medicines. To encourage transparency SAMAC believe that any payments or other transfers of value to health care professionals should be reported.

Currently the tables which are required to be completed for reporting purposes do not outline whether GST has been reported. For all reporting the document should specify whether the value reported includes or excludes GST. These values should be GST inclusive where transactions are GST taxable.

SAMAC were disappointed to see that the transparency reporting arrangements are not required to be implemented until October of 2015. It seems unnecessary to delay the implementation of these reporting requirements for over one year before improved transparency is mandated.

Generally SAMAC support the proposed transparency reporting provisions and the transition to the new arrangements. The submission notes that there are implementation issues for the industry as a whole, but these are focussed on the operation of a centralised database and should not prevent the introduction of these arrangements. It is believed that these arrangements can and should be supported to improve the application of the code.