Company Response to TGA Consultation on Transition to eCTD only for prescription medicines

Submissions due to TGA by 4-Dec-2018

Background

The Company is an innovative specialty pharmaceutical company [redacted]. Our primary objective is providing life-saving and/or hospital medicines. Our product portfolio includes both registered prescription medicines and unapproved therapeutic goods. [redacted]

TGA Question 1 (page 12)

Do you agree with the included and not included lists?

Company Response

The Company wishes to express its general support of the proposed transition to eCTD only for the prescription medicine application types listed, in regard to newly registered products. The majority of the Company's registered products are based on European dossiers. As such, the alignment of the TGA-approved dossiers with the standardised formats used in Europe will also facilitate the efficiency of the submission process for future applications/variations.

We also strongly agree that baselining of existing approved dossiers should remain voluntary in perpetuity. This is due to the extensive difficulties and redundancy of re-validating the newly created eCTD format dossier compared to the data previously submitted and approved. Creation of new eCTD copies from older NeeS and paper dossiers has numerous challenges, not least of which are due to the old source documents being: non-CTD format (Parts I-IV); poorly legible paper copies which have difficulty being scanned/optical character recognition/indexed.

TGA Question 1 (page 14)

Do you support the staged approach?

Company Response

The Company agrees that a staged approach will assist smaller Australian-only companies to adjust to the new eCTD requirements. Being an SME, the implementation of what are large and costly eCTD compilation, publication and validation platforms will take us longer than other larger, better-resourced Companies. The gradual transition proposed through the staged approach will allow the Company time to gradually learn the intricacies of the eCTD requirements without being overwhelmed.

TGA Question 2 (page 14)

Do you support the timing of the stages?

Company Response

The implementation dates for Stages 2 and 3 seem reasonable. The Company, however, would like further clarification of the implementation date for Stage 1. The consultation advises that eCTD dossiers will be mandatory for the Stage 1 applications in the First Quarter of 2019. Is this implementation date 1 January 2019, 31 March 2019 or a date in between?

TGA Question 1 (page 15)

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

Company Response

The Company is particularly interested in the transition process for prescription medicines, where the *preparation of a baseline dossier is not feasible*. Many of the Company's products are very old and were registered via a paper-based dossier. In many cases, the oldest dossiers are not even in CTD format (i.e. Parts I-IV) – making any baselining even more problematic. Further, when scanning old and sometimes poorly legible paper dossiers, even using optical character recognition (OCR) can have varying degrees of accuracy – thus making indexing of even OCR scans of paper dossiers problematic. Any recent variations that have been submitted for these products have been submitted via NeeS applications. As such, the preparation and resubmission of currently valid documents as a baseline would be an extremely arduous, extensive and redundant enterprise. We are, however, very keen to begin submitting all new dossiers, and all future variations to existing NeeS or paper dossiers in eCTD format.

Any guidance or Question and Answer document the TGA might be able to provide regarding the transition to eCTD-only for prescription medicines (without baselining) would be most welcome.

In particular, the Company would like confirmation of the following:

- Will new eSubmission Identifiers be required for any products changing from NeeS to eCTD? For any products with NeeS dossiers that have been allocated an eSubmission Identifier, will their number remain the same with a simple change of the initial letter from "n" to "e" (e.g. n123456 to e123456)? Or will Sponsors need to apply for entirely new eSubmission Identifiers for these products?
- After transition from NeeS to eCTD, what sequence number will need to be used for the first application made in eCTD? Will sequence 0000 be required, or should the sequence numbering continue with the next sequential number based on the previous NeeS variation?

TGA Question 1 (page 16)

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

Company Response

The Company agrees that the proposed working groups, meetings, presentations and preparation of new guidelines will all be beneficial to assist with the transition. The Company, however, recommends that any new guidance documents include screenshots or links to short video clips demonstrating the required steps to be completed via eBS.

The Company recently had PPF submission issues with the eBS software, which had to be resolved with the TGAs Application Entry Team. Through the use of screenshots, the AET were able to effectively communicate the necessary instructions for the Company to complete on eBS.

Submitted to the TGA 30 November 2018