MEDICINES Australia

Better Health through Research and Innovation

Submission to the Consultation on the Draft Terms of Reference for the Post-market Review of Chronic Obstructive Pulmonary Disease (COPD) Medicines

13 November 2015

Medicines Australia's response to the Draft Review Terms of Reference: Post-market Review of Chronic Obstructive Pulmonary Disease (COPD) Medicines

Medicines Australia welcomes the opportunity to comment on the Draft Review Terms of Reference of the Post-Market Review of Chronic Obstructive Pulmonary Disease (COPD) Medicines (The Review).

Medicines Australia represents the research-based pharmaceutical industry in Australia, which brings new medicines, vaccines and health services to the Australian market. Our members are responsible for the discovery, research, development and commercialisation of up to 86% of medicines currently available on the Pharmaceutical Benefits Scheme (PBS) by value. Medicines Australia's members include sponsors who discover, develop, manufacture and supply medicines that treat COPD.

This review and the concurrently announced review of ezetimibe are the first initiated under the recently agreed framework for the post-market review programme. This framework was developed between Medicines Australia and the Department of Health through the Access to Medicines Working Group (AMWG). This 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 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 above mentioned outstanding issues can be made through these reviews and the AMWG, to the benefit and 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.

This response considers these objectives while reviewing the draft terms of reference proposed for the review. In addition to the overarching recommendation that the review follow the post-market review framework, the specific recommendations of this response are:

1. Sufficient time is provided to give stakeholders the opportunity to consider the terms of reference, consider the literature and data available to them, consult adequately with constituencies and develop their responses to the public consultation.
2. A stakeholder forum should be convened for this review before the deadline for public submissions.
3. Ensure that the implementation of the review considers all appropriate options and in the context of the post-market review programme goals.
4. Process considerations, in particular the process for the implementation of outcomes, should continue to be addressed through the AMWG.

1. Patients with COPD require a range of treatment options to reduce the risk of serious events

COPD is a serious, progressive and disabling long-term condition that affects over 5% of people aged over 55 years of age[1]. In addition to distressing respiratory symptoms such as shortness of breath, cough and wheeze, it is associated with co-morbidities such as cardiovascular disease and diabetes mellitus.

The treatment of a patient with COPD should be multidisciplinary and holistic, with the principal goals of therapy to stop smoking, to optimise function through symptom relief with medications and pulmonary rehabilitation, and to prevent or treat aggravating factors and complications. The review notes that there are a number of medicines available to reduce the symptoms of COPD, and to reduce the frequency and severity of exacerbations. The associated improvement in quality of life from each medicine and the benefits they provide to individual patients should be taken into account during the review

2. Comments on the draft terms of reference

Medicines Australia notes that the draft ToR as they are written are aligned to the five goals of the post-market review programme as outlined in the post-market review framework, and whilst somewhat broad, seem appropriate given the primary objective of this review:

> *The purpose of the Post-market Review of COPD Medicines is to review the utilisation, safety, efficacy and cost-effectiveness of PBS listed COPD medicines, and to address quality use of medicines concerns associated with the apparent use of multiple products[2].*

The PBAC may wish to consider an additional ToR to identify effective interventions that result in improvement of prescribing and quality use of medicines for COPD. This may be particularly relevant in an environment where there are several recent new treatment options and more anticipated, including biologic agents. A similar ToR was included in the review of asthma medicines for children.

Medicines Australia notes that its members will provide specific comments on the draft terms of reference related to the clinical management of, and the treatment options for, COPD relevant to the review.

3. The review process should allow for adequate consultation and appropriate outcomes

The timeline for public submissions should provide sufficient time for stakeholders to provide a meaningful contribution given the diversity of stakeholders with an interest in this review and the large volume of clinical data for these treatments across a range of COPD severities. Medicines Australia suggests that the minimum six week period for stakeholders to respond to the final terms of reference will be the minimum period required, and a longer period for comment should be considered.

Medicines Australis notes that the draft terms of reference were not distributed initially to all relevant stakeholders, prior to the announcement of this consultation. Medicines Australia commends the Department of Health for providing an additional two weeks for stakeholders to consider these terms and additional information on the scope and triggers for the review.

[1] http://www.aihw.gov.au/copd/

[2] http://www.pbs.gov.au/info/reviews/post-market-review-chronic-obstructive-pulmonary-disease

Recommendation 1

Medicines Australia requests that sufficient time is provided to give stakeholders the opportunity to consider the terms of reference, consider the literature and data available to them, consult adequately with constituencies and develop their responses to the public consultation.

In addition to this, given the complexity of the review, the number of therapies associated with the review and the vast range of stakeholders involved, Medicines Australia recommends holding a stakeholder forum during the review to ensure all views are appropriately considered. This is in line with the framework provision in the case of "significant public interest, complex reviews, or large scale reviews".

Recommendation 2

A stakeholder forum should be called for this review before the deadline for public submissions.

Finally, the outcomes of this review may lead to a range of recommendations. Medicines Australia would recommend that these consider all options and 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 recommends further dialogue on the process for the implementation of outcomes through the AMWG.

Recommendation 3

Ensure that the implementation of the review considers all appropriate options and in the context of the post-market review programme goals

Recommendation 4

Process considerations, in particular the process for the implementation of outcomes, should continue to be addressed through the AMWG.