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29 March 2019
Reg ref: 79-publish-prescription-med-evaluation-feb19\01-docs-for-comment

Transparency, Reforms and Evaluation Support Section
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Closing date: 29 March 2019
Dear Sir/Madam

CONSULTATION:

WHETHER THE TGA SHOULD PUBLISH THAT A PRESCRIPTION MEDICINE IS UNDER EVALUATION

AbbVie Pty Ltd welcomes the opportunity to provide comment on the Therapeutic Goods Administration (TGA) consultation on *whether the TGA should publish that a prescription medicine is under evaluation*.

Transparency is an important part of ensuring public confidence in the regulatory review activities being undertaken. As such, AbbVie's preferred position is:

Option 2: List all applications accepted for evaluation

Please feel free to contact the undersigned if you would like further clarification on any aspect of this submission.

Yours sincerely

[redacted]

[redacted]

[redacted]

[redacted]

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OPTION 2: LIST ALL APPLICATIONS ACCEPTED FOR EVALUATION

Option 2, is the ONLY option in this consultation paper that fully supports transparency of these activities and can withstand public scrutiny as a robust policy option in the current operating environment.

AbbVie Pty Ltd **strongly opposes Options 3 and 4** as they apply very different criteria for the transparency of innovator medicines compared to generic medicines and will delay access to medicines for Australian patients. For the TGA to be appropriately transparent, all products must be treated equally. The TGA states that there is generally less interest in whether a biosimilar or generic is under evaluation compared with innovator medicines, however, in line with Health Policy in creating greater awareness of these products for HCPs and the general public, it would seem counter intuitive that interest would not significantly increase.

AbbVie Pty Ltd believes that by implementing **Option 2**, that is, list all applications accepted for evaluation, the TGA will achieve the following:

1. Be appropriately transparent about its regulatory activities;
2. Allow for increased HCP and patient awareness regarding medicines under evaluation;
3. Be able to more easily engage in meaningful stakeholder engagement and education;
4. More closely align with other current Australian Government policies;
5. Achieve closer regulatory harmonisation with key Comparable Overseas Regulators; and
6. Avoid preventable, unnecessary delays to access generic and biosimilar medicines for the Australian public.

Additionally, AbbVie has noted that the TGA has not included Medsafe NZ in their summary, which provides the name of the sponsor and the medicine/drug that has been submitted for evaluation and /or is under review.

Should **Option 2** not be the successful option for the TGA to adopt, AbbVie's next position is to support retaining **Option 1** (that is, maintain TGA's current publication arrangements – maintain status quo). Supporting **Option 1** would maintain equity for all sponsors and not provide any competitive advantage for some sponsors over others.

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