

9 October 2019

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

Dear Sir/Madam

CONSULTATION: Increased online access to ingredient information

AbbVie Pty. Ltd. (AbbVie) would like to thank the Therapeutic Goods Administration (TGA) for the opportunity to review and comment on the consultation paper *'Increased online access to ingredient information'*.

AbbVie supports the proposal to publish the names of excipient ingredients, used in therapeutic goods in the public view of the Australian Register for Therapeutic Goods (ARTG), providing the Australian population with greater transparency to medicinal formulations. As such, we support Option 1B of the consultation proposal.

As this information is already available on our company Product Information (PI) and Consumer Medicine Information (CMI) documentation, AbbVie do not foresee any problem with making this information available on the public TGA register.

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]

[REDACTED]

Option No	Proposed Change	Question	Rationale or Comment
1A	Publish names of excipients except those used in flavour or fragrance proprietary ingredient mixes	<p>Question 1: Which is your preferred option? Why?</p> <p>Our preferred option is option 1B as this represents the detail of ingredient information currently captured in the Australian Product Information and Consumer Medicine Information.</p> <p>Furthermore, as this information is captured on the websites of other agencies, including Medsafe, we feel that the ARTG should contain the same information allowing access to Australian consumers.</p> <p>Question 2: What are the risks and benefits (e.g. commercial, consumer safety, innovation) for each of the options proposed?</p> <p>For the reasons outlined in response to Question 1, AbbVie do not foresee risks in providing information as part of Option 1B.</p> <p>For option 1A, the manufacturer of a proprietary excipient, that is not a flavor or fragrance, may not disclose the ingredient information due to confidentiality issues.</p> <p>To maintain consistency with information already available in the public domain, AbbVie do not agree with maintaining the current status quo of not publishing excipient names on the ARTG (Option 2).</p> <p>Question 3: If Option 1A or 1B is implemented, are you interested in collaborating with us to help communicate this information to consumers?</p> <p>Yes, AbbVie is interested in collaborating with the TGA to communicate this information to Australian consumers.</p>	
1B	Publish names of excipients except those used in any proprietary ingredient mixes		
2	Status quo - no action by the TGA to publish excipient names in ARTG summaries		