Pfizer Australia welcomes the opportunity to provide a submission to the post-market review of authority required PBS listings (hereinafter called the review).

Criteria for authority required PBS listings

The draft terms of reference for the review, as published on the **post-market review of authority required PBS listings webpage**, are as follows:

1. Review the criteria used by the PBAC to determine if a medicine should be recommended as Authority Required or Authority Required (Streamlined) on the PBS including the advantages and disadvantages of an Authority Required or Authority Required (Streamlined) listing.
2. Systematically review the current Authority Required listings according to the proposed criteria to ensure this is applied consistently to all PBS Authority listed medicines.
3. Use the review to explore how to best use available secondary health data sources to provide information on the utilisation of Authority Required and/or Authority Required (Streamlined) PBS items.

The **public consultation webpage** invites submissions from interested stakeholders and indicates that the purpose of submissions is to collect stakeholder input on which of the authority required listings should or should not be considered for movement to an authority required (streamlined) listing or be unrestricted and the rationale for change. There appears to be some inconsistency between the previously published draft terms of reference and the request for submissions as there has not been any consultation on, or publication of, the criteria for assessment of authority required or authority required (streamlined) PBS listings (as per terms of reference 1). Without knowledge of these criteria it is difficult for Sponsors to provide informed submissions proposing changes to listings of their products. In addition, it is likely that different Sponsors will provide the post-market review team with different proposals for drugs in the same therapeutic category further complicating the process of decision-making.

A more logical process would be to publish criteria against which stakeholders should consider the listings of their products. This would make it a meaningful exercise for all concerned.

Objectives of the review

Pfizer Australia notes, and is in support of, the objectives of the review which are: *"improving patient safety and care by reducing red tape and administrative burden for health professionals".*

Membership of the review panel

Pfizer Australia welcomes the appointment of a review panel which includes stakeholders with diverse interests and experience.

Request for changes to PBS listings

Notwithstanding the lack of criteria for assessment of listings, Pfizer Australia proposes changes to the listings of two of its products (see **Table 1**). These provide examples of how we would like to reduce the administrative burden on clinicians and the Department of Human Services and ensure timely access to necessary medicines for patients.

Table 1: Proposed changes to listings

Product	Current listing	Proposed listing	Rationale
Champix (varenicline)	Authority required	Authority required (streamlined)	Champix has been PBS-listed since 1 January 2008. Medical practitioners have gained significant experience in the use of Champix. The requirement for a telephone authority has resulted in a significant administrative burden for the clinicians and the Department of Human Services. A change to an authority required (streamlined) listing for Champix will reduce the administrative burden. However, the change does not pose any quality use of medicines issues, as when medical practitioners use the streamlined authority code, they will be confirming that the patient meets the authority criteria for prescribing this product.
Enbrel (etanercept)	Authority required (written)	Initiation: Authority required (written) Continuation: Authority required (telephone)	At the July 2014, the PBAC considered a submission from Janssen-Cilag to change second and subsequent continuing treatment authorities for golimumab, infliximab and ustekinumab for all of their PBS-reimbursed indications. The submission was deferred, noting that this matter would be considered in the context of the post-market review of PBS authorities. Pfizer Australia requests that the proposed changes to the listings, as requested by Janssen-Cilag, be applied to all of the etanercept PBS-reimbursed indications. This will reduce the administrative burden associated with Authority required (written) applications for continuation of etanercept. Additionally, Pfizer Australia agrees with Janssen-Cilag's request that the Department of Human Services provide electronic PBS authority application forms for electronic completion and record. This would significantly reduce the administrative burden for clinicians and ensure timely access for patients.