

COPD Secretariat
Post-market Review Section
Pharmaceutical Benefits Division
Department of Health

RE: ACAM comments on the draft Terms of Reference and Review Scope for the PBS Post-Market Review of COPD Medicines

The Australian Centre for Airways disease Monitoring (ACAM) is a collaborating unit of the Australian Institute of Health and Welfare, and is hosted by the Woolcock Institute of Medical Research, which is an affiliate of the University of Sydney.

ACAM aims to assist in reducing the burden of airways disease in Australia by developing, collating and interpreting data relevant to the prevention and management of chronic airways diseases as well as health policy.

ACAM has published several reports about the use of medicines for obstructive airways disease in Australia, the most recent being *Respiratory medication use in Australia 2003–2013: treatment of asthma and COPD*¹ which was published on 5 May 2015.

Thank you for giving us the opportunity to comment on the draft Terms of Reference and Review Scope for the PBS post-market review of COPD medicines. We have several recommendations, which are outlined here.

1) *Include medicines listed on PBS for COPD or asthma*

We recommend that the Review should include medicines listed on the PBS for COPD or asthma (rather than COPD *and* asthma as at present) as there are acknowledged problems with diagnosis of asthma and COPD in clinical practice.

2) *Include all LABA-containing medicines*

Eformoterol and salmeterol, LABA-only medicines not currently listed in the draft Terms of Reference, must also be included in the Review even though they are not listed on the PBS for COPD, as the risk under investigation by PBAC includes patients receiving LABA in more than one formulation at the same time, regardless of the indication for which each medicine was prescribed. This includes, for example, those taking both an ICS/LABA and a LABA, such as:

- budesonide/eformoterol + e-formoterol (or + any of the listed LABA or LABA/LAMA medicines) OR
- fluticasone/salmeterol + salmeterol (or + any of the listed LABA or LABA/LAMA medicines)

It should be noted that LABA-only treatment was recommended in Australian COPD guidelines (for mild COPD) at a time when salmeterol and eformoterol were the only LABA-only medicines in Australia, before the introduction of indacaterol.

For the same reason, we also recommend adding flutiform (fluticasone + eformoterol) to the list of medicines to be included in the COPD Review, as this could be being co-prescribed with any of the medicines with a COPD indication.

3) No need to investigate some combinations

One of the main purposes of the review is to “address quality use of medicines concerns associated with the apparent use of multiple products”. Obviously, the more medicines a patient is prescribed at one time, the more potential for confusion about dosing frequency and inhaler technique. However, not all combinations of the medicines listed in the draft Terms of Reference are of concern.

The main concerns about risk, relevant to this review, are:

- (a) patients taking LABA or LAMA in more than one formulation at the same time
- (b) patients using more than one type of ICS/LABA at the same time
- (c) patients using both a LAMA and a short-acting muscarinic antagonist (SAMA; ipratropium) at the same time

The current utilisation of these multiple therapies should be evaluated in the review.

The combinations with potential concerns are:

- LABA + LABA
- LABA + ICS/LABA
- LABA + LABA/LAMA
- LAMA + LAMA
- LAMA + LABA/LAMA
- ICS/LABA + ICS/LABA.
- LAMA + SAMA

4) Low priority for investigation of some combinations that may be clinically appropriate

By contrast, there are some specific combinations of medicines which are unlikely to present a risk to patients, and, in fact, some are encouraged in COPD.

Some combinations do not need to be studied as they are actively recommended in current guidelines:

- SABA + any other medicine
- LABA + LAMA

Some other combinations may be legitimately used in clinical practice depending on disease severity. They do not carry the same type of risk as those referred to above in section 3.

These are:

- ICS + ICS/LABA
- ICS + ICS

SUMMARY OF RECOMMENDATIONS:

1. Medicines listed in the draft Terms of Reference:

- change sub-title to “medicines listed on the PBS for the treatment of COPD or asthma”
- add e-formoterol to the list
- add salmeterol to the list
- add Flutiform (fluticasone/e-formoterol) to the list
- remove salbutamol from the list
- remove terbutaline from the list
- consider excluding ICS-only therapies from the list

2. Prioritise the evaluation of multiple therapy combinations to those with potential concerns, namely:

- LABA + LABA
- LABA + ICS/LABA
- LABA + LABA/LAMA
- LAMA + LAMA
- LAMA + LABA/LAMA
- LAMA + SAMA
- ICS/LABA + ICS/LABA.

The Australian Centre for Airways disease Monitoring (ACAM)

PO Box M77

Missenden Road NSW 2050

Ph: (02) 9114 0467

21 October 2015

ⁱ <http://www.aihw.gov.au/publication-detail/?id=60129550778>