Australian Government
Department of Health
Therapeutic Goods Administration

Staged implementation plan

OTC medicines business process reform

Version 1.2, April 2014

TGA Health Safety Regulation

About the Therapeutic Goods Administration (TGA)

- The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health, and is responsible for regulating medicines and medical devices.
- The TGA administers the *Therapeutic Goods Act 1989* (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.
- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.
- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. TGA investigates reports received by it to determine any necessary regulatory action.
- To report a problem with a medicine or medical device, please see the information on the TGA website <http://www.tga.gov.au>.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	OMA - OTCME	22/03/2013
V1.1	Clarify milestone H and P	OMA - OTCME	15/04/2013
V1.2	Move milestone M to September 2014. Added explanatory footnote to Milestones K and P.	OMA - OTCME	17/04/2014

Contents

Introduction and overview

The consultation paper developed to support the introduction of a new over the counter (OTC) medicine business process noted that some aspects could be initiated immediately, whereas other aspects would be introduced over time.

In response many submitters requested more information about the phased implementation and specifically requested dates for planning purposes. Submitters also called for longer implementation in either Australia or New Zealand depending on the degree of change to current regulatory practices.

The accompanying timeline has been developed to clearly communicate the phased implementation as it applies in Australia and New Zealand. The timeline demonstrates that each regulator is seeking to harmonise the business processes for receiving and assessing new OTC medicine applications and that further harmonisation will be undertaken progressively.

Key points in the timeline

Application formats and administrative processes are common in both jurisdictions from 15 April 2013. There will be a transitional period of 12 months to allow applicants to become familiar with expected formats.

Guidance to assist applicants is available. Sponsors are encouraged to provide feedback and guidance will be progressively updated during the transitional period to improve clarity and understanding.

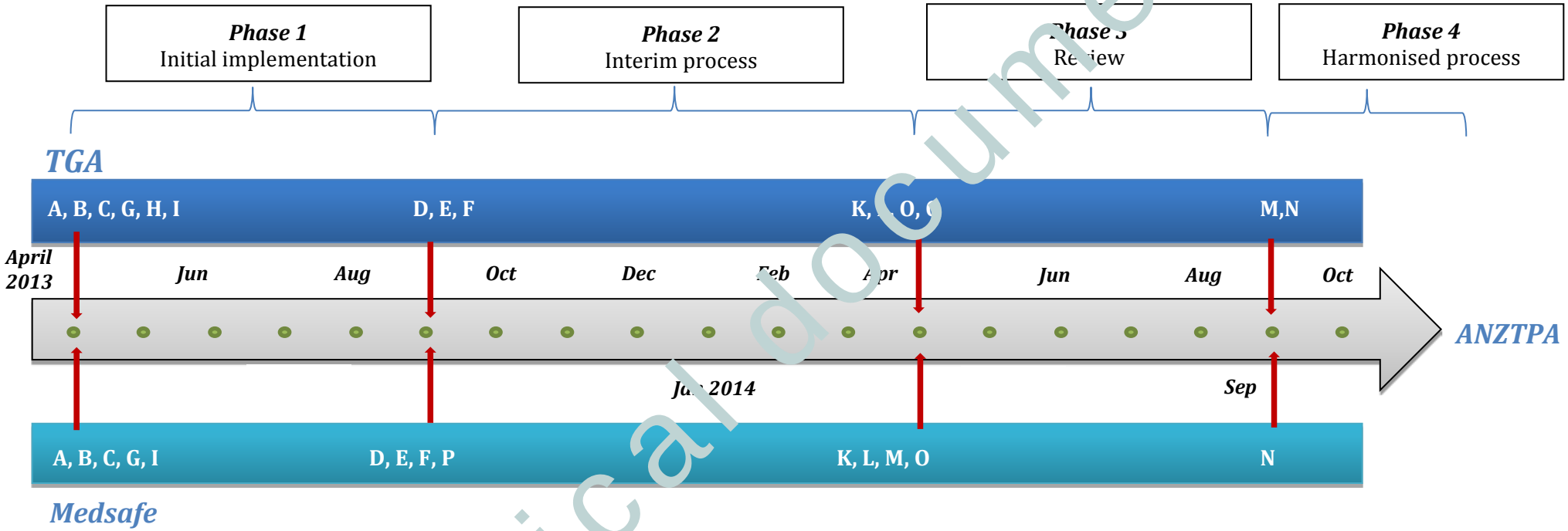
Both regulators will implement target timeframes for the administrative steps with review and modification of the target timeframes to be undertaken during an 18 month period. Both regulators will monitor and report performance against target timeframes to introduce predictability and transparency for applicants.

The monograph route to approval will be trialled by the TGA to determine the costs and benefits to the regulator and uptake by applicants. During the trial period further monographs will be developed to expand the number of eligible products.

Medsafe will monitor the trial and introduce monograph if feedback is positive.

Harmonisation of the data requirements for OTC medicine applications and categorisation of changes to existing medicines will continue, to enable a fully harmonised and integrated regulatory framework.

Staged implementation plan



Milestone	Description
A	Applications expected in Common Technical Dossier (CTD) format as described by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).[1]

[1] The TGA requires a paper copy and electronic copy (CD, DVD or data stick) must be provided. TGA will transition to paperless applications by April 2014. Medsafe require a paper copy and two electronic copies (CD or DVD). Medsafe will transition to paperless applications when trans-Tasman data sharing platforms have been enabled. Milestones for electronic submissions have not been provided as a new platform has not been fully developed and user tested. For more information on constructing applications in CTD format refer to <http://www.ich.org>.

Milestone	Description
B	Non-CTD dossiers must be cross-referenced to CTD format for ease of evaluation. Non-compliant dossiers will be returned and require re-submission.
C	Application category must be identified. If incorrect category is selected, applicant is given an opportunity to correct.
D	All applications in CTD format. Incorrect constructed applications will be returned and require re-submission (no forfeit of fee). Screening will re-start upon re-submission.
E	Applications submitted incorrectly into a lower category will be returned (no forfeit of fee). Screening will start upon re-submission.
F	Medsafe and TGA to review: a. category N3 and N4 to include an abbreviated applications for products based on a monograph b. category N2 to include toothpastes, acne cream, hand-wash etc. providing that suitable monographs can be developed.
G	All applications screened for completeness.[2] Applications not accepted unless they are complete and adhere to the relevant guidelines (ARGOM, NZRGM). Incomplete applications will be returned and will require re-submission.
H	Monograph trial commences with progressive release of draft monographs for consultation. As each monograph is finalised applications may be submitted through the N2 route.
I	Medsafe aim to achieve ANZTPA aspirational timelines. TGA will aim to achieve timeframes as specified in the consultation document. A maximum of 2 rounds of requests for information (RFI) and no new data unless in response to a specific request from the regulator.
K	Performance targets reviewed. TGA introduces a target timeline for the initial evaluation task.[3] Interim review of monograph route.[4]

[2] The TGA will collect application fees at the time of lodgement and issue effective letters if the application is deemed to be complete for evaluation purposes. Medsafe will screen upon lodgement of an application and if complete for evaluation purposes, an invoice will be issued.

[3] Commencing 9 April 2014, the TGA reduced the target total evaluation time and introduced a target for the initial evaluation for C2 category applications. The TGA will review the target times for other categories of applications based on process performance data as it becomes progressively available.

[4] A review of the monograph route will occur 12 months after the first nine specific OTC medicine monographs become available.

Milestone	Description
L	Medsafe and TGA commence review and harmonisation of changes to medicines and categorise changes according to the inherent risk.
M	CTD format and correct category of applications mandatory. Incorrect and incomplete applications will be returned and any application fee forfeit.
N	Review of OTC process, timelines and KPIs.
O	Medsafe and TGA commence review and harmonisation of data requirements for NM category applications.
P	Medsafe undertakes a review of the monograph trial with the view to introducing monographs in NZ if feasible.[5]
Q	TGA completes transition to paperless applications.

[5] The review has been completed, and Medsafe aims to introduce the monograph route in mid-2014.

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