Australian Government
Department of Health
Therapeutic Goods Administration

Over-the-counter (OTC) medicines business process reform: Outcome of consultation

13 March 2013

OTC medicines business process reform consultation

In September 2012, Medsafe and the TGA sought comments from interested parties on proposed reforms to the business processes for the evaluation of OTC medicines.

A consultation paper (/newsroom/consult-otc-bpr-120917.htm) was published on the Medsafe and TGA websites on 13 September 2012 with a deadline for submission of 7 November 2012.

A total of 21 submissions were received - including 4 from industry associations, 12 from individual pharmaceutical companies, and the remaining 5 submissions from professional body representatives or advocacy groups.

Medsafe and the TGA would like to thank those who took the time to prepare a submission and provide helpful comments and suggestions.

The submissions received (/newsroom/consult-otc-bpr-120917.htm#received) from both Australian and New Zealand submitters were jointly considered by Medsafe and the TGA for any changes to the proposed OTC medicines business process reforms.

This section of the website provides a summary and describes the outcomes of the OTC medicines business process reform consultation, which included:

- Risk based approach to the categorisation of OTC medicines
- Risk categorisation framework - new medicine applications
- Risk categorisation framework - changed medicine applications
- Five-phase process
- Monographs
- Umbrella branding
- Implementation

Risk based approach to the categorisation of OTC medicines

The majority of submissions supported the proposed risk-based approach for categorising OTC medicine applications.

One submission suggested that the risk rating for OTC medicine applications should be based on the characteristics of the medicine in terms of risk to patients (e.g. indication, side effects) rather than the data requirements.

Regulators' comment

The risk-based categorisation was established using the inherent risk associated with different OTC medicines. The risk rating is based on the risk to patients and the data requirements are proportional to the risk rating.

Outcomes

- Progress with the principals of the risk-based approach proposed in the consultation paper.
- Stream applications according to the risk associated with each type of medicine and apply risk-appropriate evaluation processes.
- Implement administrative processes that effectively and efficiently support the assessment of new and changed medicines to ensure consumers have timely access to safe and effective medicines and to increase predictability for applicants.

Risk categorisation framework - new medicine applications

The majority of submissions supported the proposed risk categories for new medicines. Two submissions did not.

Regulator's comment

The submissions that did not agree with the risk categorisation framework represent particular groups of products that include toothpastes, mouth washes, anti-acne face washes, hand sanitisers etc. Medsafe and the TGA consider that these types of products can be appropriately included in the proposed framework by further exploring the use of categories such as the monograph category.

Outcomes

- The risk categorisation framework for new medicine applications will commence phased implementation in April 2013. A phased implementation plan is being developed.

- **Application format** - CTD format will be the basis for applications commencing in April 2013. Applications will be submitted in both paper and electronic media. Guidance will be prepared to assist applicants to prepare the dossier.
- **Medsafe and the TGA** will consider how best to include product groups such as toothpastes, mouth washes, anti-acne face washes, hand sanitisers etc. in the proposed framework.
- **Medsafe and the TGA** will review:
  - Category N1 - to include extension applications for flavour/fragrance/colour variants and additional pack sizes
  - Category N3 and N4 - to include the ability to submit an abbreviated module 3 for products based on a monograph
  - Category N2 - to include toothpastes, acne cream, hand-washed etc. providing that suitable monographs can be developed.
- **N4 category** - a separate approach to data requirements will be created for Australia and New Zealand. In New Zealand, additional efficacy data requirements will only be implemented after consultation with New Zealand stakeholders. A phased approach will be used to implement these changes.

Risk categorisation framework - changed medicine applications

There was mixed support for the proposed risk categories for changed medicines and a number of queries about the proposed change tables.

Several submitters requested that the current changes tables be retained or that change categorisation be aligned with the EU (e.g. IA, IB, II). Submitters also requested that all types of changes are reviewed to extend the notified and self-assessable categories further.

New Zealand specific comments included a reduction in the timeframes for the C4 category and reinstating two 'requests for information' for the C1 category.

Outcomes

- The target timelines for processing changed medicine applications will be implemented in Australia in April 2013.
- New Zealand will continue to process changed medicine applications in accordance with current timelines and business processes.
- Further work will be undertaken to review and align changed medicine applications categories in Australia and New Zealand with consultation planned for late 2013.
- In the interim sponsors should utilise the existing Australian and New Zealand change tables.

Five-phase process

Of the submissions that responded directly to this question, there was general support for the process and the principles applied in developing a five-phase process.

A high proportion of submissions requested further definition of each phase of the proposed process including defined timelines. The screening phase was the subject of extensive comment, with particular emphasis on how to avoid refusal of applications and forfeit of the application fee. There was also extensive comment on the proposed timelines, and a request for statutory timelines.

A number of submissions requested that further clarification, on the detail of the process, be documented in guidance and that this guidance is subject to a separate consultation prior to implementation.

Outcomes

- **Consultation on guidance** - implementation will commence in April 2013. Any significant changes to guidance will be consulted on as outlined in the phased implementation plan.
- **Timelines** - defined timelines will be introduced in April 2013 in New Zealand only for all process phases. An 80% key performance indicator for completion of applications within the timelines will be implemented. The guidance will include assurance that the key performance indicator will be adjusted over time. Mandatory timelines are under consideration for the establishment of ANZTPA in 2016.
- **Screening phase** - all applications will be screened to check they have been submitted correctly and include all required information. Further details of the screening phase will be refined within the guidance documentation that will accompany process implementation. The guidance will include checklists, a data requirement matrix and other application assistance tools to assist sponsors. The regulators will implement target timeframes for screening applications in April 2014.
- **Advisory committees** - the processes for referral onto the Australian or New Zealand advisory committees will be clarified in the guidance.
- **Requests for information** - Medsafe and the TGA will implement administrative processes for requests for information (RFIs) as detailed in the consultation paper. The regulator will apply response times that are appropriate for the application type. Expected response times will be defined in the supporting guidelines.

Monographs

In general, the submissions from companies and industry bodies representing 'branded products' did not support monographs without the ability for inclusion of umbrella branded products. But the 'non-branded product' (i.e. 'house brand') companies and industry bodies did express some level of support.

Several submitters noted that the list of proposed monographs would have very limited uptake by applicants and suggested expanding the list would increase the utility. In particular, submitters requested adoption of international monographs to reduce the regulator's development costs. Others asked for the ability to submit abbreviated module 3 data that was similar to a monograph application, where applicable, in a submission of an application at a higher classification.

Outcomes

- The monographs already under development will be finalised and implemented as a 12 month trial to determine uptake.
- Further work will be undertaken to review the established monographs from other international regulators (e.g. Health Canada and the FDA).
- Further work will be undertaken to investigate the N2 category to include monographs for selected product groups (such as toothpastes, mouth washes, anti-acne face washes, hand sanitisers etc.).
- Requirements for applications with abbreviated module 3 data to be clarified within guidance.

Umbrella branding

The majority of submitters agreed with the objective of reducing potential harm to consumers by developing clear guidance for managing the higher risk associated with umbrella branded products.

Clear guidance will be required alongside additional tools to ensure a consistent approach between regulators. This guidance should be developed within the implementation plan, noting that there is a labelling and packaging review currently under way in Australia that includes matters related to umbrella branding.

Outcomes

- Category N4 umbrella branded products will be kept in the risk framework.
- Clear guidance will be developed ready for implementation in April 2013.

Implementation

The majority of submissions felt that the proposed implementation date of April 2013 did not allow enough time to develop, consult and validate the required guidance documents and application tools.

Outcomes

- A joint Australian and New Zealand 'phased implementation plan' has been developed. This outlines how the new process will start to be implemented in April 2013, with further phases implemented and refined over the next 18 months to 2 years.
- The plan will further define the project milestones. The intention is to publish it in the week beginning 18 March on the Medsafe and TGA websites.

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