

## Plain language summary

### Background

In August 2015, the PBAC recommended a Post-market Review of COPD Medicines (the Review), with the purpose of reviewing the use, safety, efficacy and cost-effectiveness of PBS-listed medicines for use in COPD. The Review was approved by the Minister for Health on 28 September 2015, and a Reference Group was established to provide independent expert clinical advice and consumer input. In line with the published Post-market Review Framework, there were a number of opportunities for stakeholder consultation and contribution to the Review.

### Key Findings for each Term of Reference

1. *Compare the prescribing restrictions for PBS-listed COPD medicines for consistency with the current clinical guidelines.*
  - The key clinical guidelines of relevance to Australian practice are the COPD-X Plan and the GOLD Strategy Report.
  - The current PBS prescribing rules and levels for dual bronchodilator combination (LAMA/LABA) and inhaled corticosteroid/bronchodilator combination (ICS/LABA) medicines do not align with the recommended medicine treatment pathway in the guidelines.
  - Many clinicians and patients are confused by the variety of available therapies and devices, which has the potential to cause inadvertent medicine duplication.
2. *Review the clinical outcomes that are most important or clinically relevant to people with COPD and the extent to which these outcomes are included in the evidence previously provided to PBAC on the cost-effectiveness of these medicines.*
  - Reduced pulmonary symptoms, exacerbations and hospitalisations are the most important clinical outcomes for patients with COPD.
  - The main outcomes measured in clinical trials and considered by the PBAC are in line with the GOLD Strategy Report recommended approach of combining symptomatic assessment with a patient's lung function results and/or risk of exacerbations.
3. *Review the evidence on the efficacy and safety of monotherapy and combinations of inhaled medicines for treatment of COPD that PBAC has not previously considered.*
  - The Review found that updated evidence on the efficacy and safety of COPD medicines was generally consistent with that previously considered by the PBAC.
  - No evidence was identified which supported triple therapy (inhaled corticosteroids plus a dual bronchodilator) as a more effective treatment than a dual bronchodilator combination medicine alone.

4. *Review the published literature on the safety of prolonged inhaled corticosteroid use in monotherapy and in combination with bronchodilators and/or muscarinic antagonists for COPD that PBAC has not previously considered.*
  - Some evidence indicated an increased risk of pneumonia with prolonged inhaled corticosteroid use. There is also some evidence of an increased risk of fracture, but this was not conclusive.
  - There are no other new significant safety concerns with inhaled corticosteroid use.
5. *Analyse the current utilisation of PBS-listed COPD medicines to identify the extent of co-prescribing and use that is inconsistent with clinical guidelines and/or PBS restrictions.*
  - Evidence suggests there is a high rate of initiation to inhaled corticosteroids/bronchodilator (ICS/LABA) combinations medicines, which is inconsistent with clinical guidelines.
  - There is evidence of widespread use of triple therapy already for COPD.
6. *Evaluate if the current utilisation of multiple therapies and the latest evidence relating to safety and efficacy justifies a review of cost-effectiveness for some or all medicines indicated for COPD.*
  - The Review did not identify any new evidence on the effectiveness of COPD medicines that would change previous PBAC decisions regarding their cost-effectiveness. Accordingly, no cost-effectiveness review was recommended at this time.
  - It was considered that improving use of inhaled medicines in accordance with current clinical guidelines would also improve the cost-effectiveness of therapies for COPD.

## **Outcomes**

The PBAC considered this report in August 2017 and its recommendation to the Minister for Health can be found in the PBAC minutes published alongside this report.