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Better Health through Research and Innovation

**Joint Submission to the Public Consultation on the
Draft Terms of Reference for the Post-Market Review
of Ezetimibe and Chronic Obstructive Pulmonary
Disease (COPD) Medicines**

22 April 2016

Medicines Australia welcomes the opportunity to make a joint submission to the Post-market Review of Ezetimibe and Post-market Review of Chronic Obstructive Pulmonary Disease (COPD) Medicines. Medicines Australia notes that prior public consultation on the draft terms of reference for these reviews was undertaken in late 2015.

Medicines Australia is the peak organisation representing the research-based pharmaceutical industry in Australia. Our members comprise over 80% of the prescription medicines market by value and play an integral role in delivering better health outcomes for Australians. Medicines Australia's members include sponsors who manufacture and supply medicines affected directly and indirectly by these reviews.

These reviews are the first initiated under the recently agreed framework for post-market reviews. This framework, which built upon previous information on the process for post-market reviews, was developed between Medicines Australia and the Department of Health through the Access to Medicines Working Group (AMWG). The framework introduced very welcome rigour and certainty into the review process, however it was agreed by the AMWG that further guidance and clarity could be provided on:

- the evidentiary requirements for reviews, or
- the implementation of review outcomes.

These two post-market reviews represent an important opportunity to build confidence in the framework, to ensure that it is applied consistently and to ensure further progress on the outstanding issues above can be made, to the satisfaction of all parties.

Medicines Australia acknowledges the government's goals in conducting reviews, namely the desire to improve patient safety, PBS viability, the understanding of utilisation & cost-effectiveness and the quality use of medicines. Medicines Australia shares the belief that reviews should help to achieve the aims of the National Medicines Policy which include timely access to medicines at a cost individuals and the community can afford and maintaining a responsible and viable pharmaceutical industry.

Medicines Australia understands that a number of its member companies will make submissions to the respective reviews to address the clinical and economic aspects of the terms of reference. Therefore in this submission, Medicines Australia will confine itself to three points related to the process for reviews:

1. The quality of evidence and data analysis that informs the COPD and ezetimibe review should be at the same level of rigour as that required for standard submissions for new PBS products;
2. Stakeholders should have meaningful opportunities to contribute fully to each review, as per the post-market review framework; and
3. A range of fit for purpose outcomes should be considered to address any issues that the review identifies, rather than simply focusing on costs.

1. The quality of evidence and data analysis that informs the COPD and ezetimibe review should be at the same level of rigour as that required for standard submissions for new PBS products

Medicines Australia has identified that previous reviews have led to significant changes to the PBS, however there has been a discrepancy, perceived or real, in the data used for decision making versus that to consider a new listing on the PBS. The data and analysis for a post-market reviews and used as the basis for recommendations should meet the same standards of rigour that the PBAC requires for routine PBS listing. Therefore analysis should not only be confined exclusively to utilisation, and should consider all other relevant data sources including those put forward by sponsors and stakeholder during the review. It would be beneficial for the review report to report on how all data sources and analysis informed decision making.

2. Stakeholders should have meaningful opportunities to contribute fully to each review, as per the post-market review framework

Post-market reviews have the potential for consequences for patients, their treating clinicians, other health professionals and sponsors. The current post-market review framework provides avenues for these stakeholders and their representatives to contribute to the review. Specifically Medicines Australia believes the below initiatives would be helpful for stakeholders in the ezetimibe and COPD review:

- i. Respective stakeholder forums, convened as early as possible.
- ii. The production of a “plain English” versions of the review draft report to facilitate comment on the report before its finalisation and consideration by the PBAC.

3. A range of fit for purpose outcomes should be considered to address any issues that the review identifies, rather than simply focusing on costs

Finally, the outcomes of these reviews may lead to a range of recommendations. Medicines Australia would recommend that these consider all types of responses, including QUM related improvements in the information circulated to prescribers and patients on CVD, and COPD management together with other changes that might be considered.

Medicines Australia also believes that recommendations should be considered in the context of how they deliver on the goals of the post-market review programme, namely

- Improved patient safety through better understanding of adverse events and medicine-related harms.
- Ensuring the ongoing viability of the PBS through targeted medicines usage and avoiding preventable wastage or inappropriate prescribing.
- A better understanding of medicines utilisation, to review intended clinical benefit and inform medicines evaluation processes.
- Ongoing cost-effectiveness, including through better management of clinical and economic uncertainty.
- Overall improvements to the quality use of medicines and education for patients and prescribers.

Medicines Australia welcomes anticipated forthcoming involvement on the respective post-market review reference groups and also recommends further dialogue on agreeing the process for the implementation of outcomes through the AMWG.