

AbbVie welcomes the opportunity to make this submission on the Terms of Reference for the Post-market Review of Authority Required PBS Listings and welcomes the initiative to reduce burden on prescribers and dispensers of PBS listed medicines by considering which medicines should retain Authority Required designation and which should be streamlined. It should be recognised as well that there are impacts on quality use of medicines and equity of access with the currently burdensome Authority Required process. The administrative burden can have negative impacts on the amount of time the physician spends with the patient and can have negative financial implications for the physician. Consideration should therefore also be given to reducing the overall burden of the Authority Required process.

Terms of Reference:

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.
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.

Point 2 refers to the 'proposed' criteria however there is no explicit mention of proposed criteria being generated. AbbVie proposes the following amends in red below.

Terms of Reference:

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.
2. **Make recommendation on amendments to the criteria and generate new proposed criteria to achieve the goal of reducing the administrative burden on prescribers and dispensers of PBS listed medicines and improve quality use of medicines and equity of access for patients.**
3. Systematically review the current Authority Required listings according to the proposed criteria to ensure this is applied consistently to all PBS Authority listed medicines and that **relevant changes are made from Authority Required to Authority Required (Streamlined) or to remove requirement if neither criteria for Authority Required nor Authority Required (Streamlined) apply.**
4. **Review the Authority Required process, make and implement recommendations to reduce the administrative burden and minimise review and approval times associated with the process.**

AbbVie agrees that Authority Required therapies with the highest volume and level of administrative burden on prescribers and dispensers should be reviewed as a priority.