SANDOZ A Novartis Division

04/12/2018

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

Dear Sir/Madam,

Re: Consultation: Transition to eCTD only for prescription medicines

Sandoz Pty Ltd welcomes the opportunity to provide feedback to the public consultation paper on TGA's electronic dossier reform and an updated electronic submission platform.

We have reviewed the consultation paper "Transition to eCTD only for prescription medicines", Version 1.1, dated Oct 2018 and have the following suggestions:

- Proposed implementation date Oct 2019, Stage 2: consider a later timeline, to allow the purchase of software and training of personnel. Dec 2020 is considered appropriate to allow sufficient time to embed the new requirements and ensure the technical requirements of eCTD does not become a barrier to register new medicines

- Managing older products – with an understanding that baseline is not a mandatory requirement, guidance/recommendation on partial baseline requirements would be useful

- Proposed transitional arrangements:
  Whilst there is a central email account set up for all eSubmission enquiries and a well-established website for frequently asked questions, it is in our experience that some matters are better explained and discussed verbally. Dedicated resource should be allocated to assist the industry on an increased demand for eSubmission queries on TGA specific requirements
  In addition, sufficient support and access to a single point of contact with clear response times agreed with industry to ensure a smooth transition with TGA support team to help with any questions

- Consider reinforcing the use of bookmarks and hyperlinks. Industry will receive greater support from their global colleagues if requirements are made mandatory (e.g. any document over 10 pages - bookmarks to be mandatory)

- PI close out sequence - is this mandatory? Sandoz would like clarity on this aspect and request a consistent approach across all evaluation sections/streams

- Ability to request exceptions to eCTD for circumstances where deemed necessary, e.g. urgent product application for a new product to meet medicines shortage or exemption applications where NeeS may be able to be requested

- Availability of or clarity on timeline for e-portal or e-gateway to allow head office publishing unit to submit and append/amend sequence in consideration of short turnaround times e.g. S31 response

Overall, Sandoz supports the move to eCTD with the required clarity and support from TGA to allow a smooth transition. We would welcome further interaction and workshops similar to the roll out for earlier initiatives like Business Process Reform and Medicines Shortage Scheme to ensure no delays or hurdles to access for products in Australia.

Should you require any further information, please do not hesitate to contact me directly on [redacted] or email [redacted].

Yours sincerely,

[redacted]