GSK Comments on TGA Consultation: Transition to eCTD only for prescription medicines

GlaxoSmithKline Australia Pty Ltd (GSK) welcomes the opportunity to comment on the Transition to eCTD only for prescription medicines consultation and is supportive of the TGA's broader electronic dossier reforms agenda to provide an updated electronic submissions platform that is appropriate for Australian stakeholders.

GSK is supportive of the efforts of the TGA to improve and standardise dossier formats by transitioning to eCTD only for prescription medicines and recognises that there are many benefits of mandating the use of the eCTD format for prescription medicine dossiers . However, GSK requests for factors outlined in the response below to be considered before the transition period.

Applications included and not included in a future eCTD requirement

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

GSK agrees with these lists. Further clarity is sought from the TGA regarding the requirement to submit Certified Product Details (CPDs) in eCTD format.

Proposed implementation strategy

1. **Do you support the staged approach?**

GSK is supportive of the staged approach to transition to eCTD format only for prescription medicines.

2. **Do you support the timing of the stages?**

GSK is supportive of the timing of each stage of the transition period, but requests, if possible, for the TGA to consider extending Stage 2 to January 2020 and Stage 3 to January 2021. Preparing and planning for eCTD submissions, particularly for those types of applications included in Stage 2, can take a number of months, and it would be beneficial for sponsors to have ample time to facilitate the transition. As sponsors work towards transitioning to eCTD format for all prescription medicines, extending the transition timeframe will support a smooth transition to new processes with minimal business impact.

It is also recognised that a number of other international regulators are also transitioning to eCTD with similar transition timelines to those proposed by the TGA, which will have particular impact on the operation of Global organisations.

Implications

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

One hurdle that sponsors face in the transition to eCTD is that there are different eCTD systems (software and platforms) used globally. It would be appreciated if the TGA could leverage tools and platforms used by other recognised regulators (e.g. EMA) to minimise complexity and resource required for eCTD publishing to meet the TGA requirements.

Further clarity is sought from the TGA regarding how variations that are classified as not reportable in Australia can be updated in future when all prescription medicines have

transitioned to the eCTD format. To ensure that files are updated in a timely manner, and to minimise discrepancies, it would be beneficial if sponsors could submit these at any time during the product lifecycle.

Proposed transitional arrangements

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

GSK believes that sponsors would benefit from adequate training and webinars provided by the TGA throughout the transition period, to ensure that all expectations are met. Appropriate planning and clear knowledge is required for sponsors to understand the TGA's requirements and the eCTD specifications, particularly those companies that do not have local publishing experience.

Due consideration should also be given to response timelines during evaluations, such as Pre-ACM/Pre-ACV responses. The current timelines can be challenging when eCTD publishing is also required, especially for sponsors whose publishing activities are completed globally.

Additional reforms

GSK wishes to seek further information from the TGA regarding its plans to implement the electronic submission gateway and the associated timelines. Further clarity is sought regarding whether this submission gateway will allow applications from outside of Australia to be submitted to the TGA, similar to the approach taken in the EU. Please consider if this gateway can also provide a platform for both sponsors and the TGA to view the overall eCTD dossier for all prescription medicines.

We thank the TGA for providing GSK with the opportunity to participate and provide feedback on this consultation.