07 November 2012

Office of OTC Medicines
Therapeutic Goods Administration
PO Box 100
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Call for comments on the Consultation Paper: Over-the-counter (OTC) Medicines Business Process Reform version 1.0 September 2012

Reckitt Benckiser Pty Ltd would like to thank the TGA for this opportunity to comment and contribute in the development of guidelines for the Over-the-Counter Medicines Business Process Reform.

In general Reckitt Benckiser Pty Ltd supports the need for OTC Medicine Evaluation process reforms to provide industry with: predictability of process and timing, clarity of the requirements for different types of applications and transparency of the process and progress and the idea on the proposed risk based approach on different categories of OTC medicines such as new medicines and changed medicines and the proposed five-phase evaluation process.

The majority of our comments stem from the following major issues:

- The need for sponsors to be given the opportunity to liaise with the TGA prior to the submission of an application in order to ensure that the category of submission (risk level) is appropriate and that the data requirements are fully met.
- The lack of decision trees to determine the relevant risk level of a proposed application.
- The lack of clarity in terms of data requirements depending on the risk level.
- The lack of transparency in terms on the proposed timeframes for each stage of evaluation, response times to TGA requests for further information and inclusion of time for referral to ACNM/MAAC.
- The lack of a transition phase in order for the industry to be given a chance to adjust to this new system.

The following are the comments made by Reckitt Benckiser Pty Ltd

1. Page 9 Phased Implementation on the new business processes

- On page 9 it states that a number of forms and guidelines will be developed including application forms that clearly specify data requirements for each category of application, updates to regulatory guidelines, assistance tools to assist sponsors to determine the appropriate application category and frequently asked questions for sponsors. When will the developed forms and guidelines be available? Industry needs to see these documents before OTC BPR goes live in April 2013.

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Reckitt Benckiser recommendation:

1. Industry must be consulted on additional guidelines, assistance tools before the new process becomes effective. The TGA should develop submission checklists In order to assist industry in preparing good quality applications that meet the TGA requirements.
2. A transition phase of 24 months must be provided for sponsors to adjust to this new system.
3. If a document is identified as missing during technical screening then an acceptable timeline should be provided to the sponsor to address the issues identified by the TGA as many multinational companies may struggle to provide requested/unexpected data on time.

2. Page 13 OTC Medicine Monographs (OMMs)

- On page 13 OTC Medicine Monographs (OMMs) it states that the proposed framework includes a category called N2 for products that are comprised of well-characterised active ingredients, provided that the product fully complies with the applicable OTC Medicine Monograph (OMM). It seems that the TGA's intention is for monographed products to be unbranded. If this is the proposal then the TGA should be clear on this point.

Reckitt Benckiser Recommendation:

Reckitt Benckiser suggests that a reference is provided to page 20 for further information on OTC Medicine Monograph and on post-market monitoring.

Reckitt Benckiser also suggests that a reference is included in this section stating that if a sponsor wants to make a change to an OTC Monograph (a notification or a variation) then one should refer to Appendix 3 of the Changes table.

3. Page 20: OTC Medicine Monographs (OMMs)

- In general Reckitt Benckiser does not agree with the introduction of OTC Monographs. We believe that companies who's applications fall under this category will have a significant advantage in terms of submitting less data and speed to market. It is not clear what the criteria will be in order for a product to fall under a monograph e.g. introduction of graphics and wording used on labels that could fall under an OTC Medicine Monograph- this needs to be clarified as at it seems that unbranded products will have a significant advantage over branded products.
- On page 20 the OTC Medicine Monograph (OMMs) requirements are mentioned. Reckitt Benckiser believes that industry needs to know what will be required as part of post-market review from sponsors that will have OMMs. TGA should provide a list of documents (CTD sections) that would be required as part of the TGA request for post-market review of an OTC registered product.
- Reckitt Benckiser would like to know what the TGA's expected response time will be for post-market audits.
- Reckitt Benckiser is also not clear on the imposed penalties by the TGA if the TGA is not happy with the documentation provided as part of the post-market review.
- The proposed OTC medicine monograph list includes the following ingredients: paracetamol, aspirin, topical antifungals such as clotrimazole and miconazole, paracetamol/codeine combination and ranitidine hydrochloride. What is the future plan for expanding the monograph list and will there be a process for sponsors to suggest ingredients that should be monographs based on established evidence?

Reckitt Benckiser Recommendation:

TGA should provide industry with a list of documents that industry would need to submit as part of post-market review as well as an overview on the imposed TGA penalties if TGA is not satisfied with the sponsor's response.

4. Pages 27-34: Appendices

- The risk categorisation tables make reference to the type of applications that can be submitted to the TGA depending on the level of risk in CTD format. Module 1 is referenced in all of the risk levels.

Reckitt Benckiser Recommendation: Module 1 requirements for OTC medicines must be developed and cannot be exactly the same as Module 1 requirements for Prescription Medicines. Industry must be also given a chance to be consulted on Module 1 requirements for OTC medicines before the new process comes into effect.

5. Proposed OTC medicines evaluation process

- On page 16 'preparation and lodgement phase' it states that '*the relevant supporting information will be required to be submitted electronically in CTD format.'* We are unsure if this means that submissions will have to be made in NeeS format. We would like to point out that alot of companies do not have the tools to complete electronic submissions. Also on page 16 to 19 the TGA has provided an overview of the proposed process which is made up of five phases. There is nothing mentioned about the chance for industry to be given the opportunity to liaise/meet with the TGA prior to submission.
- On page 16 it states that *'target timelines will be specified for the completion of each stage of evaluation process'.* Reckitt Benckiser would like to know how will the targets be set and agreed to and what consequences would be for the sponsor that fails to meet them.

Reckitt Benckiser Recommendation: Industry must be given the opportunity to consult with the TGA prior to submitting the dossier to the TGA in order to avoid an ineffective application (incl. literature search strategy, clinical data requirements, risk level determination etc.). A decision tree to determine the risk level should be provided. Industry must be consulted on the decision tree before finalisation. Industry must be given a 2 year transition phase during which the TGA cannot mandate the new requirements (e.g. electronic submissions in NeeS format). TGA need to make it clear in their guidelines what type of electronic submissions will be accepted for TGA evaluation. Reckitt Benckiser would like to see the TGA provide the industry with defined timeframes for each stage of evaluation.

6. Application categorisation for umbrella branded medicines

- On page 22 the section titled 'Application categorisation for umbrella branded medicines' appears to be very brief and not very helpful considering that umbrella branding is a major issue in the OTC arena.

Reckitt Benckiser Recommendation: The industry requires umbrella branding guidelines, there needs to be a decision tree on umbrella branding to assist with OTC product registrations and to determine level of risk.

7. Target times

- On page 24 the TGA provides aspirational timelines to be achieved by the establishment of ANZTPA in 2016. It states that the lower the risk the lower the timeframe for industry to provide responses to TGA Requests for Further Information (S31s). Although this is aspirational Reckitt Benckiser does not believe that this would be enough time to provide a response to TGA S31s.
- On page 26 two charts are provided for new medicine applications and changes to previously approved OTC medicines. It states that *'all target times are expressed in calendar days, refer to the time taken for evaluation and decision, and as stated, relate to TGA only'*. Reckitt Benckiser

would like TGA to clarify if screening and evaluation queue time will be included in the proposed timeline

- Reckitt Benckiser would also like the TGA to clarify the timeframe that sponsors will be provided to respond to TGA Requests for Further Information (S31s).
- The timelines proposed by the TGA on page 26 do not include a timeframe if an application is referred to the ACNM. Although a small percentage according to TGA's records of applications is referred to the ACNM it is vital for the industry to know how long will it take to obtain feedback from ACNM.

Reckitt Benckiser Recommendation:

1. Industry should be given the flexibility and an opportunity to be granted an extension to respond to S31s regardless of the level of risk.
2. Reckitt Benckiser recommends that a breakdown for each step of the application process is provided e.g. target timeframe for screening and evaluation queue time will take xx calendar days, target timeframe for evaluation, target timeframe for sponsor responses, target timeframe for decision etc.. rather then a total of calendar days for the overall submission process.
3. Reckitt Benckiser would like to see **all questions** covered off in the first round of questions and if the TGA is not satisfied with the sponsor responses then those pending/not fully addressed issues should be covered off in the second round of questions. Reckitt Benckiser strongly opposes any new questions that would come out from the second round of questions as we believe that only issues that the TGA believes were not adequately addressed in the first round should be covered off in the second round of questions.
4. ACNM timeframe needs to be included as well as a timeframe for the sponsor to address issues raised by the ACNM. Sponsors should also be given the following options to respond to S31 requests such as 30, 60 or 90 calendar days at the preparation and lodgement phase.

8. Appendix 3: Changes table

- On page 35 Appendix 3 Changes table it is not clear if this table will apply to all registered OTC medicines including OTC monograph products. If OTC monograph products are included and require a notification or a variation to be submitted to the TGA (e.g. due to a particular quality change for instance a change in manufacturing process) and Module 3 has not been submitted to the TGA as part of the registration process then what will be required from sponsors to submit changes to existing OTC monograph registrations (e.g.current manufacturing process not registered with the TGA versus proposed manufacturing process).Changes to OTC monographs needs further clarification from the TGA.

Reckitt Benckiser Recommendation:
This table needs to spell out that this table applies to all OTC products including OTC monographs. We have also noticed that 'O' changes are missing. We recommend the TGA include the 'O' changes in order to avoid confusion otherwise we suggest that instead of duplicating this table in the 'OTC Medicines Business Process Reform Guidelines' we recommend that the existing changes table that can be found in ARGOM includes an extra column stating the risk level and the list of assurances rather then a list of references to the Therapeutic Good Act.

9. GMP Clearances

- We would like the TGA to clarify their expectations from sponsors on GMP Clearances for overseas manufacturers. Will the TGA be open to sponsors being able to provide the TGA the updated GMP Clearance details if the existing GMP Clearance expires during the evaluation of a particular application?

Reckitt Benckiser recommendation: The TGA should allow the sponsor to provide the TGA with updated GMP Clearance details if an existing GMP Clearance for a particular manufacturing site expires during the evaluation process. Also GMP Clearance Applications should be allowed for submission of new products rather then expecting sponsors to have full GMP Clearances prior to submission of an application.

Overall we fully support comments made by the ASMI and ACCORD. We do not want the repeat of the Prescription Medicines Business Process Reforms where there is poor communication, no opportunity to discuss the submission with the delegate and/or the committee especially if a product is recommended for rejection due to minor issues that could have been resolved if there was a good and consistent communication flow between the TGA and the sponsor.

The following are our suggestions to ensure that this new process will work well for the TGA and the industry:
- There should be a transition phase of at least 24 months to allow sponsors to adapt to this new process.
- There need to be guidance tools and checklists available that would identify data requirements for different types of applications depending on the risk level to assist sponsors in preparing good quality submissions.
- Sponsors should be given the opportunity to liaise with the TGA prior to submission of an application in order to obtain advice on the data requirements for a particular proposed application.
- Sponsors should be given decision trees to determine the relevant risk level of a proposed application
- If something minor is missing and identified during screening phase then the TGA should alert sponsors and provide them flexibility to respond and to provide the missing data.
- There needs to be a chance for industry to communicate with the TGA, especially on the progress of submission status as part of the proposed streamlined submission process in order for this new system to work.
- As part of the OTC Business Process Reforms we hope that the TGA will take a pragmatic approach on submissions made by sponsors rather then being risk averse.

We hope our comments our helpful and useful in finalising guidance documents and tools for the proposed OTC business process reforms.

If further clarification of any of our comments is required please don't hesitate to contact me.

Yours faithfully

Reckitt Benckiser (Australia) Pty Limited