Medicines Australia's submission to the final report of the Chronic Plaque Psoriasis Cost-Effectiveness Review

Executive summary

Medicines Australia (MA) welcomes and thanks the Department for the opportunity to make a submission on the final report of the Chronic Plaque Psoriasis Cost-Effectiveness Review (CER).

MA 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. MA's members include sponsors who supply medicines affected directly and indirectly by the CER.

MA thanks the Post-Market Review team for its efforts and is committed to working with the Government to address the issues highlighted in this submission.

Concerns relating to the final report of the Chronic Plaque Psoriasis CER

MA members affected by this review have raised several concerns which they would like MA to bring to the attention of the Chairs and its committees as follows:

I. Concerns re inconsistencies between the model used in the CER and what was requested by the PBAC.
II. Concerns that the use of a single reference product as a proxy for efficacy and cost-effectiveness may be an inappropriate methodology.
III. Concern with the lack of opportunity for public consultation on the CER.

I. Inconsistencies between the model and the request by the Pharmaceutical Benefits Advisory Committee (PBAC)

MA is advised by its members that the evaluation in the CER may be inconsistent with the scope outlined by the PBAC in its request in 2018.

The inconsistencies raised are in relation to the definition of the **moderate population** and the use of a **single reference product**:

- **Definition of moderate population:**
  MA notes the omission of a Dermatology Life Quality Index (DLQI) component when defining the moderate population. MA is advised that this component was a specific direction given by the PBAC for the scope of the review.

  MA understands that in making the review request, the PBAC sought to understand the cost-effectiveness of biologics in patients with specific psoriasis conditions that significantly impact quality of life (assessed by the DLQI) but who would be unlikely to have a PASI greater than 12 unless their psoriasis extended to other body areas.

The outcome is that the CER report may prematurely preclude the possibility of expanding the PBS restriction of biologics to patients where a clinical need for biologic therapy remains, that is patients who don't meet the PASI 12 threshold but have psoriasis that significantly impairs quality of life.

- **Use of a single reference product:**
  MA understands that the PBAC requested that cost-effectiveness should be established for each biologic separately. The CER uses a reference product to represent the cost, effectiveness and cost-effectiveness of all other chronic plaque psoriasis biologic products.

  This resulted in a model that has not addressed the questions posed by the PBAC (i.e. relative cost-effectiveness of individual biologics).

  As such, the cost-effectiveness modelling is incomplete, and the results of the cost-effectiveness analysis may not be representative of the true cost-effectiveness of these biologics.

MA notes that stakeholders were not made aware or consulted on changes to the research questions. MA seeks confirmation that the PBAC was consulted on changes to the research questions by the evaluation group.

In the absence of consultations to the changes in the research questions, MA requests that a revised model in line with the PBAC request is presented for consideration.

II. Use of a single reference product as a proxy for efficacy and cost-effectiveness

Although the PBAC has previously identified differences (see Table 3 and Figures 1 and 2 in the PSD from the PBAC's consideration of the Post-Market Review in April 2018 and conclusion in paragraph 3.2.6) in efficacy between the biologics in psoriasis, MA is advised that this finding was not considered and the CER analysis was conducted based on efficacy data for one biologic (the biologic with mid-range efficacy), based on the assumption that it is representative of all PBS-listed biologics.

MA understands that this assumption is not consistent with the PBAC's previous findings in the Post-Market Review, but also the PBS persistence data (reflecting efficacy in clinical practice) presented in the report (Figure 4, page 22) and used in the model. MA believes that this may bias the analysis against more efficacious products and in favour of less efficacious products, rather than considering each medicine on its own merits.

The report also uses the PBAC's determination that all products are interchangeable on a patient basis to justify this approach. The appropriateness of various interchangeability determinations is currently under consideration (i.e. tofacitinib submission, deferred at the March 2020 PBAC meeting). Regardless of the interchangeability determination and the evidence upon which that has been made, the use of a reference biologic is methodologically flawed and in conflict with accepted HTA best practice. Given this approach would not be accepted by the PBAC if a sponsor had made a submission using this method, it would not be an accepted method for decision-making in a CER.

Further, the use of a reference biologic also means that critical information has been redacted for all sponsors other than the sponsor of the reference biologic. As such, sponsors were unable to fully review the report and its implications, raising the issue of procedural fairness.

A related issue is the imputation of persistence data for newer medicines using data for older products, which reflects the same flawed underlying assumption that all biologics have similar efficacy. This method is biased against newer, more effective products, and is also inconsistent with what would be done in a PBAC submission where extrapolation or other data may be used which better reflects the product.

III. Opportunity for public consultation

The CER report has not been made available for public consultation.

The Post-Market Review framework specifies that public consultation on the draft Review Report must occur for a minimum of two weeks prior to the report being considered by the sub-committees. While no specific recommendation is made for the CER. MA believes it is reasonable that the same approach is taken.

MA believes that the lack of public consultation, decreases transparency and stakeholder engagement, and prevents clinicians and consumers from having the opportunity to consider and make an informed comment.