commercial eyes
pty ltd

04 December 2018

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

Re: Consultation: Transition to eCTD only for prescription medicines

Dear [redacted],

Commercial Eyes Pty Ltd (CEPL) welcomes the opportunity to provide feedback on the Therapeutic Goods Administration's (TGA) Consultation "Transition to eCTD only for prescription medicines" released on 23 October 2018.

Our comments and feedback are based on the consultation paper dated October 2018 (version 1.1).

Please do not hesitate to contact me on [redacted] or by email at [redacted] if you would like to discuss our feedback.

Your sincerely,

[redacted]

Proposed change

1. Do you agree with the included and not included lists?

We agree with the scope of the included and not included lists.

Proposed implementation strategy

1. Do you support the staged approach?

We agree with the staged approach for the implementation of mandatory eCTD for prescription medicines.

2. Do you support the timing of the stages?

It is acknowledged that the proposed timeline for Stage 1 requires eCTD submissions by the first quarter of 2019 and that this short timeline is based on the high proportion (95%) of New Chemical Entity (NCE), New Biological Entity (NBE), Biosimilar and New Combination Medicine applications which are currently submitted in eCTD format.

For sponsors who do not currently have access to publishing software, the short timeframe for Stage 1 is unlikely to be enough time for the selection of a software vendor, procurement, preparation of IT systems, installation of software and training.

Implications

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

An additional hurdle is the changes required to work practices when transitioning from NeeS to eCTD. For example, the appropriate use of granularity and leaf titles to facilitate lifecycle maintenance. Work processes will also need to accommodate publishing lead times, particularly if publishing occurs in other time zones or is outsourced. These are topics which could be discussed in industry workshops or forums.

Cost is expected to be the largest barrier to transition to eCTD and we agree that there are a number of software and outsourcing solutions available to sponsors. It may be helpful for sponsors to consider publishing costs in context of the overall gains in efficiency. The use of publishing software can substantially reduce the administrative burden of manually creating table of contents and amending pdf properties. In addition, maintaining an eCTD dossier enhances the transparency of registered information and assists compliance activities. These benefits of eCTD could be discussed in industry workshops or forums.

It is acknowledged that eCTD baselines are not mandatory although encouraged by the TGA. It would helpful for the TGA to provide further guidance on the modules which are considered to be the minimum content for a partial eCTD baseline. This may encourage sponsors to adopt a less onerous approach to submitting an eCTD baseline for older products which could be mutually beneficial.

Proposed transitional arrangements

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

The education, collaboration and advice activities proposed by the TGA to assist with the transition to eCTD will be very helpful to industry. Updates to eCTD guidance on the TGA website may be prioritised given it is a primary source of information for sponsors. It is noted that some of the information on the "Frequently asked questions" web page is out of date. Also, some of the TGA guidance documents refer to incorrect module 1 sections which may be confusing for inexperienced or overseas publishers.

The proposed education and awareness program might include topics such as the evaluator's perspective of navigating the eCTD structure, "best practice" recommendations to facilitate the evaluation process and managing changes to the eCTD envelope.

Additional reforms

Overall, we are very supportive of eCTD and the benefits that this dossier format provides sponsors.

Future automation of dossier processing could consider streamlining the submission of information to TGA with a view to reducing the regulatory burden, duplication and leveraging the eCTD structure. Examples may include:

- Automated lodging of the Product Information (PI) and Consumer Medicine Information (CMI) onto the TGA eBusiness Services system with the sponsor's consent.

- Considering the requirement for sponsors to maintain a separate Certified Product Details (CPD) where the information is already included in the dossier. Potential alternatives may be for the TGA laboratories to directly source the information from the dossier or for sponsors to submit a hyperlinked CPD form in module 3.2.R.

- Extension of automated notifications and/or updates to TGA business units and/or systems when information has been submitted or revised in the dossier for example patent declarations.