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8th February 2019
Ref: 74-tga-tgo78-tabs-caps-consult-ddmmm19

Scientific Operations Management Section
Scientific Evaluation Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Dear Sir/Madam

Consultation: Remaking Therapeutic Goods Order No. 78
Due Date: 8th February 2019

AbbVie Pty Ltd (AbbVie) would like to thank the Therapeutic Goods Administration (TGA) for the opportunity to review and comment on the consultation document *"Remaking Therapeutic Goods Order No. 78".*

AbbVie supports the update to the existing Therapeutic Goods Order No. 78 *Standard for Tablets and Capsules*. AbbVie has reviewed the questions proposed by the TGA and provided comments in the table overleaf.

Should you have any queries regarding this submission please do not hesitate to contact me via phone on [redacted] or via email at [redacted]

Yours Sincerely
ABBVIE PTY LTD
[redacted]

AbbVie Pty Ltd
ABN 48 156 384 262

Level 7, 241 O'Riordan Street
Mascot NSW 2020
Australia

[redacted]
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Question	Rationale or Comment
• how the reintroduction of pills to the remade Order will affect your business	No impact.
• if the 12 month transition period for the inclusion of pills is suitable	No comment.
• which impurity limits should apply to medicines not following an individual monograph	For drug products without a monograph the impurity limits should follow the TGA adopted EU scientific guidelines taking into consideration the impurity limits of the drug substance and the acceptable limits for genotoxic impurities. The proposed requirement for determining acceptable elemental impurity levels (i.e. arsenic, cadmium, mercury and lead), as a routine test, should be reassessed if appropriate risk assessment has been performed.
• how the introduction of heavy metal limits in the remade Order will affect your business	Abbvie propose a transition period of approximately 12 months to perform a risk assessment on currently registered products to comply with the new requirements.
• the suitability of the requirements specified in the remade Order	AbbVie disagrees with the new dissolution requirements for products where this test is already incorporated into a product-specific monograph. If dissolution testing becomes a prerequisite for a product that follows a monograph, and does not have a dissolution test, this will limit the supply of products imported into Australia i.e. if we choose to import EU manufactured stock that has complied to the Ph.Eur/BP monographs or US manufactured stock that has complied to the USP monograph. As the Australian market is considerably smaller than the EU and US, the manufacturer may not be able to perform the additional testing required as part of the new proposal.

• the exclusion of unapproved goods from the application of the remade Order	No comment.
• the usefulness of the proposed guidance document	No comment.
• suggested improvements to either document	No comment.
• alternative options if you do not support the proposal	AbbVie disagrees with the proposed dissolution requirements. Sponsors should be required to adopt all tests covered by a product-specific monograph, as a default, instead of the requirement to add dissolution testing to the product specifications. Please note that in some cases the TGA allow disintegration testing *in lieu* of dissolution testing where dissolution tests are not performed.
• an assessment of how the proposal will positively and adversely impact on you.	The proposal may adversely impact supply of product due to the proposed dissolution requirements. For example, if products are only tested for the EU market, they may not comply with US dissolution testing requirements. This could, in turn, have an impact on the release of product in the Australian market.

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