AstraZeneca submission on Terms of Reference for the Post-Market Review of Authority Required PBS listings

AstraZeneca welcomes the opportunity to comment on the Terms of Reference (TOR) for the Post-Market Review of Authority Required PBS listings. This submission addresses the role of Authority Required Pharmaceutical Benefits Schedule (PBS) listings in current Australian clinical practice, and the scope and intentions of the TOR. It is understood that there will be further opportunities to comment on the appropriateness of Authority Required PBS listings for specific medicines at a later date, during the public consultation period for each of the proposed 'tranches' of PBS listings to reviewed.

The role of Authority Required PBS listings in enabling access to medicines

AstraZeneca acknowledges that there are a number of uses for listing medicines under an Authority Required PBS restriction. The requirement to obtain prior consent can, for example, assist with the management of quality use of medicines issues, or the monitoring of identified safety risks. The Pharmaceutical Benefits Advisory Committee (PBAC) often recommends that new medicines are listed under Authority Required PBS listings, and this presumably helps to facilitate a positive recommendation by acting as a mechanism to address residual uncertainty around the clinical efficacy, durability of treatment effect, cost containment or utilisation of a medicine in a specific patient population. Authority Required PBS listings also play an important role in enabling equitable access to medicines in situations where there are Therapeutic Group or Special Pharmaceutical Benefit premiums (e.g. due to drug interactions, contraindications or adverse events).

Having said this, however, AstraZeneca also acknowledges that the requirement to obtain pre-approval can create a significant regulatory and administrative burden for the prescribers and dispensers of medicines with Authority Required PBS restrictions. We are supportive of initiatives that aim to address the stated objective of the Review to *'improve patient safety and care by reducing red tape and administrative burden for health professionals'*[1].

Terms of Reference

Given that Authority Required PBS listings play an important role in enabling access to medicines in Australia, there may be a risk that changing the criteria for determining whether a medicine should be recommended as an Authority Required or Authority Required (Streamlined) PBS listing, could adversely impact on the PBAC's ability to provide positive recommendations for the inclusion of new items on the PBS. It is therefore essential that the scope of the Review includes careful identification and consideration of the risks and benefits associated with all proposed changes to PBS listings.

There may be opportunities to further reduce the administrative burden on health care professionals by considering whether current Authority Required or Authority Required (Streamlined) PBS listings could be transferred to other types of listings (i.e. restricted or general benefits).

AstraZeneca recommends that:

1. The Review include an additional TOR, to evaluate the advantages and disadvantages associated with each type of PBS listing, i.e. Authority Required,

[1] http://pbs.gov.au/info/reviews/authority-required-listings

Authority Required (Streamlined), restricted and general benefits. This will assist in the review of the proposed criteria for determining whether a medicine should be recommended as an Authority Required or Authority Required (Streamlined) PBS listing (TOR 1). It will also enable the identification and mitigation of any unintended consequences or risks associated with proposed changes to the PBS.

2. The Review provides full transparency around the proposed criteria for determining whether a medicine should be recommended as Authority Required or Authority Required (Streamlined) PBS listing (TOR 1). Stakeholders should be provided with opportunities for public consultation on the specific nature of the proposed criteria prior to commencement of the systematic review of all PBS Authority listed medicines (TOR 2).

3. Consideration is given to the type(s) of data that are currently collected as part of the pre-approval process for medicines with an Authority Required PBS restriction. This may include clinically meaningful information about the disease, the clinical justification for using the item, the patient's age, or prescribed daily dose. Such information is useful for enabling detailed analyses of de-identified, patient-level utilisation data (e.g. to identify trends in the length of therapy, co-prescribed therapy, medicine history etc). The same level of detail is not currently available for medicines that are listed under Authority Required (Streamlined), restricted or general benefits, so there is a risk that some information could be lost.