Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Prescription medicine
BPR update newsletter

March 2011

The TGA—*Safeguarding public health through the effective and timely regulation of therapeutic goods*

Introduction

The March edition of the *Prescription medicine BPR update newsletter* focuses on the streamlined submission process project.

In this edition:

- streamlined submission process—progress to date
- regulatory requirements for PPFs and submission dossiers
- consultation process for electronic format submission dossier regulatory requirements
- information for sponsors on signing up for secure email
- new PI format requirements
- requests to vary Register information under s. 9D(2) (safety related notifications).

The TGA is pleased with progress to date under the transition period, and is engaged in ongoing work to ensure documents specifying the regulatory requirements for the streamlined submission process are updated as necessary in light of experience with the new process.

The TGA appreciates the feedback it has been receiving on the streamlined submission process from sponsors and encourages sponsors to email the BPR project with any questions. The information gathered from this process assists in refining the regulatory documents and supporting material.

The *Prescription medicine BPR update newsletter* (BPR update) reports on progress in the BPR program. Each month, the *BPR update* reports on the progress of the streamlined submission process. Each quarter, an update is provided on the PI/CMI project and the AusPAR project.

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1—Streamlined submission process project

1.1 Progress to date

The following table provides a summary of the November to March batches of PPFs received under the streamlined submission process, and the TGA's performance against milestones 1 and 2.

	Batch				
Item	**November**	**December**	**January**	**February**	**March**
Pre-submission planning forms					
Date processing PPFs commenced	1 Nov 10	1 Dec 10	1 Jan 11	1 Feb 11	1 Mar 11
PPFs received by processing date	28	34	24	25	27
S. 31 response—sponsor nominated 60 day	46%	68%	38%	48%	52%
Assessment status					
Number incomplete	5	3	2	1	pending
Number withdrawn or deferred	n/a	1	1	3	pending
Deficiencies (48 hours to address)	n/a	4	3	6	pending
Progress to planning letter	23	30	21	21	pending
Application type					
New entity – A	2	4	3	2	2
New fixed dose combination – B	0	1	1	1	0
Extension of indication – C	10	2	3	0	2
Generic – D	8	12	8	11	9
Minor variation – J, G, H	4	11	5	7	12
Major variation – F	3	2	1	4	2
(multiple application types)	2 with 3	2 with 2	3 with 2	-	-
M1 – Outcome of pre-submission sent					
M1 target date	15 Dec 10	15 Jan 11	15 Feb 11	15 Mar 11	15 Apr 11
Number met target date	23	30	21	4	pending
M2 – Outcome of submission consideration sent					
M2 target date	31 Jan 10	28 Feb 11	31 Mar 11	30 Apr 11	31 May 11
Number withdrawn	-	3#	3§	pending	pending
Deficiencies (48 hours to address)	15	12	pending	pending	pending
Number met target date	21	11	pending	pending	pending
Number effective notification letter	20	27	pending	pending	pending
Number not effective notification letter	3	0	pending	pending	pending

Includes 1 submission that was deferred until March 2011.
§ Includes 2 submissions that were re-lodged for consideration in the February batch.

1.2 Pre-submission planning form—regulatory requirements

The following information draws on common issues identified with PPFs submitted to date under the streamlined submission process. This information will assist sponsors in meeting the regulatory requirements of the streamlined submission process.

Problem	TGA requirement
Sponsors not referring to the current list of Australian Approved Names (AANs)	The current list of AANs can be found on the eBS website by clicking on the 'ingredients' link under 'public TGA information'. *See—* Module 1.2.1—Application form, in draft *CTD Module 1—Administrative information and prescribing information for Australia* January 2011.
Number of trade names	Sponsors are advised that the number of trade names nominated in the PPF must not be increased at the submission phase. Increasing the number of trade names in the submission phase constitutes a change in the scope and scale of the submission and may be grounds for considering a submission not effective and not accepted for evaluation. *See—* · *Transitional prescription medicine streamlined submission process* January 2011 · Module 1.8.3 of transitional draft *CTD Module 1* January 2011 · 'There are some differences between the information provided in my PPF and the submission. What do I do?' on the Q&A page on the TGA website.
Clearance of trade names	The TGA requires sponsors to include proposed trade names in their submission dossiers, and if available at the time, on the pre-submission planning form. The TGA recognises there is value in providing sponsors with advice on proposed trade names prior to lodgement of the PPF and this was proposed by the TGA in the streamlined submission process training sessions. However, a review of trade name assessment has confirmed it is not currently feasible for the TGA to implement a full advisory and approval process prior to PPF or submission lodgement. As such, PPFs can be lodged without advice from the TGA on the trade name(s) proposed. The TGA strongly advises that prior to lodging a PPF or submission dossier, sponsors: · perform a search on the public ARTG view to confirm the proposed trade name is not already registered · perform a search on the public ARTG view to confirm the proposed trade name is not similar to a trade name(s) already registered, for example, to ensure it does not look-like or sound-like an existing trade name · assess the proposed trade name against section 12 of the

Problem	TGA requirement
	Best practice guideline on prescription medicine labelling, section 1.5.4 of *CTD Module 1* January 2011, and other relevant guidelines · prepare at least one alternative name for each product should the TGA evaluation identify issues with the proposed trade name(s). This procedure is recommended for all proposed trade names, irrespective of whether they have been approved elsewhere in the world. The TGA advises that this procedure will provide sponsors with a level of confidence, but will not guarantee the acceptance of the proposed trade name. The TGA can only evaluate the proposed trade name during the assessment phases.
Justifications	Sponsors are reminded that at the pre-submission phase they are confirming their understanding of the guidelines that apply to their submission. Sponsors are reminded they should be aware of: · the content required for the submission · the guidelines that apply to the submission · where the submission deviates from the relevant guidelines · the need to prepare a robust scientific justification for any deviation from the relevant guidelines. *See—* Module 1.8.3 of *CTD Module 1—Administrative information and prescribing information for Australia* January 2011.
After-hours lodgement of PPF via eBS	Sponsors are able to lodge their PPF via eBS until midnight AEST of the lodgement date. However, sponsors should be aware the TGA does not provide after-hours support if sponsors encounter difficulties. If sponsors experience difficulties after hours, it may jeopardize the ability of the sponsor to meet the lodgement date.

1.3 Guidance for an effective submission

The following information identifies some regulatory requirements which are not being met, thereby risking that a submission will be considered not effective.

Problem	TGA requirement
Lodgement dates	The TGA planning letter identifies the date by which the submission dossier must be lodged. The submission dossier can be lodged anytime between the receipt of the planning letter and the required date for lodgement identified in the planning letter. However, submissions will not be processed until the lodgement date. In accordance with batch processing principles, submission processing activities commence on the fifteenth day of each month (or the following working day where the fifteenth falls on a weekend or public holiday in the Australian Capital Territory). For a submission to be processed in a given month it must be received by close of business on the working day immediately before the fifteenth day of that month, unless specified otherwise in the planning letter. Sponsors should be aware of the dates for public holidays in the ACT and plan to lodge their submissions accordingly. For a list of public holidays in the ACT, see www.cmd.act.gov.au. *See—* Section 4.3 of *Transitional prescription medicine streamlined submission process* January 2011.
Lodgement via eBS	The TGA advises the eBS system is not equipped to process major variation submissions (F), extension of indication submissions (C), product information changes (J), or minor variations (G&H). Lodgement via eBS is only available for: · new chemical entity (A) · new combination (B) · new generic (D).
Payment of fees	Fees are payable at the time of lodgement of the submission dossier. If sponsors are sending payment for which they have an invoice (for example, from electronic lodgement), they should either attach a copy of the invoice with the payment or reference the ONL/INV number in the covering letter.

1.4 Regulatory document for consultation

The TGA is engaged in a process which will result, in the longer term, in the phasing out of paper submission dossiers. This transition to a fully electronic environment is complex and requires several intervening phases.

The first phase was the TGA requirement under the streamlined submission process that submission dossiers be lodged in both paper and electronic format. The TGA is pleased that sponsors have generally adhered to this requirement. The electronic submission dossier, compiled according to regulatory requirements, is a critical part of the streamlined submission process as it allows the TGA to meet the timeframe allocated to milestone 2 where the TGA must consider a submission as either effective and accepted for evaluation, or not effective and not accepted for evaluation.

The second phase is to ensure clarity and to mandate the regulatory requirements for an electronic submission dossier. To this end, the TGA has opened a consultation process on the proposed mandatory regulatory requirements. The outcome of this second phase will inform the shape and scope of the third and subsequent phases towards the goal of fully electronic eCTD submission.

The TGA invites comment on the proposed mandatory requirements for electronic submission dossiers lodged under the streamlined submission process.

Full details on the consultation process, including the draft regulatory requirements are available at www.tga.gov.au. The consultation period is now open and will close on 1 May 2011.

It is the intent of the TGA to mandate the regulatory requirements from 1 July 2011.

2—Other news

2.1 Secure email

The TGA is encouraging sponsors to register for the TGA secure email service through eBS. Secure email, using digital encryption, is a way for the TGA and sponsors to send information by email where the content is considered sensitive and requiring protection.

For information on setting up the secure email service, sponsors should follow the instructions on the eBS website at www.ebs.tga.gov.au under the 'secure email' link in the menu bar.

When all sponsors have signed up for this service, the TGA will be able to explore the feasibility of using this platform to deliver letters to sponsors.

2.2 New PI format requirements

Currently, applications for the inclusion of prescription medicines in the Australian Register of Therapeutic Goods (ARTG) under the *Therapeutic Goods Act 1989* (the Act) must include a draft product information document as part of the required registration package. It is also a condition of registration of these medicines that the product information document approved by the Secretary of the Department of Health and Ageing at the time of registration of the medicine can only be varied with the Secretary's approval.

Recent amendments to the Act formalise the process for the approval of product information for medicines and introduce the concept of a 'restricted medicine'. Restricted medicines will include prescription medicines (see schedules 4 and 8 of the current Poisons Standard) and medicines only available from a pharmacist (schedule 3 of the current Poisons Standard). It will be open to the Secretary

to require other high risk medicines to have approved product information as a condition of registration where appropriate.

Under the new section 7D of the Act, the draft product information document must be lodged in a form approved by the Secretary. The TGA has not yet released this form, but it will be based on Appendix 8 of the current *Australian Regulatory Guidelines for Prescription Medicines* (ARGPM). As currently occurs during the evaluation of a prescription medicine, the evaluation of restricted medicines, or medicines for which a product information document is required to be approved, will take into account the product information provided by the applicant in relation to the medicine. Applicants will be formally notified of the approval of the product information at the time of notification of registration.

When the new form is released, details will be posted on the TGA website and information provided in the BPR update newsletter.

2.3 Requests to vary Register information under s. 9D(2)

The TGA is receiving a growing number of requests under s. 9D(2) of the *Therapeutic Goods Act 1989* (referred to as 'safety related notifications') to vary information included in the Register that fail to meet the requirements for consideration under this section of the legislation.

Sponsors are reminded of the legislative and regulatory requirements for requests made as safety related notifications, specifically, the requests must be limited to:

- reducing the patient population
- adding warnings, precautions, contraindications or adverse events
- removing one or more indications.

Further, requests made as safety related notifications must not require the evaluation of data.

Where the TGA receives a request for which these requirements are not met, and the request cannot be considered under s. 9D(3), the TGA will advise the sponsor that they will need to lodge a pre-submission planning form for a category 1 submission before lodging their application to make the changes. In addition to delays in making the changes, sponsors may also forfeit the fee paid for a request under s. 9D(2) where the requirements are not met.

Sponsors are encouraged to discuss potential safety related notifications with the TGA before lodgement to ensure the above requirements are met. Contact aet.application.entry.team@tga.gov.au for more information.