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Mr [redacted],
Project Manager, OTC Medicines Regulatory Process Review
Therapeutic Goods Administration
PO Box 100
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Dear [redacted],

Pfizer Consumer Healthcare (PCH), a division of Pfizer Australia Pty Ltd would like to thank the TGA & Medsafe for the opportunity to comment on the proposed reforms, in particular the proposed ***'Over the Counter Medicines Business Process Reforms Version 1.0 September 2012'.***

PCH is a member of the industry bodies, ASMI and NZSMI, and fully endorse the submissions that are made by ASMI and NZSMI as they reflect the position of PCH.

Overview

In principle PCH agrees with, and supports the need for OTC Medicine Business Process Reforms. Having predictability of process and timing, clarity of the requirements for application and transparency of the process and progress of submissions is vital to industry.

The success of these reforms is going to hinge on high quality guidelines and job aids (such as checklists), that provide clarity in relation to the data requirements and rigidity of process. It is absolutely imperative that these guidelines and job aids are made available at least 6 months (preferable longer) in advance to the new process being implemented (hence April 2013 is considered ambitious). From PCH perspective, it is important to get this right. It would be foolish to implement a process just for the sake of meeting a timeline, if the process and supporting materials have not been through adequate review and are of a sufficiently high quality.

As it is apparent that there is no pilot to be undertaken (this too is highly desirable), PCH would also request a commitment from the TGA that the OTC BPR will be reviewed by the TGA, Medsafe and Industry to understand where the process is working and areas where improvements could be made. This is a commitment that was given to industry at the time of implementation of the Prescription medicine BPR implementation.

PCH supports the principle of the risk management approach that is underpinning the risk classification of application categories. This is clearly in line with the approach that has been taken by a number of other well respected regulators.

The concerns that PCH has with the proposal are outlined below:

Reform Timing

As mentioned above, the key to the success of this project is having high quality guidelines and job aids for industry (and the regulator). Whilst admirable that there is desire there to implement the process as soon as possible, however, with the amount of work required to make this project a reality, such as developing of clear guidelines, monographs, checklists and forms (which need to be

drafted, consulted, and finalised), we believe that April 2013 is unrealistic. PCH would prefer to see a slight delay in implementation, to ensure that the process is right and that the support materials and IT solutions are of sufficiently high quality.

Project Plan Visibility

It is important that the TGA continue to work with Industry on the project plan and support material will be important for industry to have some visibility of the proposed project plan to understand the timing of the:

- Development and consultation on the necessary guidelines, checklists and IT solutions required to provide the fine details of the reforms.
- Cost Recovery Impact Statement consultation for Fees and Charges for the new process.
- Information sessions on the practicalities of the new process and its implementation.

Additionally, there have been an extraordinary number of consultations issued by the TGA in the last year. It is important for the project plan have visibility to the industry working group to ensure resource planning. These consultations have had a huge impact on business and no doubt the TGA. Having this visibility will allow resource planning to ensuring adequate time and attention can be given to this project.

Communication

The introduction of the monograph type system is a paradigm shift for OTC medicines in Australia and New Zealand. It is absolutely critical that the TGA undertake an education program prior to commencement of the new process to ensure consumers are aware of the benefits. Additionally, communications post-implementation will be essential so as to inform stakeholders as to the progress of the reforms, the performance of the regulators, the performance of sponsors and to advise on the inevitable changes that result from the program of continuous improvement.

IT Functionality

It is currently unclear as to when a revised eBS solution for the proposed changes will be available. It is imperative that the solutions that are developed are put into pilot testing. The solution needs to be user friendly to sponsors and the regulator. If the changes to OPAL are profound, the TGA will need to consider whether public training workshops on the system should be provided to sponsors, as was the case at the implementation of ELF. The planned functionality in OPAL to support the process is not described in the consultation paper.

Guidelines and Job Aids

PCH cannot stress enough the importance of high quality guidelines and job aids. These are without question critical to the success of the proposed changes. These materials must be available sufficiently in advance of the commencement of the reforms to allow sponsors to prepare effective applications. Additionally ramifications for failing to adhere to the guidance need to be highlighted to sponsors.

Complex Applications

The consultation paper appears to lack true reform with regard complex applications (N4, N5 and C4), other than the freeing of resource by streaming of applications by risk category. There appears to be a lack of review of the issues causing the current timeframes associated with complex

applications, including, but not limited to the time taken to undertake evaluations be external evaluators. There needs to be a greater understanding why issues arise whether it is lack of clarity or absence of guidelines and/or subjectivity around umbrella branding and what really poses risk to the consumer. There is concern that freeing up resources within the TGA will result in a better outcome for complex submissions

Timelines

PCH supports the assignment of different timelines based on the category of application. At the launch of the BPR, it appears as though the TGA's timelines are aspirational and will not be to be backed up by legislated timeframes (as is the case for prescription medicines). With a target of 80% meeting the aspirational timeframes, it means that 1 in every 5 applications will fail to meet this. If one of the key goals is to allow for predictability, then this milestone is not adequately being met. PCH proposes that legislated timeframes be introduced – If the TGA are prepared to commit to reviewing the process 12-18 months post implementation – this would represent a good opportunity to set legislated timeframes for the evaluation.

There is concern amongst many sponsors that they will be penalised if they don't meet the required timeframes, but that no such penalty will apply to the TGA if the timeframes are not met. Where a sponsor misses a deadline in a response, the application "may" proceed to decision and risk rejection or forced withdrawal. Where the TGA misses an average target timeline there will be no consequence.

There are a number of overseas jurisdictions that have mandatory timeframes for OTC medicine evaluations, some with penalties for failing to meet those timeframes. This is also the case with prescription medicines.

TGA Timelines

For predictability of the process from end to end, timeframes must be defined, measured and reported. PCH is concerned with the "Queue" time – i.e. accepted for evaluation, but no evaluator assigned. Without transparency of this part of the process there is potential for a queue to develop. There is an apparent asymmetry in consequences for meeting the proposed timeframes of the new process.

Further, it is not apparent if the Advisory Committee process will be outside the target timeframes. It is noted the reduced number of Committee meetings held this year and the likely impact on predictability for industry.

Sponsor Timelines

PCH has concerns with the proposed fixed times for responding to questions. The current S31 requirement for "reasonable" timeframes remains appropriate. It would assist sponsors if at commencement of evaluation the evaluator could provide advice as to when questions can be expected to allow sponsor companies the best opportunity to ensure resources are available in a timely manner. PCH has no objection committing to a response timeframe after the questions have been reviewed by the sponsor. (e.g. 30, 60 or 90 days).

In the public forums the TGA indicated there would be an allowance of a short timeframe for sponsors to address suspected administrative omissions at the screening stage. This was suggested as 48 hours. PCH believes that one week might be more suitable so as to allow for part time staff, or an absence from the office. Communication should preferably be electronic to ensure out of

office responses can be addressed. One week would still not be long enough for sponsors to actually generate missing data (and so would still only allow provision of material left out through oversight).

Process - Request for Information (RFIs)

PCH is pleased the OTC BPR process allows for up to two RFIs. Clarity of the intent of a question will be critical with RFIs. If there is ambiguity of the evaluator's intent the sponsor's RFI opportunity may be wasted. The existing opportunity for the sponsor to have access to clarify issues with the evaluator is expected to be important to response timeframes and quick resolution of deficiencies.

It is important that the first RFI is provided with the evaluator's report and includes a single consolidated list of deficiencies sent in accordance with section 31. Where a second RFI is required it should not introduce new questions but should only request information not addressed to the satisfaction of the evaluator from the first RFI.

No New information

The public forums addressed this area for non-complex issues such as stability time points. However there are issues with complex applications where the sponsor could not have reasonably anticipated questions and where items like additional tests may be requested which will require validation, or where a name may be considered unsupported after evaluation of the data. N Additionally if new safety signals become apparent during the evaluation, it is in the best interest of all concerned parties that the provision of this data be allowed

CTD Format

PCH is supportive of mandating the format to be consistent with the ICH-CTD format. Further clarification on the electronic formats of the dossier is required prior to implementation. The guidance documents for Module 1, 2 and 3 must be provided well in advance of the CTD format being adopted as the mandated format for dossiers.

Umbrella Branding

There is a lot of confusion within this area – it is imperative that guidelines relating to umbrella branding are very clear. PCH fully endorses the objective of avoiding possible harm which may result from confusing different medicines, and is an area that has caused problems for both regulators and sponsors.

In line with the recommendations made for the medicine labelling and packaging reform, the TGA and Medsafe need to develop relevant and evidence-based guidelines to assist both sponsors and evaluators in relation to umbrella branding (and the related topics of look-alike sound-alike products and indication specific branding).

New Medicine Applications

There is general agreement as to the risk level categories for new products.

The greatest concern the PCH has is that that where an application would otherwise comply with the OTC medicine monograph apart from either an umbrella brand name (N4) or a new claim or

indication (N5), the application should require for Module 3 the abbreviated data package for the N2 application plus the additional data requirements to justify name/claim/indication etc. This may be the intent, but is not clearly confirmed in the text of the consultation.

In the public forums the TGA indicated that categories N4 and N5 would require the submission of the complete Module 3 and that only N2 applications would be able to use the abbreviated data package. **If this is in fact the case, there appears to be limited benefits to the industry for the monograph system, and as such, PCH cannot endorse the use of the monographs (as there would be benefits to some sponsors and not others)**. **If the (module 3) data requirements for products that would otherwise be entered onto the register via a monograph route with the exception of the product branding, were the same as monograph products, there would be equity amongst sponsors (no single sponsor would be more advantaged than another by this proposal) and the monograph system would be endorsed by PCH.**

There is still great confusion s amongst sponsor with the use of the "Monograph" terminology – Monograph is typically considered "pharmacopeial". TGA & Medsafe are strongly encouraged to adopt other terminology as to not result in further confusion

The TGA's proposal provides no detail on Post Market Monitoring (PMM) for N2 applications. At the Public forums it was advised PMM would include targeted and random auditing of N2 applications, where the module 3 data would be required to be provided within a yet to be defined period. PCH fully endorses the PMM activities, however further details do need to be provided.

A number of countries rely on Australia to obtain registration and provide a CPP prior to registration in their own countries. It is imperative that sponsors are made fully aware that whether or not an entry onto the register via a monograph route, will have an impact on the CPP, and if so, what the perceived impact is. Consultation with the export section might be appropriate.

Changed Medicine Applications

The format in the Consultation Paper used to present the change categories is not user friendly. PCHS recommends that the presentation in the current ARGOM be retained (i.e. a table listing changes by attribute of the product being changed, with additional columns to indicate change category). This would allow for the additional useful guidance on what is not considered a regulatory change (i.e. current change category "O"). This would also allow for identification the changes which result in a separate and distinct good (i.e. a new product application).

This is an opportune time to register the disappointment that notifications are no longer allowable The TGA has suggested that such changes are incompatible with the *Therapeutic Goods Act* and that all changes must be approved by the TGA prior to implementation. There are a number of regulators in other jurisdictions (e.g. NZ, UK, Canada) all allow changes by way of notification or self-assessment.

Summary

PCH is pleased that the TGA & Medsafe are reviewing the business process for OTC medicines, and the work completed to date demonstrates how well industry and regulators can work together to define a mutually agreeable solution to an issue that is a problem for both Industry and the regulators. There are clearly a number of issues that need to be addressed as outlined above. Additionally, there are a number of critical elements (such as guidelines) that need to be in place prior to the "go-live" date of the new process. Given the magnitude of work that needs to be undertaken prior to the proposed implementation date, PCH believes the target date is a little

ambitious and advocates for the delay in implementation date to make sure that all of the key elements are of sufficient quality to ensure that the business process proposed has the greatest chance of success.

I would again like to thank you for the opportunity to make comments on this proposal and do hope that the TGA/Medsafe takes the issues raised above and in the ASMI and NZSMI submissions into consideration when revising the process.

Yours sincerely,

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