Transparency Reforms and Evaluation Support
Prescription Medicine Authorisation Branch
Medicines Regulation Division
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606
Email: TGA Regulatory Reforms Team tgaregreforms@health.gov.au

Dear Sir/Madam,

Re: TGA consultation on modification of an existing provisional registration – guidance update

Medicines Australia welcomes the opportunity to provide comment on the Therapeutic Goods Administration (TGA) consultation on modification of an existing provisional registration – guidance update, relating to extension of provisional registration and transition to full registration, to incorporate requirements for variations and modifications that may occur prior to the transition to full registration is completed.

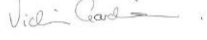
Our submission has been prepared with the expert input of Medicines Australia's Regulatory Affairs Working Group (RAWG). Members are selected for their regulatory experience and industry knowledge and bring a whole-of-industry perspective to the consideration of regulatory issues that stand to impact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

Our detailed feedback on the guidance is contained in Attachment 1 based on the consideration of the following:

- Is the draft guidance usable including being sufficiently clear and easy to follow?
- Are there any other issues that may affect the usability of the guidance?
- Are there any aspects that are not currently covered in the guidance that will be important for sponsors to have guidance on?
- 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 that will support practical implementation as well as identifying key areas of concern. Medicines Australia looks forward to discussing this further with you on 7 November and we appreciate any dates on further developments as they arise. Please do not hesitate to contact Betsy Anderson-Smith (banderson-smith@medaus.com.au) if you require more information on our submission.

Yours faithfully



Dr Vicki Gardiner

Director of Policy and Research

Medicines Australia

Attachment 1:

Consultation: Modification of an Existing Provisional Registration

General comments

- The guidance is difficult to follow and a summary of key points would be helpful to orientate the reader as outlined below;
    - any variation or modification will not alter the duration of the originally approved provisional registration
    - any variation or modification that creates a separate or distinct good under S 23 requires approval of a provisional determination for the intended change.
    - the determination is an administrative process that has no associated fees to confirm
        - same sponsor
        - same medicine
        - same indication
        - same actives
    - only the initial provisional determination will be published on the TGA website and not any associated amendments
    - variations or modifications are made via the standard application pathways eg SAR; Cat 3; Cat 1 depending on proposed changes
    - extensions of indications to be submitted under the provisional approval pathway need to meet the full provisional determination criteria and process requirements to be eligible for review under the provisional pathway. Extensions of indications to be submitted under the standard pathway only need to meet the administrative criteria for a provisional determination.
- Readability would also be improved by use of additional bullet points rather than paragraphs of text. A tabulation of the types of changes under Section 23 that require a provisional determination prior to submission of an application would provide more clarity
- The first part of the document sets out that the TGA may initiate variations – this is not new information and was part of the original guidance. However, the guidance only states that the Secretary can vary the ARTG, but no reference to CMO or a delegate from prescription medicines. In addition, in relation to the Secretary altering the conditions of a provisional registration, any action should be based on new information that comes to hand that alters the risk/benefit profile.

Specific comments

Page	Item	Comments and Rationale
1	**TGA Initiated Variations** This section is identical to that in the current guidance with addition sections relating to other variations/modifications added in the update.	• The original guidance lacks clarity around the interpretation of 'reasonable opportunity' to respond that would enhance usability. Dependent on the nature of the quality, safety or efficacy concerns there will be differing levels of complexity in creating a response. Consequently timelines may vary for a Sponsor to consider they had been given a 'reasonable opportunity'. In addition, global co-ordination may be important to seek an aligned approach across different jurisdictions. • Including a clearer description of steps that will be taken to provide a 'reasonable opportunity' would assist Sponsors understanding of the expected process steps. For example, a statement along the following lines: *Following dialogue between the TGA and a Sponsor a timeline for a response will be agreed on a case by case basis depending on the nature of the issues raised*
1-4	**Sponsor Initiated Variations**	• Where the determination is only an administrative check of simple details, this process should be automated so that approvals are issued immediately to avoid delays for Sponsors needing to submit urgent variations • Timelines for the additional determination step required prior to submission of a variation of modification need to be specified. This is critical for planning purposes. • The process in cases where an urgent change needs to be made should be clarified to ensure there is no adverse impacts due to delays whilst awaiting approval of a determination