



30 September 2014

**PBS Post-Market
Department of Health
MDP 900
GPO Box 9848
Canberra ACT 2601**

Via email to: PBSpostmarket@health.gov.au

Dear Sir/Madam,

Re: Public Consultation on Authority Required Medicines for the Post-market Review of Authority Required PBS Listings

AbbVie Pty Ltd welcomes the opportunity to comment on the above review regarding which products should retain Authority Required designation and which should be moved to a streamlined listing. Specifically, AbbVie would like to address the Authority Required restriction of bDMARDs, including adalimumab, for initiation and continuation in rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, juvenile idiopathic arthritis, Crohn's disease, fistulising Crohn's disease and chronic plaque psoriasis.

AbbVie proposes that bDMARDs should be moved from written Authority Required to Authority Required (Streamlined), particularly for continuing prescriptions. Feedback from rheumatologists, gastroenterologists and dermatologists indicate that as a consequence of the current complexity and administrative burden of the written authority process, they have less time to spend with patients. Larger centres deal with this increased burden by employing nurses or administrative staff to complete forms and chase up delayed or lost scripts, at considerable expense to the centre. In terms of continuing supply of drug, patients can only be issued their continuation script when there is one month supply of drug remaining. As there are often delays with the receipt of scripts, patients can be left with no supply of drug exposing the patient to a potential disease flare associated with considerable psychological stress, pain and the risk of irreversible damage.

AbbVie is cognisant that the bDMARDs are associated with a high cost and that these medications need to be used in line with the PBS restrictions but believe this can be achieved through the use of the Authority Required streamlined process, particularly for continuing prescriptions. This process was established in 2007 with the aim of reducing the administrative burden for prescribers, providing them with more time to devote to patient care without compromising the integrity of the authority system¹. The initial approved listing of Authority Required (Streamlined) medicines was limited to those Authority Required medicines that treat chronic and stable long-term conditions, with stable dosage regimes, and those that are less susceptible to risk of misuse or increased prescribing outside of restrictions¹. The bDMARDs, including adalimumab, have been available on the PBS for more than 10 years, they are used to treat chronic and stable long-term conditions and have stable dosage regimens, satisfying the criteria for Authority Required (streamlined) selection.

A 12 month review of the streamlined listing process found that overall there were no substantial changes relative to historical growth trends observed in either total script volume or total PBS outlays for streamlined

AbbVie Pty Ltd
32-34 Lord Street
Botany, NSW, 2019
Australia
+61 2 9035 9700 (OFFICE)
+61 2 9035 8601 (FAX)
abbvie.com
ABN: 48 156 384 262



authority medicines for the first year of operation¹. Considering the vast experience of clinicians with the use of bDMARDs in clinical practice and the lower than expected uptake of these medicines across all indications, AbbVie believes that moving bDMARDs to an Authority Required (streamlined) listing will result in a minimal increase in prescriptions.

AbbVie is supportive of any mechanism to improve the quality of care patients receive and to reduce the administrative burden on clinicians, nurses and pharmacists. We trust that this view will be considered when determining what medications should be moved from Authority Required to Authority Required (streamlined) at the upcoming PBAC meeting.

Yours sincerely,

Dr Jodie Wilson
Market Access Manager
Market Access and External Affairs
AbbVie Pty Ltd

References

1. 12 Month Review of the Introduction of Streamlined Authorities (2009).
<http://www.pbs.gov.au/reviews/streamlined-authorities/streamlined-authorities-12-month-review-2009.pdf>