Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Prescription medicine
BPR update newsletter

September 2011

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

Introduction

The September 2011 edition of the *Prescription medicine BPR update newsletter* provides an update on the streamlined submission process.

In this edition:

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

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1—Transition period ends soon

The streamlined submission process for prescription medicines was introduced on 1 November 2010. To assist sponsors with changes under the new processes, the TGA agreed to a twelve-month transition period. This period finishes at the end of October 2011.

During the transition period, the TGA has assisted sponsors to correct deficiencies in pre-submission planning forms (PPFs) and submission dossiers. This has included the provision of a transitional 48 hour 'grace period' for sponsors to correct such deficiencies. The impact of this grace period on TGA internal processes has been significant. Each 48 hour period translates to 2–7 days for the TGA, thus throwing the batch processing out of step. This, in addition to the parallel processing of applications that were received before 1 November 2010, has placed significant pressures on the TGA's ability to meet the streamlined submission process milestones for all applications, not just the ones that have required such corrective action. The key finding has been that even if only a minority of applications require this level of effort from the TGA, the entire batch of applications will be affected. And of course there are the flow on effects to subsequent batches.

The TGA is therefore not able to extend these transitional assistance measures beyond the transition period. It is critical that sponsors take responsibility for ensuring their PPFs and submissions include all the required information. Section 23 of the *Therapeutic Goods Act 1989* (the Act) specifies that an application is not effective unless it meets a number of criteria. One of these criteria relates to the information that must be provided to the TGA to allow a determination of the application. This information must be provided in accordance with the approved form. Information on the approved form is available in the legislation and legislative instruments section on the TGA website. If these mandatory requirements are not met, a PPF may be considered not complete or a submission may be considered not effective.

Early indications are that complete and quality submissions are progressing along timelines that are shorter than the average pre-BPR timelines. The TGA will continue to monitor and report on progress under the streamlined submission process. Once the first few batches of BPR submissions have completed the evaluation and decision phases, we will gain a clearer picture of how we're tracking against timelines.

The lessons so far are that the parallel processing of pre-BPR and BPR submissions is impacting on TGA resources and processes. We anticipate that the pre-BPR submissions will be finalised by the end of the 2011-12 financial year. This will allow the TGA to focus all our internal and external evaluation resources on new applications. This will result in fewer extensions of milestone dates. Although it is important to note that in some cases the need to extend milestone dates is related to the quality of the applications received by the TGA. The TGA will continue to review regulatory and supporting documents, but it is ultimately a sponsor's responsibility to ensure they understand the regulatory requirements. In relation to reviewing the *Australian regulatory guidelines for prescription medicines*, the BPR Industry working group is discussing options for working together to achieve the best possible outcome.

2—Streamlined submission process

2.1 Summary of progress to date

The following is a summary of key statistics from applications under the streamlined submission process. For a full record of progress to date under the streamlined submission process, see the attachment at the end of the newsletter.

- September 2011 batch
  - 33 PPFs lodged
  - 46% nominated 60-day response period to s. 31 request
  - new entity – 4; new fixed combination – 1; generic – 16; minor variation – 9; major variation – 3

Streamlined submission process—deficiency statistics										
Item	**Nov-10**	**Dec-10**	**Jan-11**	**Feb-11**	**Mar-11**	**Apr-11**	**May-11**	**Jun-11**	**Jul-11**	**Aug-11**
Pre-submission planning forms										
PPFs lodged	28	34	24	25	27	33	28	29	35	26
Deficiencies	-	12%	12%	24%	30%	24%	7%	28%	25%	31%
Not complete	5	3	2	1	0	0	1	0	0	-
Submission dossiers										
Lodged	23	30	21	21	27	33	27	29	34	-
Deficiencies	65%	40%	43%	29%	48%	52%	67%	69%	-	-
Not effective	1	0	1	0	0	1	2	-	-	-

During the transition period, rather than immediately considering a PPF not complete or a submission dossier not effective, the TGA has given sponsors a 48 hour 'grace period' to address any deficiencies identified by the TGA. The aim of this process, which will be phased out when the transition period ends, has been to assist sponsors as they become familiar with the changes in requirements that have accompanied the introduction of the streamlined submission process. As the transition period has progressed and the regulatory requirements have been clarified, the TGA expected to see a significant reduction in deficiencies. The 48 hour grace period, in practice, adds between 2 and 7 days to TGA processing times and is a significant burden on TGA resources. See the discussion in this newsletter in section *5—Industry working group*, for further detail. Sponsors should also read section *2.5—Regulatory requirements* which explains the regulatory requirements for a complete PPF and an effective submission.

2.2 Pre-submission planning form—common issues

The following information draws on common issues identified with pre-submission planning forms (PPF) lodged to date under the streamlined submission process. This information applies to all applications lodged under the streamlined submission process.

As part of the transition period, the TGA committed to assisting sponsors adapt to the streamlined submission process. As a part of this commitment, the TGA has been providing sponsors with opportunities to resolve issues that would otherwise result in the PPF being considered not complete. This has posed a significant drain on TGA resources and will be phased out when the transition period concludes at the end of October 2011. Sponsors should therefore ensure they address the PPF issues the TGA has been communicating to industry through *BPR update* newsletters and the application planning and notification letters, before submitting the PPF.

Pre-submission planning form—regulatory requirements		
Deficiency	**TGA requirement**	**TGA workflow impact**
Section 1.3 – Product details table	Sponsors must complete the product details table in section 1.3 of the PPF. *See—* · *Information for sponsors completing a pre-submission planning form*	This information allows the TGA to understand the number and types of products that will be affected by the submission and thus requiring evaluation. Without this information the TGA is unable to assess or arrange the evaluation resources required.
Sterile products	If sponsors are seeking to register sterile products that rely on parametric release systems, they must contact the TGA prior to lodging their PPF to receive advice on the type of information that will be required to support such an application. Sponsors need to understand the data requirements for this type of product as it will affect the content of the submission dossier. The data in the submission dossier must be foreshadowed in the PPF.	If sponsors do not provide an accurate description of the information/data that will be presented in the submission dossier, the TGA cannot assess the scope and scale of a submission and plan resources accordingly. If the submission subsequently differs in scope and scale, it will be considered not effective and not accepted for evaluation.
Justifications for not providing biopharmaceutic studies	The TGA regulatory documents, EU guidelines adopted in Australia, and other Australia-specific guidelines determine what sponsors must include in modules 1, 2, 3, 4, and 5 of a submission dossier to demonstrate quality, safety, and efficacy. A justification is a reason given by the sponsor for not complying, in the submission dossier, with a specific requirement or guideline. In completing a PPF, sponsors provide a summary of any justifications they will use in their submission dossiers. Where a submission dossier requires the inclusion of biopharmaceutic studies but such studies are not available for the full suite of products proposed, sponsors must provide an overview, in the PPF, of the justification they will use for not providing these studies in the submission dossier. In the submission dossier, this justification is provided at	The nature of the justification provided will impact on the scope and scale of the submission and thus on resourcing required for processing and evaluation. If information on justifications is not provided, the TGA is unable to proceed to the planning letter and will consider the PPF not complete and not acceptable.

Pre-submission planning form—regulatory requirements		
Deficiency	**TGA requirement**	**TGA workflow impact**
	module 1.11.2 in instances where: · part 3 of appendix 15 of the ARGPM indicates that biopharmaceutic studies are required, and · the biopharmaceutic studies indicated in part 3 as required have not been provided. For example, a justification is required for tablets containing a new medicine where the biopharmaceutic data provided does not cover all of the different strengths proposed for registration. *See—* · module 1.11.2 of *CTD Module 1: Administrative information and prescribing information for Australia* · appendix 15 of the *Australian regulatory guidelines for prescription medicines*	
Module 5.2 Tabulated list of clinical studies	Module 5.2 is required for the TGA to assess the scope and scale of the clinical studies being provided in the submission dossier. The information in module 5.2 is also needed when the TGA has to engage external evaluators. *See—* · *Information for sponsors completing a pre-submission planning form*	If the information provided in module 5.2 is not accurate and complete, the TGA is unable to assess the scope and scale of a submission, and unable to engage external evaluators where required.
Literature references	Literature references are often required in an application. The CTD format specifies where these references are located, namely modules 2.5.7, 2.7.5, 3.3, 4.3, and 5.4. If any of these sections appear in a table of contents submitted with the PPF, the full bibliographic details of all of the references in these sections of the submission dossier must be included in the table of contents. At a minimum, the following information for each literature reference must be listed in the table of contents: · author/s · date · title of article/chapter · name of journal/book · page numbers. Furthermore, the TGA will need to undertake detailed evaluation of references where sponsors are either: · submitting a literature-based submission · propose to include in module 4 or 5, publications that form part of the direct evidence to support the application. In such cases, sponsors must list all references in a separate bibliography titled 'module 4 literature to be evaluated' and 'module 5 literature to be evaluated'. Alternatively and if appropriate, the references may be included in the relevant sections of the 'tabular listing of all clinical studies' (module 5.2) and 'non-clinical tabulated summaries' (module 2.6).	If the full list of literature references is not provided, and if page numbers are not included, the TGA is unable to assess the scope of the evaluation required for the application.

2.3 Guidance for an effective submission

Submissions that do not meet the following regulatory requirements may be considered by the TGA to be not effective and not accepted for evaluation.

Guidance for sponsors—submission dossiers		
Deficiency	**TGA requirement**	**TGA workflow impact**
Language requirements	Information in the submission dossier must be in English, and be legible. Where material is not originally in English, a copy in the original language and a full translation must be lodged. The accuracy of the translation is the responsibility of the sponsor. Section 23 of the *Therapeutic Goods Act 1989* (the Act) specifies that: · an application is not effective unless a sponsor supplies to the TGA information that will allow the determination of the application · information must be in the approved form. Details of the approved form and the information it must contain are provided in the legislation and legislative instruments section on the TGA website. *See*— · part A of *CTD Module 1: Administrative information and prescribing information for Australia*	If information in the submission dossier is not provided in English, the TGA is unable to make a determination of the application.
Product information documentation	A product information document lodged in the submission dossier must meet the following requirements: · if applying for the registration of a restricted medicine, the application must include a PI document for the medicine that is in the form approved under section 7D of the (the Act) · proposed changes to a PI document (where the sponsor is altering a PI already lodged/approved) must be clearly highlighted—track changes mode is preferred All PI documents must be annotated to include sufficient information to direct evaluators to the evidence base in modules 2, 3, 4, and/or 5 that support any changes or new information being proposed. *See*— · appendix 8 of the *Australian regulatory guidelines for prescription medicines* · module 1.3.1 of *CTD Module 1: Administrative information and prescribing information for Australia* · PI information on the TGA website.	Information in the PI must be linked to the evidence base in modules 2, 3, 4, and/or 5 or the PI cannot be evaluated.
Module 1.8.3 Declaration of compliance with PPF and planning letter	In this document, the sponsor: · declares the submission dossier is consistent with the information provided in the PPF · where applicable, outlines where differences exist between the PPF and the submission dossier · explains how any issues raised by the TGA in the	The TGA assigns and schedules all processing and evaluation resourcing for an application based on the information provided in the PPF. The evaluation plan for the application is established

Guidance for sponsors—submission dossiers		
Deficiency	**TGA requirement**	**TGA workflow impact**
	planning letter have been addressed. In cases where there is a difference between the information provided in the PPF and the subsequent dossier, sponsors should contact the TGA in advance of submission lodgement. *See—* · module 1.8.3 of *CTD Module 1: Administrative information and prescribing information for Australia*	in the planning letter sent to sponsors whose PPFs have been considered complete and acceptable. If the submission dossier does not reflect the information provided in the PPF, the resourcing and expertise arranged by the TGA to process and evaluate the submission will no longer be appropriate and as such, the application cannot proceed.
Module 3 Sterility data	All sterility information in relation to a proposed or revised medicine must be included in the submission dossier. This includes sterile presentations that are either a new registration or a variation to an existing registration for which there is new/amended sterility information. *See—* · *Transitional mandatory requirements for an effective submission*	Sterility data is required during the 1st round assessment phase. If it is not provided, the evaluation cannot begin and the submission will be considered not effective and not accepted for evaluation.

2.4 Understanding the streamlined submission process

The TGA has recently received some questions about aspects of the streamlined submission process. The following information will help sponsors understand issues that sometimes arise and impact milestone dates under the streamlined submission process.

Explaining the streamlined submission process	
Issue	**Explanation**
Why does the TGA require such comprehensive information about my submission dossier in the PPF?	The TGA uses the information lodged by sponsors in the PPF to assess the scope and scale of the submission. This allows the TGA to plan the necessary resourcing to process and evaluate the submission, and thus to commit to milestone dates in the planning letter. The information is particularly crucial when the TGA needs to secure external evaluators (see below). It is essential therefore that sponsors provide an accurate and complete picture of their submission dossier. The TGA recommends all sponsors review and consider the information on PPFs provided in each *BPR update* to ensure common pitfalls are avoided. Furthermore, sponsors should take special care when reading the PPF, and *Information for sponsors completing a pre-submission planning form*. The TGA also alerts sponsors to issues relating to their submission in the planning and notification letters. During the transition period, the TGA has worked with sponsors to address such issues. With the conclusion of the transition period at the end of October 2011 approaching, sponsors should be aware they are responsible for ensuring their PPFs and submissions meet all legislative requirements.

Explaining the streamlined submission process	
Issue	**Explanation**
My planning letter extends milestone 3 because evaluation resources are not available. What does this mean?	TGA staff include evaluators who have specific expertise in chemistry, biological, non-clinical, and clinical evaluations. At times, the TGA will receive more submissions than TGA staff are capable of evaluating within the streamlined submission process timeframes. This is because the TGA does not limit the number or type of submissions it will accept in a given batch. Furthermore, some submissions will require specific evaluation expertise that is not available internally. Some submissions may be evaluated by a combination of internal and external evaluators. In these circumstances, the TGA will contract external evaluators. The TGA has established, through tender process, a panel of external evaluators who possess skills across a broad range of areas. When the TGA receives a PPF, a TGA evaluator assesses whether an external evaluator will be required for the evaluation of data in the submission dossier. In completing this assessment, the internal evaluator prepares a briefing that identifies which aspects of the submission require evaluation by an external evaluator, and details the scope and scale of this work. This briefing may include some or all of the documents provided in the PPF by the sponsor. The TGA uses the briefing to seek quotes from suitably qualified external evaluators who are on the TGA panel of external evaluators. Based on these quotes, an evaluator will be engaged. On occasion, the TGA encounters periods where: · evaluators are not available (this is often during January) · external evaluators with the required expertise are engaged in other activities and cannot commit to the TGA evaluation · an appropriately qualified external evaluator cannot meet the timeframe requested by the TGA. This necessarily delays the process of engaging an external evaluator. Where any of these are the case, and the TGA cannot conduct the work internally, milestone 3 will be extended to ensure the 1st round assessment phase is completed before the s. 31 request is issued. It should be noted that a complicating factor is that the TGA is currently also processing pre-BPR submissions. Once this backlog is cleared (we anticipate by the end of the 2011-12 financial year), more evaluation resources will be available for new submissions. In addition, the TGA is also pursuing options for expanding the available pool of evaluation resources.

2.5 Regulatory requirements

As sponsors are aware, the success of the streamlined submission process is predicated upon sponsors lodging quality and complete PPFs and submission dossiers. Applications that meet the regulatory requirements of the streamlined submission process are vital to allow the TGA to commit to predictable timeframes for the evaluation of prescription medicines.

Category 1, category 2, and category 3 applications for new registrations are made under s. 23 of the *Therapeutic Goods Act 1989* (the Act). A new registration is one that requires a new ARTG entry by reason of being separate and distinct goods under s.16 of the Act. Section 23 requires that applications are made in a form approved by the Secretary.

Pre-submission planning forms

The currently approved form is the *pre-submission planning form—January 2011*. This must be completed in accordance with the requirements set out in *Information for sponsors completing a pre-submission planning form*.

Submission dossiers

The currently approved form is described in the legislation and legislative instruments section on the TGA website. The form mandates the following documents:

- *CTD Module 1: Administrative information and prescribing information for Australia*
- EU CTD modules 2–5
- *Transitional mandatory requirements for an effective submission*.

Category 1, category 2, and category 3 applications requesting a variation to an existing registration are made under s. 9D(3) of the Act. The TGA requires that such applications are also provided in CTD format.

The exact content of the submission dossier will vary according to application category and application type. A dossier documents matrix is provided at part D of *CTD Module 1*. This provides a high-level overview of the submission dossier CTD section requirements for different application types.

CTD Module 1 establishes the content for module 1 for different application types.

Module 2 is a summary module which provides an overview of the information/data provided in the quality (module 3), non-clinical (module 4), and clinical (module 5) modules of the dossier. Information on the content of module 2 is provided at the beginning of EU CTD modules 3, 4, and 5.

The content of modules 3, 4, and 5 is loosely prescribed by the EU CTD modules 3, 4, and 5. These modules contain headings and sub-sections under which sponsors must insert relevant data. To determine technical data requirements—the information that must be provided under the headings and sub-sections—sponsors must consult relevant EU guidelines adopted in Australia, and other Australia-specific guidelines.

Technical data requirements

The submission dossier must provide appropriate documentation (in the correct location, as determined by the CTD modules), including outcomes of trials and studies, to adequately support quality, safety, and efficacy claims. Failure to establish quality, safety, and efficacy for the purpose for which the goods are to be used will result in rejection of the application.

The adopted EU guidelines and other Australia-specific guidelines specify the information required by the TGA, and are the regulatory requirements against which the TGA considers a submission dossier, and assesses quality, safety, and efficacy. Sponsors must consider these guidelines when compiling the information for their submission dossier.

The use of EU guidelines adopted in Australia and other Australia-specific guidelines is not mandated in the legislation. However, s. 25(1)(d) of the Act requires that when making a decision on whether to approve a medicine for registration, the delegate determines:

> *whether the quality, safety, and efficacy of the goods for the purposes for which [the goods] are to be used have been satisfactorily established.*

Failure to address the applicable requirements/guidelines in a submission dossier, or failure to adequately justify why an applicable requirement/guideline has not been addressed in the submission, carries a high risk that the application will be rejected. The sponsor must provide the appropriate documentation to adequately support their quality, safety, and efficacy claims.

- Australia-specific requirements—these requirements are identified in *CTD Module 1* and the *Australian regulatory guidelines for prescription medicines* (ARGPM). Where there is conflict between *CTD Module 1* and the ARGPM, *CTD Module 1* takes precedence.

- EU guidelines adopted in Australia—guidelines prepared by the European Committee for Medicinal Products for Human Use (CHMP) and/or those prepared within the ICH process that have been adopted by the TGA.

2.6 PI/CMI documents

Product information (PI) and consumer medicine information (CMI) documents can only be lodged when the sponsor has received formal approval from the TGA delegate, and after the product is registered on the ARTG. The approval is provided in the letter of decision issued at milestone 7 of the streamlined submission process. Until such time that approval had been granted, and an entry made to the ARTG, sponsors must not lodge PI or CMI document(s) through the TGA eBS PI/CMI facility.

All PI and CMI documents must be uploaded to the specific ARTG entry for which they are approved—these documents cannot be uploaded using the ARTG entry of a related product.

3—Christmas-new year arrangements

3.1 TGA shutdown

The TGA will close at 3.00 pm on Friday 23 December 2011 and will re-open on Tuesday 3 January 2012. During this period, no TGA personnel will be answering phone calls or monitoring the BPR or streamlined submission process email inboxes. To accommodate this Commonwealth public service shutdown period, the following arrangements will be made.

3.2 Arrangements for December/January batches

As a consequence of the TGA shutdown, PPFs lodged in the December batch (before 1 December 2011) will be processed in accordance with January 2012 batch milestone dates. This means, the planning letter for PPFs lodged in the December batch will not be issued until 15 February 2011.

3.3 Arrangements for other milestone dates

The TGA has made the following arrangements for other milestone dates falling over the Christmas-new year period. The TGA has considered these arrangements carefully so as to not impact on eligibility for planned ACPM meetings.

The TGA estimates that approximately 100 submissions currently in the streamlined submission process that will be impacted by these arrangements. Sponsors should ensure they are familiar with these arrangements as the TGA may not be able to issue revised dates on a submission-by-submission basis until the next milestone.

Streamlined submission process Christmas-new year arrangements				
Milestone/phase	**Affected batch/es***	**Original due date**	**Revised due date**	**Comments**
MS1 PPF (December batch)	Dec 2011	15 Jan	15 Feb	Milestones for all December PPFs will be aligned with those of the January batch of PPFs. The default dates for both December and January batches will therefore be: · submission dossier lodged by COB 14 March · milestone 2 – 31 March 2012 · milestone 3 – 31 July 2012 (assuming default evaluation period)
MS2 Outcome of submission consideration sent	Oct 2011	31 Dec 2011	16 Jan 2011	The milestone 3 for these submissions will be extended to align with the end of the month.
MS3 Outcome of 1st round assessment sent	May 2011 June 2011	31 Dec 2011	21 Dec 2011	Due dates for relevant responses will be remain as specified in the planning letter to ensure statutory timeframes are met.
MS4 End of s.31 response period	March 2011 April 2011 May 2011	31 Dec 2011	3 Jan 2011	As the TGA will not be open to accept deliveries or post during the shutdown period, the due date for sponsors to deliver their responses is extended to the first working day of the new year.
MS5 Outcome of assessments sent	Feb 2011 March 2011 April 2011	31 Dec 2011	16 Jan 2011	The sponsor's response period to advise the TGA of any errors of fact or omission in the evaluation report will be maintained at two weeks.
MS7 Decision made by delegate	Nov 2010 Dec 2010	31 Dec 2011	case-by-case	The TGA will, wherever possible, complete the decision phase before the Christmas shutdown.
MS8 Administrative and regulatory activities complete	Nov 2010 Jan 2011	31 Dec 2011	case-by-case	The TGA will, wherever possible, complete the post-decision phase before the Christmas shutdown. Note, however, that there are sponsor dependencies.
MS1 (January batch)	January 2012	1 Jan 2012	3 Jan 2012	Milestones for this batch will be as per prescription medicines streamlined submission process.

* This information is provided as a guide only and sponsors should check the most recent milestone letter from the TGA for each submission to determine if it is affected by these arrangements.

4—Fees

Legislative changes in relation to fees payable to the TGA came into effect on 1 July 2011. These changes were explained in the July 2011 edition of the *BPR update*. In response to sponsor queries, the TGA provides the following information to clarify the fee arrangements as they apply to the streamlined submission process.

Streamlined submission process fee arrangements		
Phase/milestone	**PPFs lodged until 30 June 2011**	**PPFs lodged from 1 July 2011**
Phase 1 Pre-submission phase	No fee payable at lodgement of the PPF	Sponsor pays the application fee when lodging the PPF. If the application fee is not paid at the time of PPF lodgement, the TGA will invoice the sponsor.
MS1 Outcome of pre-submission sent	If the TGA considers the PPF not complete and not acceptable, there is no financial penalty.	If the TGA considers the PPF not complete and not acceptable, the sponsor forfeits the application fee.
Phase 2 Submission phase	Sponsor can pay 75% of evaluation fee at submission lodgement. If no fee is paid, the sponsor will be invoiced for the appropriate amount (see MS2 below).	Sponsor can choose to pay the evaluation fee at submission lodgement.
MS2 Outcome of submission consideration sent	If the TGA considers the submission not effective and not accepted for evaluation, the sponsor is liable to pay 20% of evaluation fee up to a maximum of $7,780. If the TGA considers the submission effective and it is accepted for evaluation and a decision on the application is made within the statutory timeframe, the sponsor must pay the remaining 25% of the evaluation fee.	If the application fee is not paid prior to submission lodgement, the submission will be automatically considered not effective and will not be accepted for evaluation. If the TGA considers the submission not effective and not accepted for evaluation, the sponsor forfeits the application fee. If the TGA considers the submission effective and it is accepted for evaluation, the sponsor will be informed in the notification letter of the evaluation fee amount (if it has not already been paid). The TGA will issue an invoice for the evaluation fee shortly after the notification letter where the fee has not already been paid. If the evaluation fee is not paid within two months of the date of the notification letter, the application lapses in accordance with s. 24(2) of the *Therapeutic Goods Act 1989*. If the sponsor has already paid the evaluation fee at submission lodgement but the submission is considered not effective and is not accepted for evaluation, the TGA will refund the evaluation fee. If a decision on the evaluation is not made within the statutory timeframe, the TGA will refund of 25% of the evaluation fee.

5—Industry working group

The BPR industry working group met on 8 September 2011. A summary of the discussion is provided below.

Industry working group—8 September 2011 summary of discussion	
Issue	**Summary of discussion**
Pre-BPR applications	**Current TGA workload** · 244 applications lodged prior to the introduction of the streamlined submission process (pre-BPR) **Implication for TGA resources** · evaluation of pre-BPR applications is a substantial drain on TGA evaluator resources · 117 of pre-BPR applications are scheduled for completion by the end of 2011 · the completion of pre-BPR applications will increase available evaluation resourcing
BPR progress 48 hour grace period	**Poor quality submissions** · a high number of poor-quality PPFs were received in the August 2011 batch **Implication for TGA resources** · the TGA provides a 48 hour 'grace period' for sponsors to rectify identified deficiencies · grace period places an increased burden on TGA resources, adding between 2 and 7 days to TGA processing times: – prepare and issue deficiency notice – review and respond to any queries or extension requests from sponsors – receive deficiency response – confirm the response is acceptable – update files, dossiers, and repositories – reassess scope and scale of submission – prepare necessary documents to secure external evaluator if required – proceed to notification letter **Response from IWG members** · despite some areas of concern and recognising the work in progress to improve the streamlined submission process, IWG members agreed they were happy with BPR progress to date, particularly in terms of: – improved transparency – predictability in process – enhanced communication
External evaluator procurement	**Procurement process** · extensive discussion around external evaluator procurement · explanation of TGA process—TGA is required, as a government entity, to follow a particular external evaluator procurement process with various legislative and operational requirements and timeframes **TGA activity** · the TGA is examining options to improve procurement timeframes to reduce the impact on sponsors of any delays involved in confirming external evaluator resources
Communication	**Future for IWG** · agreement that the implications of the prescription medicine BPR program will persist for some time · IWG will convene throughout 2012 to maintain communication and industry support for reforms