MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH

The Trans-Tasman Early Warning System

Summary of consultation responses from Australia and New Zealand

May 2013

MINISTRY OF HEALTH
MANATU HAUORA

New Zealand Government

About Medsafe

- Medsafe is the New Zealand Medicines and Medical Devices Safety Authority and is responsible for the regulation of therapeutic products in New Zealand through administration of the *Medicines Act 1981*.
- Medsafe is a business unit of the New Zealand Ministry of Health.
- Medsafe's Mission is: 'To enhance the health of New Zealanders by regulating medicines and medical devices to maximise safety and benefit.'
- In working to achieve the stated mission Medsafe:
  - applies accepted international practice to the regulation of therapeutic products
  - provides efficient services measured against agreed stated performance indicators
  - prepares and maintains regulatory guidelines reflecting sound science and promoting evidence based decisions
  - applies processes that are consistent, transparent and minimise the costs of regulatory action
  - provides timely and unbiased information to health professionals and consumers about the safe use of therapeutic products.

About the Therapeutic Goods Administration (TGA)

- The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health and Ageing, 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.

Introduction

On 8 March to 7 April 2013 the Therapeutic Goods Administration (TGA) and the New Zealand Medicines and Medical Devices Safety Authority (Medsafe) jointly consulted on the proposed process for the trans-Tasman early warning system. Twenty eight submissions were received by the TGA and seven submissions were received by Medsafe. These submissions have been reviewed by the TGA and Medsafe and over 200 different comments were identified.

This document summarises the main themes identified from these submissions and outlines the TGA's and Medsafe's responses. The TGA and Medsafe would like to thank everyone who provided a submission for their valuable contribution to this project.

Trans-Tasman Early Warning System Process

There were no general objections to the creation of an early warning system, though there were some concerns regarding the potential impacts of the monitoring communications. It was suggested that international best practice should be considered.

The TGA and Medsafe have noted these comments.

Scope and workflow

There were a number of comments requesting clarification and/or more detail on the early warning system processes. There were also requests to use the system to provide advice on other issues relating to therapeutic products e.g. medicine shortages or illegal supply.

The TGA and Medsafe will publish a document providing further details on the processes for the trans-Tasman early warning system. The trans-Tasman early warning system will only be used to communicate safety concerns with medicines and medical devices. The TGA and Medsafe will continue to publish communications on other issues using existing processes (where required).

Stakeholder Engagement

A number of submissions commented that the proposed interaction with the sponsor/manufacturer described in the consultation paper was limited. Some submissions also recommended earlier interaction with professional bodies and other agencies prior to issuing any communication.

The TGA and Medsafe will publish a document providing further details on the processes, including stakeholder engagement, involved in the trans-Tasman early warning system.

Definitions

Several definitions used in the consultation document were questioned.

The TGA and Medsafe have noted these comments. However, the glossary used in the consultation document is not part of the early warning system (EWS). The definitions used within the EWS webpages are broad enough to encompass all types of therapeutic products and are intended to be easy to read.

Decision Criteria

Respondents considered that decisions to publish communications should be based on objective criteria and should be transparent. There were concerns regarding the reliability of information

used in the decision making process. There were also mixed opinions on whether communications should be made in response to international safety alerts.

The TGA and Medsafe will publish a document providing further details on the processes for the trans-Tasman early warning system.

Funding

Submissions noted that funding was not addressed in the consultation.

The TGA and Medsafe will operate the trans-Tasman early warning system within existing resources.

Timelines

A number of submissions noted the importance of timeframes for investigation of safety concerns and communication with stakeholders.

The TGA and Medsafe have noted these comments. However, in general, it is difficult to ascertain how long an investigation might take.

Implementation

Respondents considered that the system should be reviewed 18 months to two years after the start. Education and communication initiatives should be part of the implementation.

The TGA and Medsafe have noted these comments and agree to review the system.

Trans-Tasman early warning system webpages

The majority of submissions considered that overall the webpages were acceptable, though one respondent thought the sections were confusing. It was suggested that the layout should be 'user-tested' with consumers. It was also suggested that more detail was needed around the decision making process.

The TGA and Medsafe considered that the consultation process enabled a wide range of potential users to check the acceptability of the early warning system explanatory text. The TGA and Medsafe will publish a document providing further details on the trans-Tasman early warning system processes.

Landing Webpage

Respondents suggested the landing page should have a feature to highlight new items, modifications to the linked webpages, and links to the email subscription service and how to report a problem webpage.

The TGA and Medsafe have incorporated these suggestions into the final webpage.

Consumer Questions and Answers Webpage

A number of specific comments on the text were made. It was suggested that the order of the questions should be amended and that health professionals should have their own questions and answers.

The TGA and Medsafe have adopted the specific text changes where these aligned with the respective website style guides. A webpage containing health professional questions and answers will be developed.

Additional Comments

Other suggestions included: dating information, consistent presentation of information, the need to outline which products are included in the system, identifying other sources of information on therapeutic products and the need for links to other information on the TGA and Medsafe websites.

The TGA and Medsafe have incorporated these suggestions into the final system.

Trans-Tasman Early Warning System Communications

A number of submissions emphasised the need to ensure that the information presented was not alarmist. Other comments included the need to explain differences in communications between Australia and New Zealand and that information should be as specific as possible.

The TGA and Medsafe agree with these comments and will incorporate the suggestions into the early warning system communications.

Monitoring Communications

Concerns were raised about the impact of monitoring communications and several submissions noted that other mechanisms of encouraging reporting could be used. Other submissions considered that monitoring communications were critical for consumers and praised the M² scheme in New Zealand.

The TGA and Medsafe have noted these comments.

Content

A number of comments were made around providing more explicit guidance for consumers and health professionals following a monitoring communication. Some submissions noted that monitoring communications needed to be easier to distinguish from alert communications. Respondents felt that it was important to highlight that these safety concerns had not been reviewed. It was also suggested that the efficacy benefits of therapeutic products should also be mentioned.

The TGA and Medsafe have incorporated these suggestions into the final system.

Updates

More information on the process for updating monitoring communications was requested in the submissions.

The TGA and Medsafe will publish a document providing further details on the processes, including the publication of follow up communications, involved in the trans-Tasman early warning system.

Alert Communications

There was support for alert communications but it was noted that they need to be clear and concise. It was also considered that there was the possibility for confusion if there are multiple

communications from difference sources. There was some confusion around the difference between safety alerts and recall actions.

The TGA and Medsafe have noted these comments. A webpage containing health professional questions and answers will be developed.

Content

The submissions highlighted that the content should use absolute values for risks. Information for consumers and health professionals should be distinguished from each other and the rest of the text. In addition it was suggested that useful (external) links should be incorporated. The legal basis of suggested actions for health professionals was questioned.

The TGA and Medsafe have incorporated these suggestions into the final system. A section on health professional questions and answers will be included in the system.

Trans-Tasman Early Warning System Channels for Communication

The submissions noted that professional bodies and consumer organisations could assist with disseminating communications. Other submissions noted that the proposed channels were appropriate or that only the regulator's website was required.

The TGA and Medsafe have noted these comments.

Monitoring Communications-Communication Channels

A number of submissions considered that monitoring communications should be actively provided to consumers and health professionals.

The TGA and Medsafe have noted these comments. Interested parties will be able to subscribe to receive email alerts when new communications are published.

Alert Communications-Communication Channels

Submissions requested further detail on the process for informing stakeholders about alert communications. Respondents suggested that alerts should be sent to relevant stakeholder groups e.g. professional colleges and social media such as facebook/twitter could be utilised. In addition relevant stakeholder groups should also provide links from their websites to the early warning system.

The TGA and Medsafe will publish a document providing further details on the processes for the trans-Tasman early warning system. Both the TGA and Medsafe note that current organisational access to social media is very limited.

Other Comments

Some submissions also outlined additional comments outside the scope of the consultation on the Trans-Tasman early warning system of safety concerns with medicines and medical devices.

The TGA and Medsafe have noted these comments.