abbvie

28th November 2018

The Director
Business Systems Review and Reporting Section
Prescription Medicines Authorisation Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Dear Sir/Madam

Consultation: Transition to eCTD Only for Prescription Medicines
Due Date: 4 December 2018

AbbVie Pty Ltd (AbbVie) would like to thank the Therapeutic Goods Administration (TGA) for the opportunity to review and comment on the consultation paper 'Transition to eCTD only for prescription medicines'.

AbbVie supports the staged approach for transitioning to eCTD only for prescription medicines. AbbVie has reviewed the questions proposed by TGA throughout the paper and provided comments in the below table.

To ensure a smooth transition to eCTD, we encourage the TGA to prioritise the Electronic Submission Gateway for earlier implementation. As a consequence, this will reduce the administrative burden associated with CDs, as well as automatic notification of validation errors.

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]

Page; Question No.	Proposed Change	Question	Rationale or Comment
Page 12; Q1	**Proposed change** Required for: • Category 1 • Additional Trade Name • Category 3 • Minor Variations • Notifications • Master Files • PSUR • RMP Not required for: • Medical Devices • Listed Medicines • Designation and Determination applications Optional for: • Biologicals/Biological Master Files • Clinical Trials • Over the Counter Medicines • Registered Complementary Medicines	Do you agree with the included and not included lists?	• Yes, AbbVie agrees with the contents of all three lists. • AbbVie notes that GMP is not included in the scope and recommends that it be added to the "Not required list".
Page 14; Q1, Q2	**Proposed implementation strategy** Stage 1: eCTD mandatory 1 Jan 2019 • NCE • NBE • Biosimilar • New Combination Medicine Stage 2: eCTD mandatory 1 Oct 2019 • Extension of Indications • Major Variation • New Generic Product • Changes to PI involving the	Do you support the staged approach? Do you support the timing of the stages?	• AbbVie agrees with a staged approach, but would like to suggest combining the application types in Stages 2 and 3 to avoid complexity in meeting multiple deadlines. • AbbVie can adopt eCTD submissions immediately; however has decided to create CMC baselines prior to the first eCTD submission sequence. • AbbVie suggests amending the Stage 1 transition date to

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	evaluation of data <u>Stage 3:</u> <u>eCTD mandatory 1 Jul 2020</u> • Extension of indications – Generic Product • Additional Trade Name • Category 3 • Minor Variations • S14 • Notifications • Master Files • PSURs		March 2019 as most companies will have already determined their internal submission strategy for January 2019 submissions by the end of 2018. • AbbVie encourages the TGA to expedite the Electronic Submission Gateway to support the TGA's approach to transition at the earliest implementation, thereby reducing the administrative burden of CDs and validation errors.
Page 15; Q1	**Implications** • Resources and training • Cost • Managing older products – baselines	Please outline any additional hurdles and also strategies to mitigate these hurdles.	• AbbVie has no issues from a resource, training or cost perspective. AbbVie has overcome the issues identified previously in regards to lack of eCTD expertise, clarity around baseline requirements and publishing deadlines. • AbbVie appreciates the flexibility in allowing partial modules and multiple sequences for baselines. This will greatly assist sponsors to transition smoothly and effectively without delaying patient access to medicines. • AbbVie encourages all sponsors to generate

Page; Question No.	Proposed Change	Question	Rationale or Comment
			baselines in order to validate their current registration details.
Page 16; Q1	**Proposed transitional arrangements** • Education • Collaboration • Advice	Are there any other tools or services the TGA could provide to assist with the transition.	• AbbVie would appreciate a combined education session to increase awareness of eCTD changes e.g. updates to eCTD specifications, as well as how to use the proposed Electronic Submission Gateway. It would also be helpful to provide clear guidance on how to transition concurrent applications that may still be in NeeS format to eCTD format. This would reduce any confusion for the sponsor and support any administrative concerns. • AbbVie would also appreciate training sessions or workshops for transitioning older products. • It would also be helpful if TGA could share the benefits for companies who have submitted baselines, compared to a company that does not submit baselines.