

The Director
Business Systems Review and Reporting Section
Prescription Medicines Authorisation Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606
DUE DATE: 4 December 2018

Dear Sir/Madam

Consultation: Transition to eCTD only for prescription medicines

Medicines Australia welcomes the opportunity to provide comment on the Therapeutic Goods Administration (TGA) consultation paper 'Transition to eCTD only for prescription medicines'.

Our submission has been prepared with the expert input of Medicines Australia's Regulatory Affairs Working Group (RAWG). Members are selected for their regulatory and pharmacovigilance experience and industry knowledge and bring a whole-of-industry perspective to the consideration of regulatory issues that stand to impact to our sector.

Our feedback on the guidance (attached) includes answers to the specific questions included in the consultation paper and based on consideration of the following:

- Is the guidance sufficiently clear and easy to follow?
- Are there any aspects that are not currently covered in the guidance?
- Are there any other issues that may affect the usability of the guidance?
- Are there any major issues relating to the content of the guidance that are likely to affect Industry?

The response includes suggestions for changes to provide better clarity on requirements which will support practical implementation as well as identifying key areas of concern.

We would be happy to discuss or provide further comment on any aspect of our response and we appreciate being kept up to date on further developments.

With regards,

[Redacted signature]

Elizabeth de Somer
CEO

Consultation: Transition to eCTD only for prescription medicines

Page	Item	Comments and Rationale
	General Comments	<p>A vast majority of Medicines Australia member companies are currently using eCTD formatted dossiers for new prescription medicines. However, some of our member companies are still submitting certain types of applications as NeeS. Those applications that are still submitted as NeeS include:</p> <ul style="list-style-type: none"> • Applications for older products • CMC variations • Other applications where it is an internal decision to do so
Q1	Applications included/not included in a future eCTD requirement - Do you agree with the included and not included lists?	<ul style="list-style-type: none"> • Notably S19A and Annual batch reports are not explicitly mentioned • Section 19A exemption reflect a time point in a products history that should be reflected in the eCTD lifecycles similar to the existing requirements for Section 14 exemptions
Q2	Proposed implementation strategy - Do you support the staged approach?	<p>Medicines Australia member companies support the staged approach. Specifically, if baselines are not required for submissions, there will be no impact. However, if baselining is required prior to a variation being lodged, it can be addressed with prioritisation.</p>
Q3	Proposed implementation strategy - Do you support the timing of the stages?	<ul style="list-style-type: none"> • No, the timing is not sufficient especially for older products requiring minor category 1 variations or other minor variations which are currently compliant to NeeS. Additional time is required also to accommodate Sponsors with large portfolios of products that will require transitioning and to enable the option of creating baselines that will support future lifecycle updates. • Proposed timings are: <ul style="list-style-type: none"> ○ Stage 2 – 1 January 2020 ○ Stage 3 – 1 January 2021
Q4	Implications – baselines Please outline any additional hurdles and also strategies to mitigate these hurdles.	<ul style="list-style-type: none"> • Some flexibility could be given to submissions requiring to meet short deadlines such as PSUR or pre-ACM responses. It is proposed that submissions could be initially done by email to avoid missing a deadline and followed by a proper sequence later. • In the consultation paper a baseline is defined as the resubmission of currently valid documents that have previously been provided to the TGA in another format

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		<p>such as NeeS or paper. With the EU transition to eCTD only for all submissions from 1 January 2019, most global companies will have baselines available for EU dossiers. The TGA should consider accepting EU baselines, where the products do not significantly differ from the products registered in Australia and the Sponsor can provide an appropriate justification that any differences are editorial in nature. This would allow the correct lifecycle operations to be applied to documents for Australia, when they are sent from Global publishing hubs, to allow for faster submissions and to ease review of dossiers.</p>
Q5	<p>Proposed transitional arrangements - Are there any other tools or services the TGA could provide to assist with the transition?</p>	<ul style="list-style-type: none"> • An e-Portal that accepts all application sizes would assist with transition. Sponsors have previously provided the TGA with a proposed e-portal specification and are willing to participate to user testing should this be required. • The “Australian eCTD submissions: Frequently asked questions” was a good tool for Sponsors when eCTD was first introduced in Australia. However, it has not been updated since with learnings from both TGA and Sponsors. It would be beneficial to both parties to have this FAQ page proactively updated.
Other	<p>Impact of proposed changes on industry</p> <ul style="list-style-type: none"> • Likely benefits <p>Costs – financial and non-financial</p>	<p>The major benefits of the eCTD format relates to simplification of life cycle management based on full transparency of a products regulatory history. In responding to a request for feedback, over half of Medicines Australia member companies have confirmed that the proposed changes have minimal impact on their operations with several members already having a transition plan in place.</p> <p>Areas of impact relate to:</p> <ul style="list-style-type: none"> • Increased local workload and resource needs that will increase costs over the transition period • Impact on global support and resourcing needs, due to establishment of eCTD baselines for older products that were approved via paper-based applications. • Increase costs for licensing of software and training of all regulatory staff