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

4th December 2018

Dear Sir/Madam,

RE: Novartis Pharmaceuticals Australia's submission to the TGA's proposal for transition to eCTD only for prescription medicines

Novartis Pharmaceuticals Australia Pty Ltd welcomes the opportunity to comment on the consultation paper for the transition to eCTD only for prescription medicines proposed by the TGA. In general, Novartis supports TGA's proposal and in this submission, we address the particular questions that the TGA has sought industry's comments on.

Applications types included and not included in future eCTD requirement

Do you agree with the included and not included lists?

The TGA proposal includes application and other non-application types related to prescription medicines that will and will not be included in future eCTD requirements. Notably, Pre-ACM responses, and Section 31 Requests are not explicitly mentioned in these lists, but it is understood that they are included. It would be useful for Sponsors to understand if TGA will make submission of these important documents in eCTD format mandatory in the future. It would also be useful to understand if other submission types, such as Section 19A, Annual batch reports, Patent certification, and Certified Product Details will also be transition to mandatory eCTD format in the future too.

Proposed implementation strategy

Do you support the staged approach?

Yes, Novartis supports the staged approach outlined by the TGA in the consultation document. Novartis eCTD uptake is not dissimilar to the industry average uptake for all submission categories.

Do you support the timing of the stages?

Yes, Novartis supports the timing of the stages outlined by the TGA in the consultation document.

Implications

Please outline any additional hurdles and also strategies to mitigate these hurdles

Often Sponsors are required to meet short deadlines for submissions, such as Pre-ACM responses, Section 31 requests or PSUR submissions. The time taken to validate and publish these documents often eats into an already compressed timeframe. Some flexibility in such cases could be granted by the TGA whereby submission of the required documents could be performed by email and followed-up by an eCTD sequence at a later date to avoid missing a deadline.

In some instances TGA eCTD validation criteria is stricter than in the EU. For example, broken bookmarks or hyperlinks result in a validation 'Error'. However, the same is only considered 'Best practice' in the EU and will not result in rejection of the eCTD sequence like for the TGA. Since many pharmaceutical companies recycle the EU dossier for use in Australia, alignment of TGA eCTD criteria to those of the EU would simplify preparation of Modules 2-5 for submission in Australia.

Proposed transitional arrangements

Are there any other tools or services the TGA could provide to assist with the transition?

Provision of an electronic submission gateway by TGA that validates and accepts eCTD sequences for submissions online would assist with the transition to eCTD only for prescription medicines. Current TGA systems allow for minor variations, up to 100mb in file size, to be submitted online via the eBS portal. However, minor variations > 100mb or major Category 1 applications are required to be submitted to TGA via other electronic media, such as USB or DVD, with greater storage capacity. Preparation of an eCTD sequence already involves longer lead-times due to publishing and validation steps. In addition, USB/DVD need to be posted by mail or couriered to TGA which involves additional time, cost and pose IT security concerns. Therefore, submission via an online gateway would be safer, more efficient and also reduce associated costs.

Novartis has already provided electronic gateway specifications to the TGA. Novartis is willing to support development and implementation, including participation to user testing of the gateway should this be required by the TGA.

General comments -Impact of proposed changes on industry

Financial considerations

Transition to mandatory submission in eCTD format involves an additional cost consideration vs. NeeS format. That is, additional resources for publishing in eCTD vs. NeeS are required, especially where the requirements are different to the EU. Nevertheless, eCTD offers many advantages and Novartis supports the full transition as outlined by TGA.

Yours sincerely,

[redacted]

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Australia and New Zealand

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