

Media Coverage

Company: AusBiotech
Date: 8 February 2010
Publication: The Pharma Letter
Page: Online

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the pharma letter

Australia's TGA consults on requirements for the Rx medicine streamlined submission process

Australia's Therapeutic Goods Administration has completed a review of the prescription medicine evaluation process, with a number of areas for streamlining being identified. Prior to implementation of the new streamlined process the TGA is inviting external stakeholders to review the proposed changes and provide comment on the underlying requirements that have been developed to underpin the process.

In the modern regulatory environment health regulators around the world, such as the TGA, are being asked for greater transparency in their regulatory processes, earlier access to novel therapies and more cost effective regulatory processes. Mindful of these sometimes competing demands, the TGA says it is progressing the prescription medicines Business Process Reforms (BPR).

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The TGA notes that, currently, it takes on average approximately 500 days for a new prescription medicine to be approved by the agency. The BPR has identified a number of areas for process improvement to reduce this time significantly, to around 300 days. This will be achieved by eliminating unnecessary queues and delays in the evaluation process that have developed over time. It is important to note that this can be achieved without compromising the scientific rigor of the evaluation process; ensuring appropriate standards of quality, safety and effectiveness are maintained, the TGA stressed.

Since April 2009, the TGA has been working with an industry working group which assisted in developing concepts and identifying issues that need to be considered. Consultation has also occurred with various industry bodies including Medicines Australia, the Generic Medicines Industry Association, **AusBiotech** and the Consumer Health Forum.

The key elements of this streamlined process are:

1. Clearly detailed submission and associated dossier requirements;
2. Sponsor lodgement of proposed submission details (via a Pre-submission Planning Form) two and a half months prior to lodgement of their complete submission and associated dossier;
3. TGA scheduling of resources to handle a submission it knows is coming on a certain date;
4. Careful checking of the submission and associated dossier prior to commencement of evaluation to ensure compliant with application form and Common Technical Document (CTD) requirements;
5. New business processes within TGA to more effectively manage workflow and queues;
6. Consolidation of regulatory questions to avoid unnecessary steps in the process;
7. Requirements for sponsors to answer regulatory questions in a defined timeframe to allow the new work processes to proceed without delay;
8. Publication of a summary of the regulatory decisions made in relation to evaluate; and
9. Publication of Product Information and Consumer Medicines Information on the TGA web site.

The streamlined process clearly articulates what is required for an effective submission, and makes clear that submissions that do not meet these requirements will be deemed not effective, says the TGA. At present, prescription medicine submissions are generally accepted irrespective of whether or not all necessary information is present. This has contributed significantly to the queues and delays in the evaluation process. In addition, currently companies are asked for clarifications on evaluation matters throughout the process, requiring the evaluation to repeatedly stop and start. This, coupled with often lengthy response times to the questions of clarification, can further lengthen the evaluation completion time.

Sponsors of submissions found to be deficient at the submission phase will have their submission deemed not effective and they will not be accepted for evaluation. They will then be required to resubmit a new submission, and pay a new application fee, once they have obtained all necessary information.

This fundamental change requires the TGA to provide clear requirements for an effective submission. The current CTD requirements for quality, safety and efficacy, as adopted in Australia from the European Union, are being supplemented with a clear list of the requirements that must be addressed in the CTD provided with the submission.