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OVER THE COUNTER (OTC) MEDICINES BUSINESS PROCESS REFORM CONSULTATION PAPER (version 1.0 September 2012)

Introduction

The New Zealand Self Medication Industry (NZSMI) is the representative trade organisation for the major *"Over the Counter"* (OTC) medicine sponsor companies within New Zealand.

We appreciate the opportunity to make comment on the consultation paper and do hope that our comments are taken in a constructive manner to assist in developing a robust and effective OTC product application process.

We are willing to support our comments verbally if required or meet with representatives of either Medsafe or the TGA at an appropriate time.

Yours faithfully

[redacted]

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Executive Summary

- NZSMI is supportive in principle of the OTC Business Process Reform and agrees that as part of the development of a future under ANZTPA a process that improves predictability and timing and provides for transparency throughout the application process is critical.

- NZSMI has concerns that some of the processes currently enjoyed in New Zealand under Medsafe and the results achieved, will become less reliable and potentially more costly under the new process.

- NZSMI has a fundamental concern that the OTC process for registration of products has the potential to become as detailed as prescription applications particularly in the area of pre-screening with risk of the loss of the application fee.

- NZSMI has a real concern that the difference in culture and operation between the TGA and Medsafe and the individual regulator's apparent understanding of the implications of the implementation of the new revised process; has not been fully appreciated.

- NZSMI questions the value of the Monograph application process. With only 15% of applications in Australia and 4% in New Zealand (estimates) to go through this route we question its' relevance. There are minimal savings in terms of cost and by our calculations a gain of 30 days in time is insufficient for the extra resource that will be required.

- NZSMI does not believe the time allowed before the proposed date of introduction in April 2013 is sufficient to ensure all support materials are available and have been tested by industry. If there is a delay in the release of these support materials and they are only made available immediately prior to the commencement date – inevitable delays in processing applications under the new system would result. We would suggest a start date nearer October 2013 as optimal to avoid these issues.

- NZSMI is concerned that there seems a disconnect between the surety of timelines for approval between Medsafe and the TGA. We have concerns at the commitment to meet 80% of applications in a certain timeframe. This means that 20% of applications may be outside this timeframe and this is unacceptable as a target. A better figure in our view would be 95%. The issue of timelines being non-mandatory for TGA but only aspirational is also concerning.

- NZSMI believes the requirement for applications to be available in electronic CTD format to be unacceptable in the timeframe. Not all sponsors have the necessary software to provide ECTD format applications. In any event testing between the regulator and the sponsor would be required to avoid unnecessary errors and delays.

Review of the Document

Page 3:
In the comparison between the TGA and Medsafe, we note the following:

1. The TGA has a strong risk focus.

2. Medsafe prefers a focus on benefit and acknowledges international best practice as a key component of its policy mandate whereas this is not highlighted to the same extent in the TGA preamble.

We would encourage an embracing of **"international best practice**" rather than a focus on a regional best practice.

Page 8 – Objectives and scope of the OTC medicines business process review project:

- **Deliver more efficient and cost effective OTC medicines evaluation processes.**
  NZSMI believes that Medsafe achieve this currently but have concerns that this will change in the future in a negative way as the process evolves.

- **Define application requirements, business processes and target times for applications in each application risk category.**
  The question that arises out of this statement is whether data requirements will be harmonised and during what timeframe. NZSMI has concern that there has been no New Zealand consultation and the indication is that ARGOM will be adopted with New Zealand variations from April 2013 without this consultation process. We believe this to be unacceptable. Greater clarity on this point is required. If this does not occur the result will be that the agency is able to cherry-pick requirements from ARGOM, with extra requirements added on from the current Medicines Act and Regulations. We recommend that we keep to the New Zealand requirements and then have full consultation before any implementation of a piece of work the size of ARGOM. The new guidelines could come in under ANZTPA in 2016.

- **Require applications to be in the common technical document (CTD) format.**
  As mentioned in our Executive Summary, NZSMI has real concerns about the intent to have electronic submissions in the CTD format required by April 2013 – especially without prior testing with industry. We would seek clarification and confirmation that Medsafe will be requiring electronic submissions in the CTD format from April 2013 and would propose a trial system and a transitional phase for sponsors. We also seek clarification that both NMAs and CMNs will be required to be in the CTD format, and have concerns around the practicality of the extra resources required to submit CMN's for old products if the original dossiers were not in CTD format.

Page 9:
- **Phased implementation of the new business processes.**
  We do not believe the scope of the project as outlined in the consultation document is truly reflective of all the topics under consideration, e.g:

  1. *Umbrella branding;*
  2. *Data requirements (we request that any change to data requirements should be the subject of a separate consultation)*

- **Development of a number of forms and guidelines including…**
  *We recommend on this point that the forms should be able to be easily and simply completed and that the data requirements should be in the guidelines NOT in the forms. We would recommend that training workshops are made available before the new business process goes live as we believe this will save a significant amount of time for both sponsors and evaluators. NZSMI also has concerns re the **Labelling and Packaging consultation** which was initiated by the TGA earlier this year. Our concern is that we do not wish to see this impact on New Zealand sponsors at this stage with the full implementation of ANZTPA not occurring until 2016.*

- **Development of a cost recovery impact statement…**
  NZSMI has concerns regarding the implication of cost to New Zealand sponsors. Because any decision made for Australia will by definition impact in New Zealand in the longer term.

Page 15:

- **The applications relating to some quality changes…**
  NZSMI disagrees with this point as this will move a current legislated 45 day application to 120 days evaluation and our understanding was that this was not the intent of the revised process. We propose that CMNs for all quality changes that are currently C4 should be C2 to align with the table on page 14 and with the proposed categories in Australia. We also seek clarity that sponsors will continue to be able to submit a single CMN for identical changes where a product has multiple classifications registered, i.e. RX and OTC together.

General questions:

- **Do you support the concept of risk based categories for OTC medicines?**
  Yes, NZSMI does support this.

- **Do you agree with the proposed risk categories for new medicines?**
  Yes, NZSMI does support this.

- **Do you agree with the proposed risk categories for changed medicines?**
  No, NZSMI does not support this. See our comments in the body of the document. We would also note at this point that we have real concerns about the loss of Australia to submit the equivalent of self-assessable applications as we would strongly wish to retain this system under ANZTPA.

Page 16:

- **Applications will be screened by the regulator upon receipt.**
  NZSMI needs clarity around what the screening will involve. We believe it should be administrative only and not technical to avoid double handling by evaluators. Some form of right of appeal process should be mandated. No specific timeframe is given for this screening process and this needs to be defined.

- ***Incomplete applications will not be accepted for evaluation and fees will be forfeited***
  NZSMI believes this to be punitive, rather than a fee for service type arrangement. There should be only a partial forfeit.

- **Applicants will be able to monitor progress of applications.**
  NZSMI understands that this will limit the tracking to only the sponsor of the application therefore reducing transparency which is currently available in New Zealand. NZSMI would wish to retain the current situation.

Page 17:

- **Application screening phase**
  Currently Medsafe have a pragmatic approach to applications and make contact for a simple query without forfeiting the fee. NZSMI would require assurance that this status would remain.

Page 18:

- **Evaluation and review phase**
  *For the first RFI industry expects a full consolidation set of questions and that no new issues would then be raised in the second RFI that had not been initially highlighted. NZSMI would also seek clarification and assurance that RFI issues can be queried and clarified as part of the process without impediment. The comment in the paragraph starting "**the RFI will include sufficient information**…", the words "**whereas the TGA will allocate a reasonable period of time on a case by case basis**", we find this approach unacceptable and would encourage the TGA to adopt the Medsafe response specifying a fixed number of days.*

  NZSMI suggests that if the same NMA/CMN is submitted simultaneously to TGA and Medsafe, the sponsor should be able to request that the two agencies collaborate on the evaluation and provide a "common" consolidated RFI letter, to which the sponsor could provide a common response. This would facilitate communication between TGA and Medsafe and move the ANZTPA process forward. In addition the regulator's evaluation report should be routinely provided to the sponsor with the RFI.

General questions:

- **Do you support the proposed five phase process?**
  Yes, NZSMI supports this.

- **Do you agree with the principles that were applied when developing the proposed process?**
  We would refer to our specific comments in answering this question.

Page 20:

- **OTC medicine Monograph**
  The NZSMI view is with the knowledge that estimates for New Zealand of 4% and Australia 15% that following a monograph process is flawed, in that cost benefit is limited. For example the only gain for a monograph application is 30 days of evaluation time with no cost saving. These slight benefits are negated subsequently when any variation is required for full data and full evaluation. NZSMI would propose two alternative processes:

  1. *The proposed monograph concept for NMA – with a self-assessable notification process for all variations provided the product continues to comply with the monograph, instead of having to submit variations for evaluation. This would have an ongoing benefit for both the regulator and sponsors.*

  2. *Introduction of an OTC abbreviated process for Australia and New Zealand as an interim, until a single application under ANZTPA is in place. We acknowledge that both countries will still need to evaluate the country specific requirements but one or other of the regulators do the majority of the evaluation which would reduce the evaluation effort required by the other regulator.*

- **Cost of Monographs**
  We anticipate that the submission fee for a monograph product will reduce under ANZTPA because less evaluation resource will be required.

- **How do Monographs get updated?**
  Clarification is required around the intended process going forward.

Page 22:

- **Umbrella branding**
  NZSMI suggests that guidelines on umbrella branding with a decision tree to clearly categorise umbrella branding must be available for a period prior to the commencement of the new business process. Currently the document leaves a great deal to interpretation between the sponsor and the regulator (evaluator) and the level of risk of losing the application fee is unacceptably high.

Page 24:

- **Process and timeline proposals**
  NZSMI is unclear from the consultation document of the process of referral of an application to the Expert Advisory Committee. We would seek clarity around this matter. Clarity of the intent of a question will be critical if the RFI timeline is to be met. The accessibility of telephone meetings with the evaluator is expected to be important to the success of the new process.

  The timeline for screening is not defined and needs to be clarified.

  It appears that C1 self assessability is going to be lost and this is something that we would rigorously oppose.

  If a C2 is submitted the suggestion is that only one RFI will be available whereas currently with Medsafe there are no fixed number. We would propose that the process allows for 2 rounds of RFI's (if required) to align with new medicine applications..

  The document does not make clear what changes are permissible by notification only for both Australia and New Zealand.

Page 25:

- **The final paragraph, starting "later in 2013 the TGA will be releasing…"**
  NZSMI believes that this is a confusing statement and seeks greater clarification.

Page 29:

- **Note 1, third bullet point – product includes a new excipient.**
  We would suggest that the word should be "novel" replacing the word "new". NZSMI queries whether there will be a list of excipients made available and if so how is this list added to over time.

Page 31:

- *If C4 quality changes go ahead with the extended timeline then this may result in more submissions as sponsors will be reluctant to consolidate self assessable change with assessable changes as is current practice. This has an extra financial burden to sponsors.*

Page 45:

- *We would highlight an error under the first subcategory. Manufacturing process should be replaced with "specification test methods".*

Page 47:

- **Under Medsafe changes table to…**
  The third box manufacturing grade 2 should in fact be grade 3.

Page 57:

- ***Glossary-House Brand***
  NZSMI believes this needs to be better defined and differentiated from "Umbrella brand" (for which there is no definition in the glossary).

Conclusion

NZSMI believes that this project, even after implementation, will require regular review and refinement. It is not possible to trial such a project in a prototype virtual system. It must be tried and refined in practice. Therefore the greatest period of transition and preparation should be made to ensure a smooth introduction. All parties need to work together to ensure that this occurs.