Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Australian regulatory guidelines for prescription medicines

Appendix 6: Notification and submission of new data

June 2004

TGA Health Safety Regulation

About the Therapeutic Goods Administration (TGA)

- The TGA is a division of the Australian Government Department of Health and Ageing, and is responsible for regulating medicines and medical devices.
- TGA administers the Therapeutic Goods Act 1989 (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.
- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.
- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. TGA investigates reports received by it to determine any necessary regulatory action.
- To report a problem with a medicine or medical device, please see the information on the TGA website.

Appendix 6: Notification and submission of new data

Background

Submission of new data during the evaluation process may be allowed with the following provisos:

- inadequate or premature submissions continue to be rejected at the time of application;
- sponsors are encouraged to state at the time of submission what new data are expected to be submitted during the evaluation process.

As timely availability of therapeutic goods is a principal objective of the Therapeutic Goods Act 1989 (the Act), The Therapeutic Goods Administration (TGA) needs to reconcile the need for timely decision making with the expected delay arising from submission of new data in its consideration of applications.

New data

Sponsors should advise TGA at the time of initial application of known, ongoing or anticipated studies of relevance to that application that may be submitted subsequently.

TGA acceptance of new data for evaluation depends upon the sponsor's agreement to stop the clock pursuant to regulation 16A (2)(C) of the Therapeutic Goods Regulations for a period adequate for its processing and evaluation.

New data should be submitted in the format of Common Technical Document (CTD).

New data must relate to the scope of the original application and must not relate to an extension of indication, new population or dosing regimen etc. New data does not relate to the submission of information in response to a request made under section 31 of the Act.

New data can be submitted in relation to Category 1 submissions only. Category 2 applications are excluded because they require submission of 2 completed overseas evaluations from the outset. Category 3 applications are also excluded from the submission of new data.

Revision of the submission's Overviews and Summaries (Module 2) is not required. If necessary, an addendum to the clinical or non-clinical summaries may be submitted to explain or clarify the significance of new data. In some cases, the TGA may require such an addendum. The Product Information (PI) and Consumer Medicine Information (CMI) may require revision to take into account the new data.

Furthermore, the sponsor should recognise that any new data may not be accepted if they do not have a reasonable prospect of facilitating registration of the relevant application.

Procedure

The decision to submit new data remains solely with the sponsor. In submitting new data, it is considered that the sponsor recognises that this will delay the evaluation process and that the sponsor agrees to the clock stops described in this document.

The TGA may decline to accept new data if either the format or content of the submission is considered inadequate to determine the application.

Other regulatory agencies, which have cooperative evaluations in progress, should be advised by the sponsor of any lodgement of new data to TGA. Similarly, sponsors should advise TGA of any submission of new data to an overseas regulatory authority, especially if a shared evaluation is in progress.

For administrative purposes, new data are classified in terms of additional data and supplementary data.

1. Additional data

Additional data are data, identified prior to the acceptance of an application, which the TGA agrees to accept during the course of the subsequent evaluation. Additional data are circumscribed, relate to a particular aspect of the submission and are not intended to facilitate inadequate or premature submissions. Acceptance of additional data for evaluation is at the discretion of the TGA.

When additional data may be submitted

Any additional data are to be submitted to the TGA by a date mutually agreed between TGA and the sponsor at a pre-submission meeting.

Clock stops for additional data will be negotiated on a case by case basis. Pursuant to section 31 of the Act, further clock stops may arise.

Submission of additional data does not impact on the submission of supplementary data.

2. Supplementary data

Supplementary data are non-clinical data (Module 4) or clinical data (Module 5), submitted at the initiation of the sponsor, that require evaluation and which address any possible or perceived deficiencies that may be identified in a primary evaluation report received by the sponsor.

So as not to limit current practice regarding Module 3 data, the guideline is primarily intended to allow for the submission of new non-clinical and clinical data. Only one submission of supplementary data will be permitted for each of Modules 4 and 5, unless otherwise agreed by TGA in writing.

Supplementary data will not be accepted after the pre-ADEC process has commenced, ie: when the Delegate's Request for ADEC Advice has been sent to the sponsor.

When supplementary data may be submitted

Supplementary data may be submitted:

- After a sponsor has received a Module 4 or 5 evaluation report, the sponsor may notify its intention to submit supplementary data relevant to that Module, that is, during the evaluation process whilst other evaluations are still in progress.
- Once the Module 4 and 5 evaluation reports have been received, the sponsor will have five working days to notify its intention to submit supplementary data for these evaluation reports. The 5 day period starts at the completion of the evaluation process and finishes prior to the beginning of pre-ADEC process, which is signified by the issuing of the Delegate's *Request for ADEC Advice*. This is preferable as it would enable cross referencing between the evaluation reports of all the data sets by both TGA and the sponsor and so avoid the unnecessary submission of data which would delay finalisation of the application. If supplementary Module 4 or 5 data have previously been submitted following receipt of an evaluation report, submission of further supplementary data relevant to that Module requires appropriate justification and written approval by the TGA.

Acceptance of the supplementary data is at the discretion of TGA and depends upon mutual agreement to the following clock stops:

- For up to 60 working days from the date of notification of an intention to submit supplementary data until the date that all data are received. If the data have not been received within this 60 working day period the clock will be reactivated and the application will proceed to the next step, either recommencement of the evaluation process or continuation to the pre-ADEC process. The TGA may decline to accept any subsequent submissions of such data.
- For up to 135 working days from the date of receipt of all the data. Once data are received within the 60 working day limit of the initial clock stop, a second agreed clock stop will commence to allow for evaluation of the data. For supplementary data submitted in the evaluation process, there may be a mutual clock stop for up to 135 working days for each submission of supplementary data.
- As required to respond to requests for additional information (S31 requests).

The originally unelapsed evaluation time shall remain unaffected by these clock stops. The clock will be reactivated once the evaluation/s of supplementary data is complete and the application will proceed.

Should the TGA fail to evaluate supplementary data within the specified 135 working days, the clock will recommence with the remaining evaluation of supplementary data being completed in TGA time.

The pre-ADEC consultation letter including the Delegate's Request for ADEC Advice will include a copy of the evaluation report/s for any supplementary data.

If there is no intention to submit Supplementary data the Sponsor is to inform the TGA as soon as possible to enable the application to proceed to the next phase of the registration process without delay.

Further information about supplementary or additional data can be obtained by contacting, The Manager, Application Support Team on (02) 6232 8121.

Therapeutic Goods Administration

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Reference/Publication #