The Trans-Tasman Early Warning System

How the process will work in Australia and New Zealand

Contents

Background to the Early Warning System

The Prime Ministers of Australia and New Zealand agreed on 20 June 2011 to proceed with a joint scheme for the regulation of therapeutic products. The creation of a joint regulatory scheme across both countries will safeguard public health and safety, while encouraging economic integration and benefitting health professionals, consumers and industry in both countries.

A number of initial joint TGA/Medsafe projects have been agreed aimed at initiating the alignment of regulatory procedures. One of these business to business projects is to establish a trans-Tasman early warning system of potential safety concerns around therapeutic products. Further information about the formation of the Australia New Zealand Therapeutic Products Agency (ANZTPA) can be found on the TGA, Medsafe and transition to ANZTPA websites.

Introduction to the Early Warning System

The purpose of this business to business project between the TGA and Medsafe is:

- to establish a trans-Tasman early warning system for advising the public about potential safety concerns associated with medicines and medical devices.

As a first step in this project, the TGA and Medsafe consulted with the United States Food and Drug Administration (FDA), Health Canada and Health Singapore regarding their current alerting systems for medicines. The information provided by these regulators helped inform the background document produced for the jointly organised workshops with stakeholders held during April 2012. There were three workshops held in Melbourne, Sydney and Wellington which were attended by consumer, health professional, government and industry stakeholder representatives. The aim of these workshops was to gather opinions on what safety concerns should be included in an early warning system, and when and how these safety concerns should be communicated. The results of these workshops have been compiled and shared with participants. The final compilation document and workshop background document are available on the Medsafe , TGA and ANZTPA websites.

Medsafe has already trialled an early communication system called M^2. Information from this trial indicates that the publication of early communications can stimulate further reporting of adverse events. Actions have been taken as a result of these stimulated reports to improve medicine safety. For other concerns, which did not receive further reports, the lack of new reports assisted Medsafe's decision not to investigate the concern further.

The next stage of this project was to identify and agree on a process for the early warning system. To facilitate the development of the process, the TGA and Medsafe held a series of internal workshops and discussions in August 2012. The process described in this document is based on the results of these joint discussions and the stakeholder workshops.

The scope of this project encompasses the creation of parallel communication systems in Australia and New Zealand that use the same process.

The TGA and Medsafe will apply the agreed communication process independently to potential safety issues identified with therapeutic products through their existing therapeutic product vigilance processes. These communications will be country specific and may differ reflecting

different legislative requirements and different availability and/or usage of certain therapeutic products between Australia and New Zealand.

Outside the scope of this project:

- The therapeutic product safety vigilance processes in Australia and New Zealand as outlined in figure 1 below (grey boxes).
- The creation of a single integrated early warning system (this may be considered in the future).
- Development of a monitoring communication scheme for therapeutic products new to the market. The TGA is undertaking a feasibility study into the development of an early post-marketing risk communication scheme for therapeutic goods, with consideration of international models as part of the Blueprint reforms program.

Overview of the Early Warning System

The key principles of the early warning system are:

Timely	This will be achieved by prioritisation of safety concerns and prompt assessment and communication of these concerns (where required) during the normal vigilance process.
Sustainable	The process, procedures and thresholds for communication have been designed to ensure the scheme will be sustainable by the TGA and Medsafe.
Responsive	The scheme will identify and communicate safety concerns relevant to stakeholders and incorporate stakeholder feedback.
Engaging	The scheme will provide useful advice targeted for different stakeholders.

The location of the early warning system in the overall therapeutic product vigilance process flow is outlined in Figure 1 below (green boxes);

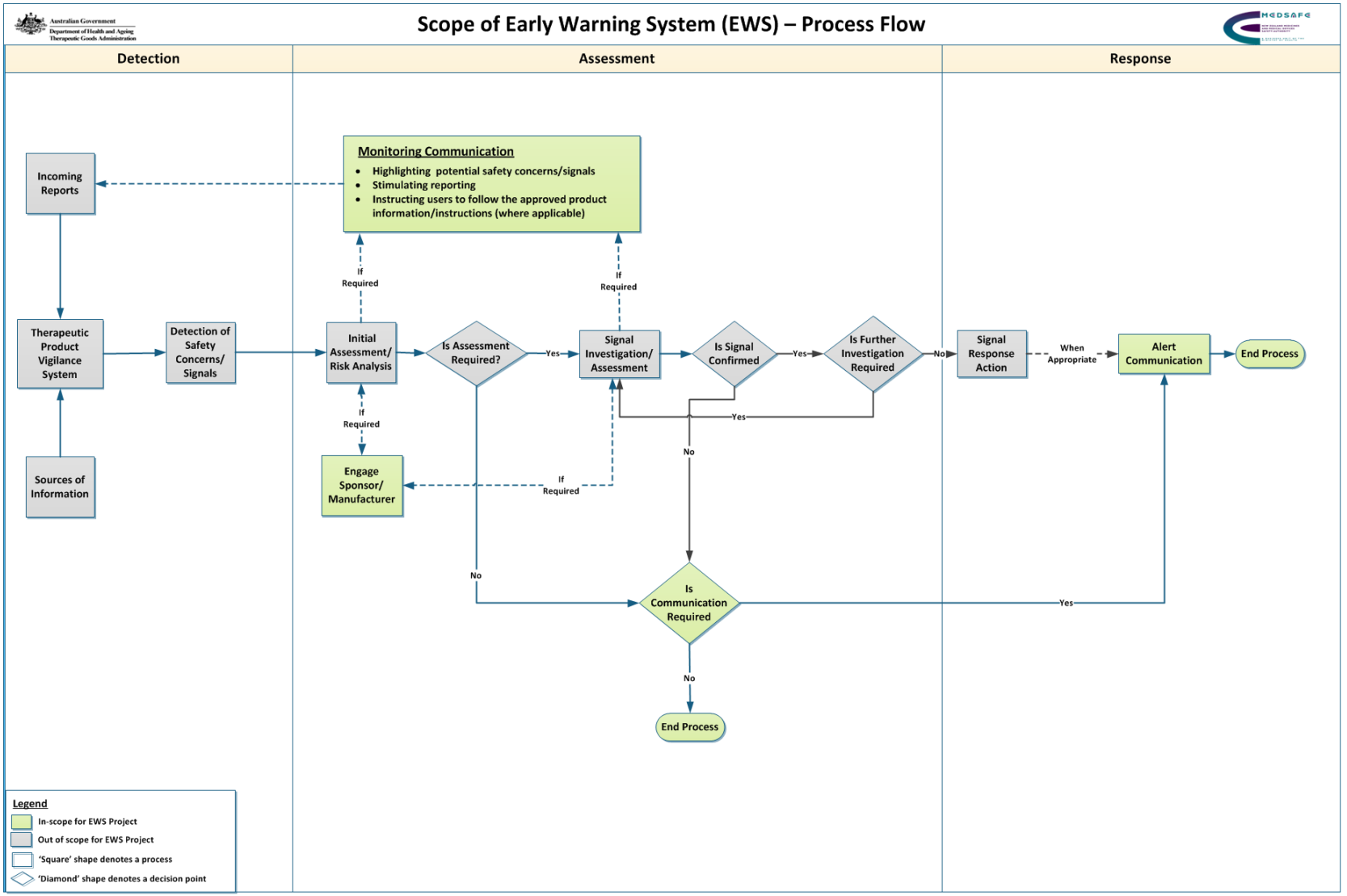


Figure 1 Location of the Early Warning System in the Therapeutic Product Process

There are several points in the therapeutic product vigilance process where the decision to issue a communication can be made. Two different types of communication are possible: monitoring communication and an alert communication.

The decision to issue a monitoring communication can be made either at:

- the initial assessment/risk analysis step when all safety concerns are considered and may be communicated; or
- the signal investigation/assessment step when concerns deemed to be safety signals are considered and may be communicated.

All the monitoring communications issued will have a subsequent communication advising the outcome of the safety concern. The decision to issue an alert communication is made at the conclusion of the signal investigation/assessment and is made independent of whether a monitoring communication was issued or not.

Follow up communication(s) may be issued after a monitoring communication and prior to a final communication. These will be assessed on a case-by-case basis and will consider such factors as:

- the estimated length of time the signal investigation/assessment will take to complete
- time since the monitoring communication was issued
- the complexity of the material
- the level of public interest in the potential safety concern/signal
- feedback from consumers and/or health professionals on previous communications.

These communications will take the form of an alert communication if sufficient information is available, otherwise an update will be made to the monitoring communication.

Monitoring Communications

Monitoring communications are intended to:

- highlight potential safety concerns
- stimulate adverse event reporting
- instruct users to follow the manufacturer's product information/instructions for the medicine or medical device (where applicable).

These communications will advise consumers and health professionals of the nature of the potential concern, encourage consumers and health professionals to report adverse events and where appropriate emphasise that they should follow the manufacturer's product information/instructions for the medicine or medical device. As the safety concern will not have been reviewed in detail by the regulator at the time the monitoring communication is published it is unlikely that any further advice will be available.

These communications may be issued at two stages of the therapeutic product vigilance process:

- initial assessment/risk analysis step
- signal investigation/assessment step.

The criteria for issuing these communications are described below.

Initial Assessment/Risk Analysis

Safety concerns at this stage include all those detected by the regulator. These concerns include those that are already known, coincidental events and safety signals.

Medsafe and the TGA already communicate on a regular basis to discuss new safety concerns detected by each regulator. Medsafe currently informs the TGA about concerns selected for inclusion on M^2. Communications between the two regulators will continue and expand as part of the early warning system.

Decision Criteria

Safety concerns with medicines and medical devices will be considered for a monitoring communication at the initial assessment/risk analysis step if they meet the following criteria:

The product is available in Australia and/or New Zealand.

Australia

Entered on the Australian Register of Therapeutic Goods (ARTG).

New Zealand

Approved medicines can be found in Medsafe's product/application search. Certain unapproved medicines are funded by PHARMAC. Medical devices are contained in the WAND database.

AND AT LEAST ONE OF THE FOLLOWING

The potential safety concern could be serious by international standards and there may be insufficient information available to support a review at the time of the communication.

For medicines, the definition of serious according to the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) – Clinical safety data management: definitions and standards for expedited reporting (E2A) is:

- A serious adverse event or reaction is any untoward medical occurrence that at any dose results in death, is life threatening, requires inpatient hospitalisation or results in prolongation of existing hospitalisation, results in persistent or significant disability/incapacity, is a congenital anomaly, is a medically important event or reaction.

For medical devices the definition used is an adverse event that has led to or might lead to:

- death to a patient, user or other person; or
- a serious injury or serious deterioration to a patient, user or other person, including
  - a life-threatening illness or injury
  - permanent impairment of a body function
  - permanent damage to a body structure
  - a condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure.

OR

There is or is likely to be interest in the potential safety concern from consumers, health professionals, government or media.

This will be determined though the volume and/or nature of enquiries received by the TGA and or Medsafe for the current concern or previous similar concerns. Enquires may come from consumers, media, health professionals or other government agencies.

OR

Advice from an Expert Advisory Committee.

The TGA and Medsafe have a number of statutory advisory committees from which independent expert advice on specific scientific and technical matters can be obtained. This advice assists with the TGA and Medsafe's regulatory decision making and other regulatory processes. Relevant Expert Advisory Committees that may be consulted on potential safety concerns include:

In Australia – Advisory Committee on the Safety of Medical Devices (ACSMD), Advisory Committee on the Safety of Medicines (ACSOM) and Advisory Committee on the Safety of Vaccines (ACSOV). Further information on each committee is available on the TGA website.
In New Zealand - Medicines Adverse Reaction Committee (MARC), Medicines Classification Committee (MCC) and Medicines Assessment Advisory Committee (MAAC).

Signal Investigation/Assessment Step

Safety concerns at this stage will generally only include new concerns or changes in frequency of known concerns (ie a safety signal).

The TGA and Medsafe regularly discuss safety concerns considered to be safety signals. Communications on these concerns will continue and expand as part of the early warning system.

Decision Criteria

Safety concerns with medicines and medical devices will be considered for a monitoring communication at the Signal Investigation/Assessment step if they meet the following criteria:

The product is available in Australia and/or New Zealand.

Australia

Entered on the Australian Register of Therapeutic Goods (ARTG).

New Zealand

Approved medicines can be found in Medsafe's product/application search. Medical devices are contained in the WAND database.

AND

Previously unknown safety concern or a significant change to the frequency of a known safety concern.

A concern is considered to be previously unknown if it is the first time the regulator has become aware of the concern, ie a new concern which is not outlined in the product information for the therapeutic product.
A change in frequency is based on the previously reported frequency either from clinical trials (as outlined in the product information) or as previously estimated from reporting rates to the regulator.

AND

The source(s) are considered reliable.

Reliable sources include: spontaneous reports that meet the World Health Organization causality assessment of definite or probable for medicines, or spontaneous reports that meet the guidelines set out by the International Medical Device Regulators Forum for medical devices, other regulatory agency reports which include assessable data, peer-reviewed journal papers, unpublished data from sponsors where the study had an independent monitoring board or Periodic Safety Update Report (PSUR)/Periodic Benefit-Risk Evaluation Report (PBRER) special review topics, evidence of a safety concern provided by a member of a professional college.

AND

The regulator (TGA/Medsafe) is undertaking an investigation/assessment of the safety concern.

AND AT LEAST ONE OF THE FOLLOWING

The safety concern is serious by international standards.

For medicines the definition of serious according to ICH E2A is: A serious adverse event or reaction is any untoward medical occurrence that at any dose results in death, is life threatening, requires inpatient hospitalisation or results in prolongation of existing hospitalisation, results in persistent or significant disability/incapacity, is a congenital anomaly, is a medically important event or reaction.

For medical devices the definition used is an adverse event that has led to or might lead to:

- death to a patient, user or other person; or
- a serious injury or serious deterioration to a patient, user or other person, including
  - a life-threatening illness or injury
  - permanent impairment of a body function
  - permanent damage to a body structure
  - a condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure.

OR

There is or could be significant interest in the safety concern from consumers, health professionals, government or media.

This will be determined through the volume and/or nature of enquiries received by the TGA and or Medsafe for the current issue or previous similar issues. Enquires may come from consumers, media, health professionals or other government agencies.

OR

Advice from an Expert Advisory Committee.

The TGA and Medsafe have a number of statutory advisory committees from which independent expert advice on specific scientific and technical matters can be obtained. This advice assists with the TGA and Medsafe's regulatory decision making and other regulatory processes. Relevant Expert Advisory Committees that may be consulted on potential safety concerns include:

In Australia – Advisory Committee on the Safety of Medical Devices (ACSMD), Advisory Committee on the Safety of Medicines (ACSOM) and Advisory Committee on the Safety of Vaccines (ACSOV). Further information on each committee is available on the TGA website.
In New Zealand- Medicines Adverse Reaction Committee (MARC), Medicines Classification Committee (MCC) and Medicines Assessment Advisory Committee (MAAC).

Content of Monitoring Communications

Following the decision to issue a monitoring communication, the communication will be drafted for publication on the TGA and/or Medsafe early warning system webpages. A copy of the draft communication will be shared with the other regulator. General information on these types of safety concerns and how to report will be contained on the early warning system webpages (see Attachment 1). Hypothetical examples of monitoring communications are also included in Attachment 1.

Sponsor/Manufacturer Engagement

The sponsor(s) of all relevant products will be informed of communications. Sponsors are requested to point out any factual inaccuracies in the communications but are not expected to provide other comments. Sponsors may also be requested to provide information about safety concerns which the regulator has decided require investigation.

Monitoring Communication Publication

Once the communication has been approved a copy will be provided to the other regulator and it will be published on the TGA and/or Medsafe websites. The location and format for these publications is outlined below in the section describing the webpages. It is not intended that these communications are actively provided to consumers and health professionals. However, interested parties may subscribe to a website update email list, which will notify users of these communications. Also users may subscribe to the RSS feed to receive the latest content published on the TGA Internet site.

Alert Communication

The aim of the alert communication is to provide important information and recommendations about therapeutic products (including where the TGA/Medsafe has investigated a safety concern and no actions are required). Alerts will be provided once a safety concern has been investigated. At this stage the TGA/Medsafe will have concluded whether the safety concern is valid and what actions should be taken to improve the safety of the product (including if no action is required). The alert communication may be published prior to all the recommended actions being completed. Some safety concerns may have had a monitoring communication published. Where this is the case, there will be links on the website between the alert communication and the original monitoring communication.

The TGA and Medsafe regularly discuss safety concerns including the results of any investigations undertaken. The TGA and Medsafe will share information on decisions to issue alerts.

Decision Criteria

Safety concerns with medicines and medical devices will be considered for an alert communication if they meet the following criteria:

The safety concern has been assessed by the regulator (TGA/Medsafe)

This will be according to the existing therapeutic product vigilance procedures of the TGA or Medsafe.

AND AT LEAST ONE OF THE FOLLOWING

The safety concern could be avoided by a behavioural change.

For example, by not using the therapeutic product in a particular patient group.

OR

The safety concern could be detected prior to the use of the therapeutic product.

Medicines - these are detectable risk factors such as renal function that can be assessed before use.
Medical devices - there is a system or diagnostic test that can determine if the medical device is faulty prior to use.

OR

There is or likely to be interest in the safety concern from consumers , health professionals, government or media, .

This will be determined through the volume and/or nature of enquiries received by the TGA and/or Medsafe for the current concern or previous similar concerns. Enquires may come from consumers, media, health professionals or other government agencies.

OR

Advice from an Expert Advisory Committee.

The TGA and Medsafe have a number of statutory advisory committees from which independent expert advice on specific scientific and technical matters can be obtained. This advice assists with the TGA and Medsafe's regulatory decision making and other regulatory processes. Relevant Expert Advisory Committees that may be consulted on potential safety concerns include:

In Australia – Advisory Committee on the Safety of Medical Devices (ACSMD), Advisory Committee on the Safety of Medicines (ACSOM) and Advisory Committee on the Safety of Vaccines (ACSOV). Further information on each committee is available on the TGA website.
In New Zealand- Medicines Adverse Reaction Committee (MARC), Medicines Classification Committee (MCC) and Medicines Assessment Advisory Committee (MAAC).

Content of Alert Communications

Following the decision to issue an alert, the communication will be drafted for publication on the regulator's website. A copy of the draft communication will be shared with the other regulator. General information on these types of safety concerns will be contained on the early warning system webpages (see Attachment 1). Hypothetical examples of alert communications are also included in Attachment 1

Sponsor/Manufacturer Engagement

The sponsor(s) of all relevant products will be informed of communications. Sponsors are requested to point out any factual inaccuracies in the communications but are not expected to provide other comments.

Sponsors may have also been requested to provide information about the safety concern during the regulator's investigation.

Alert Publication

Once the communication has been approved, a copy will be provided to the other regulator and it will be published on the TGA and/or Medsafe websites. The location and format for these publications is outlined below in the section on early warning system webpages and in Attachment 1.

Alert communications will be actively shared with relevant stakeholders (including other government departments, health professionals and consumers) as well as published on the TGA and/or Medsafe websites. It is likely that for some shared concerns that the actions described in the alerts will be different. This is due to the differences in legislation, usage and healthcare systems between Australia and New Zealand.

Early Warning System Website Content

All safety communications will be published on either the TGA or Medsafe websites. Some safety concerns may be published on both websites, but in country specific format. In future, communications may also be published on the transition to ANZTPA website.

These communications will be country specific and may differ reflecting different legislative requirements, and different availability and/or usage of certain therapeutic products between Australia and New Zealand.

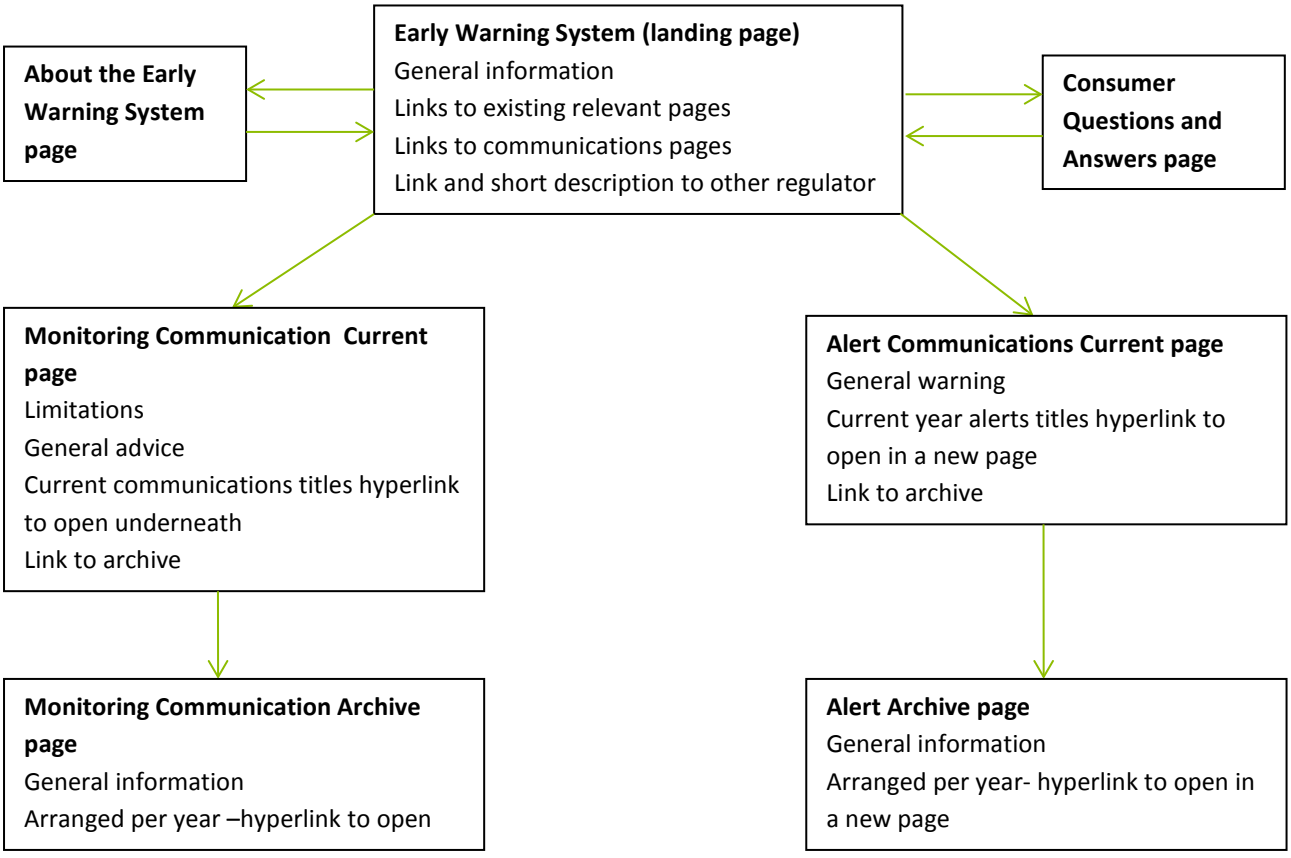
Location

In Australia the safety communications will be located on the TGA website in the safety information tab with links from the consumers and health professional tabs. Links to the alerts will also be available in the news section.

In New Zealand the safety communications will be located on the Medsafe website under safety topics.

Structure

The structure of the early warning website content is shown below.



Text for Webpages

The proposed text for inclusion on the Medsafe website for the Early Warning System is shown in Attachment 1.

Glossary

Term	Definition
Adverse event	Any untoward medical occurrence in a patient (or care giver in the case of medical devices) who has used a therapeutic product and which does not necessarily have to have a causal relationship with this therapeutic product.
Adverse reaction	An unintended and noxious effect that is attributable to a therapeutic product used correctly.
Alert	An identified risk associated with the use of a medicine or medical device which requires urgent measures to protect patients.
ANZTPA	Australia New Zealand Therapeutic Products Agency, which will replace the TGA and Medsafe.
CARM	Centre for Adverse Reactions Monitoring. Contracted by the Ministry of Health, New Zealand, to collect reports of suspected adverse reactions to medicines in New Zealand.
CMI	Consumer Medicine Information. The CMI is based on the product information/ data sheet but is written in plain language to assist consumers to use medicines safely and effectively.
Data Sheet	A summary of the known information about a product in New Zealand; known as the PI (Product Information) in Australia.
Identified Risk	An untoward occurrence for which there is adequate evidence of an association with the medicine or medical device of interest.
Medical Device	In general an instrument, apparatus, appliance, material, or other article (whether for use alone or in combination), together with any accessories or software required for its proper functioning which is intended for use in the diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap; investigation, replacement or modification of the anatomy or of a physiological process; control of conception and does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means. For the legal definitions used in Australia and New Zealand, refer to the Therapeutic Goods Act 1989 and the Medicines Act 1981, respectively.
Medicine	A substance or preparation used in the prevention, diagnosis treatment of a disease, ailment, defect or injury or used to influence, inhibit or modify a physiological process that achieves its principal intended action by pharmacological, chemical, immunological or metabolic means. For the legal definitions used in Australia and New Zealand, refer to the Therapeutic Goods Act 1989 and the Medicines Act 1981, respectively.
Medsafe	New Zealand Medicines and Medical Devices Safety Authority. Medsafe is a business unit of the Ministry of Health and is the authority responsible for the regulation of therapeutic products in New Zealand.
PHARMAC	The Pharmaceutical Management Agency is the New Zealand Crown agency that decides, on behalf of District Health Boards, which medicines and related products are subsidised for the use in the community and public hospitals.
Product Information	A summary of the known information about a product, known as the PI in Australia and the data sheet in New Zealand.
PSUR/PBRER	The Periodic Safety Update Report (PSUR)/Periodic Benefit-Risk Evaluation Report (PBRER) provides a comprehensive and critical analysis of new or

	emerging information on the risks of the product, and, where pertinent, on its benefit in approved indications, to enable an appraisal of the product's overall benefit-risk profile.
Safety concern	An untoward occurrence for which there is some basis for suspicion of an association with the medicine or medical device of interest, but where this association has not been confirmed.
Safety signal	New information that suggests a new potentially causal association, or new aspect of a known association, between an intervention and an event(s) that is judged to be of sufficient likelihood to justify further action to verify.
Serious (safety signal)	For medicines the definition of serious according to ICH- E2A is: • A serious adverse event or reaction is any untoward medical occurrence that at any dose results in death, is life threatening, requires inpatient hospitalisation or results in prolongation of existing hospitalisation, results in persistent or significant disability/incapacity, is a congenital anomaly, is a medically important event or reaction. For medical devices the definition used is an adverse event that has led to or might lead to: • death to a patient, user or other person; or • a serious injury or serious deterioration to a patient, user or other person, including – a life-threatening illness or injury – permanent impairment of a body function – permanent damage to a body structure – a condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure.
Sponsor	In general the company responsible for distributing a therapeutic product. For the legal definitions used in Australia and New Zealand, refer to the Therapeutic Goods Act 1989 and the Medicines Act 1981, respectively.
Spontaneous report/notification	An unsolicited communication to a company, regulatory authority, or organisation that describes an adverse event in a patient given one or more therapeutic products and which does not derive from a study or organised data collection scheme.
Stimulated reporting	Reports following communication of a safety concern and describing that concern.
TGA	The Therapeutic Goods Administration is Australia's regulatory authority for therapeutic goods. The TGA carries out a range of assessment and monitoring activities to ensure therapeutic goods available in Australia are of an acceptable standard with the aim of ensuring that the Australian community has access within a reasonable time to therapeutic advances.
Therapeutic product	Any product for which therapeutic claims are made. This includes medicines, vaccines and other biological products and medical devices.
Therapeutic product vigilance	The science and activities relating to the detection, assessment, understanding and prevention of adverse effects of medicines and medical devices.

Attachment 1 – Medsafe proposed website content with examples

- **Early Warning System (Landing page)**
- **Early Warning System: consumer questions and answers**
- **Monitoring Communications**
- **Monitoring Communications Archive**
- **Alert Communications**
- **Alert Communications Archive**

PROJECTS

- Suspected Medicine Adverse Reaction Search (SMARS)
- Joint Adverse Event Notification System (JAENS)
- Early Warning of Safety Issues with Therapeutic Products
- OTC Medicines Processes

Early Warning System

The Medsafe early warning section includes current and historical information on safety concerns for medicines and devices. These communications are issued as part of a joint project between TGA and Medsafe. Whilst the communication process is the same in both countries the communications themselves are country specific and the recommendations may differ. View Australian communications.

No therapeutic product is completely safe. Whilst many risks are identified before the product is used in New Zealand some are identified later. The process of identifying these risks is described in the safety section.

The known risks associated with medicines are outlined in the data sheet and the consumer medicine information (CMI). The known risks for medical devices are generally outlined in the product information/user manual.

There are two parts to the Early Warning System:

Monitoring Communications

Very early communications about potential safety concerns are provided in the Monitoring Communication section. At this stage little information is known about the safety concern. The intention of these communications is to provide early information as safety concerns are identified by Medsafe. In addition Medsafe aims to stimulate further reports and research to provide more information on these safety concerns. Safety concerns for which Medsafe is actively seeking further reports are included in

Not all of these concerns will result in any action. This is because after investigation Medsafe may not find evidence to support a link between the events and the therapeutic product. Medsafe may reinvestigate if more information is identified at a later date.

Alert Communications

Alert communications are issued once a review of the safety concern is complete. Alerts contain more information on the safety concern and provide advice on actions that may need to be taken by healthcare professionals and consumers.

How to Report Adverse Events to Medicines and Medical Devices
Medsafe advises you to consult your healthcare professional if you suspect that you are experiencing an adverse event to a medicine or medical device.

Please report all adverse events suspected to be linked to medicines or medical devices.

Medicines

Phone	+ 64 3 479 7247 to speak to a Medical Assessor
	From your iPhone using the ADR online app
Online	Submit a report
	General Practitioners can submit using the online reporting tool available in patient management software
Yellow Card	A completed Yellow card can be submitted to CARM via email, fax or mail (address is on the card)
Email	carmnz@otago.ac.nz
Fax	+64 3 479 7150

Medical Devices

Post	Compliance Management Branch, Medsafe, PO Box 5013, Wellington 6415
Online	Submit a report
Email	devices@moh.govt.nz
Fax	+64 4 819 6806

Summaries of medicine adverse events reported to Medsafe can be viewed in SMARS and JAENS.

Safety concerns which identify defective medicines or medical devices supplied in the market may result in a recall action. This can include removal of the product from supply or undertaking corrective action. A summary of recent recall actions initiated in New Zealand can be viewed in the publicly accessible Medsafe Online Recall Database (MORD).

Consumer Questions and Answers on the Early Warning System

Early Warning System

Consumer Questions and Answers

What are safety concerns?

A safety concern is any potential safety problem linked to a medicine or medical device. Safety concerns include known safety problems, changes to known problems, new problems and coincidental events. At the time the safety concern is detected, Medsafe may not know if the concern is really caused by the medicine or medical device.

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How are safety concerns identified?

Medsafe use many sources of information to identify safety concerns. These sources include adverse event notifications, published papers, information from sponsors, clinical studies, information from researchers, health professionals, other regulatory authorities and government agencies.

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What is Medsafe doing about these safety concerns?

Medsafe investigate safety concerns to determine if the concern is caused by the medicine or medical device. Medsafe identify all the possible information available on the safety concern and review this information. Medsafe also seeks advice from experts for example the Advisory Committee on the safety of Medical Devices/ Medicines Adverse Reactions Committee. Medsafe also work closely with other regulatory authorities.

If there is a causal relationship between the therapeutic product and safety concern, Medsafe will consider the appropriate action/s that need to be taken to improve the safe use of the medicine or medical device.

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What actions can Medsafe take?

As a regulator, Medsafe has to consider the balance between the benefits offered by any therapeutic product and the potential risks associated with its use for the population as a whole (or individual patient groups where the risks may be higher) before it makes a decision on the appropriate response. There are a range of actions that can follow when a potential safety issue is identified. These include:

- informing health professionals and consumers through alerts and other communications such as articles in *Prescriber Update*
- requiring changes be made to the data sheet
- changing the conditions of use or narrowing the population in which it can be used
- change the legal status of a medicine, for example make a medicine only available with a doctor's prescription
- requesting the sponsor to complete a study to investigate the concern
- withdrawing or suspending the market approval for the medicine
- removal of a medical device from the market.

In some cases no action may also be recommended and Medsafe will continue to monitor the safety concern.

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Why is Medsafe publishing these safety concerns?

The early warning system is designed to support better health outcomes by providing better access to information on safety concerns. It is part of the work we do to monitor the safety of medicines and medical devices for consumers.

As demand for information about medicines and medical devices grows, along with our ageing population, publishing information on medicine and medical device safety concerns online by a reputable government agency improves public access to this important information. Medsafe is committed to improving transparency to build trust and confidence in our work.

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What is an adverse event?

Adverse events are unwanted and sometimes harmful outcomes from taking a medicine or using a medical device.

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What is a side effect?

Side effects are known unintended effects of a medicine or medical device.

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How can I find information on the known side effects of medicines and medical devices?

Consumer medicine information (CMI) is available for some medicines. In New Zealand the CMI is provided on a voluntary basis by the sponsor. If no CMI is available, a data sheet for all prescription and pharmacist only medicines is published on the Medsafe website. Data sheets are designed for health professionals; if you have problems understanding a data sheet, your doctor, pharmacist or nurse can help you.

The instructions for use, or user manual for your medical device is a useful source of information.

How do I report an adverse event?

If you suspect that you are experiencing an adverse event you should consult a healthcare professional. You or the healthcare professional can then report the event. Medicine related events should be reported to the Centre for Adverse Reactions Monitoring. Medical device related events should be reported to Medsafe.

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My medicine or medical device is mentioned in a safety communication, what should I do?

Medsafe advises all consumers to follow the advice provided in the safety communication. Consumers should NOT stop taking any medicine or stop using any medical device without first seeking the advice of their health professional; unless this is advised in the safety communication.

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How does the early warning system alert differ from Medsafe recall communications?

The early warning system alert advises consumers, health professionals and industry about new safety information on therapeutic products following the outcome of an investigation. An alert does not necessarily mean that a product is considered to be unsafe.

Consumer Q & A

A recall communication provides advice to consumers, health professionals and industry about a defective therapeutic good and the recall action undertaken in the New Zealand market usually due to unacceptable quality, safety, efficacy /performance or presentation.

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Early Warning System

Monitoring Communications

This section contains communications issued by Medsafe for safety concerns with medicines and medical devices shortly after they have been identified. These communications highlight *potential* safety concerns.

The appearance of a safety concern in this section does not mean that Medsafe has concluded that the medicine or medical device causes the adverse event.

Medsafe emphasises that patients should NOT stop using any medicine or medical device subject to a monitoring communication. If you have any concerns with a therapeutic product you are using, please contact your health professional.

Consumers are advised to use products according to the instructions provided with the medicine or medical device. For medicines these are outlined in the Consumer Medicine Information. For medical devices these are outlined in the instructions for use or user manual supplied with the medical device.

If you are aware of someone who may have experienced one of these safety concerns please send a report. This helps Medsafe to investigate these safety concerns and decide if any action needs to be taken. Safety concerns for which Medsafe is seeking further reports are included in

It is likely that the some monitoring communication safety concerns will not result in any action being taken and the monitoring communication will be updated accordingly. If the Medsafe review of the safety concern concludes that there is a true link with a medicine or medical device an alert may be issued. Medsafe will take appropriate action to improve the safe use of this medicine or medical device, where required.

Monitoring Communications Issued in the Last Three Months

Date	Medicine/Device	Title
20 Jan 2013	Medicine	Noxuout (morestapam) and tendonitis
21 Jan 2013	Device	Hearalot hearing aids and overheating battery

Archived list of monitoring communications

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Noxuout (morestapam) and tendonitis

20 January 2013

Medsafe has received three reports of tendonitis suspected to have been caused by Noxuout. The three reports from healthcare professionals were received through the Centre for Adverse Reactions Monitoring. The tendonitis started one to three weeks after starting Noxuout. All the pateints recovered after stopping Noxuout.

Noxuout is the trade name for morestapam. Noxuout is a new medicine used to help people with problems sleeping (insomnia). This medicine is only available in tablet form for use in adults. Like other medicines used for sleeping problems, Noxuout should only be used for short periods.

Medsafe is continuing to monitor reports of adverse events associated with Noxuout.

Consumers and healthcare professionals are encouraged to send reports of suspected adverse reactions to the Centre for Adverse Reactions Monitoring.

Medsafe cannot give advice about an individual's medical condition. You are strongly encouraged to talk with a healthcare professional if you are concerned about a possible adverse event associated with a medicine.

Hearalot hearing aids and overheating battery

21 January 2013

Medsafe has received three reports from consumers regarding their Hearalot hearing aids overheating. In each case after replacing the battery no further heating problems were experienced.

Medsafe advises consumers to use the specified battery type and installation instructions in the Hearalot user manual when replacing the battery.

Medsafe is continuing to monitor the rate and pattern of occurrence of this issue.

Consumers and healthcare professionals are encouraged to report problems with medical devices to Medsafe.

Medsafe cannot give advice about an individual's medical condition. You are strongly encouraged to talk with a healthcare professional if you are concerned about a possible adverse event associated with a medical device.

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Monitoring Communication Archive

This section contains a list of previous monitoring communications for medicines and medical devices.

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Date	Medicine/Device	Title
20 Jan 2013	Medicine	Noxuout (morestapam) and tendonitis
21 Jan 2013	Device	Hearalot hearing aids and overheating battery

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Monitoring Communication Archive 2013

This section contains the monitoring communications for medicines and medical devices for 2013.

Noxuout (morestapam) and tendonitis

20 January 2013

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Early Warning System

Alert Communications

This section contains safety alerts for medicines and medical devices. More information on how Medsafe investigates safety concerns is available on the safety monitoring section.

The safety concerns described here have been investigated by Medsafe. For some safety concerns Medsafe may conclude that no actions are required, but may still issue an alert if there is public concern. For other safety concerns Medsafe may conclude that there is evidence of a link between the medicine or medical device and the safety concern. In these cases the alert provides advice for health professionals and consumers. Alerts also contain a summary of the available evidence supporting the safety concern.

Alert Communications in the Last Three Months

Date	Medicine/Device	Title
1 Feb 2013	Medicine	Noxuout (morestapam) and reports of seizure
14 Feb 2013	Medicine	Lowklot (finagrel) association with cancer – No increased risk identified
1 Mar 2013	Device	Speediwiz wheelchairs:elevated failure rates of brake mechanism
6 March 2013	Medicine	Germzoff (kilzamycin) – Not to be used in patients with severe renal failure
7 March 2013	Device	Reliachex blood glucose monitoring system – Do not store the test strips in the fridge

Archived list of Alert Communications

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Early Warning System

Alert Communications

Noxuout (morestapam) and reports of seizure

Related information

- Recall: Noxuout (morestapam) - Lozamed Pharmaceuticals Ltd
  1 February 2013

1 February 2013

Healthcare professionals and consumers are advised of new clinical study information showing that patients taking Noxuout are at risk of experiencing a seizure. Consumers are advised to stop taking Noxuout and contact their healthcare professional. Supply of this medicine is being suspended whilst its safety is being reviewed.

Products affected

This alert applies only to Noxuout the trade name for morestapam. Noxuout is used to help people with sleeping problems (insomnia). This medicine is only available in tablet form for use in adults.

Information for Consumers

- Noxuout has been shown to cause seizures in a small number of consumers.
- Seizures may include events such as black outs, confusion, deafness, out of body feeling, eyes rolling, falling down, foot stomping, hand waving, shaking, stiffening, teeth clenching or memory loss.
- You should stop taking Noxuout and contact your health professional to discuss alternative treatments.
- If you have a seizure or think you may have had a seizure you should seek medical advice straight away.
- If you have any concerns or questions please discuss these with your doctor, pharmacist or nurse.
- Report any problems you experience with medicines to the Centre for Adverse Reactions Monitoring (CARM); see below for how to report.
- Medsafe cannot give advice about an individual's medical condition. You are strongly encouraged to talk with a healthcare professional if you are concerned about a possible adverse event associated with a medicine.

Information for Healthcare Professionals and Retailers

- The risk of seizure in patients taking Noxuout in the new clinical study was 2.2 (adjusted OR) (95% CI 1.5-9.3) compared with no treatment.
- Noxuout should not be prescribed to new patients.
- Patients should be contacted and informed to stop taking Noxuout and an alternative treatment initiated if required.
- Noxuout is being recalled from pharmacies. More information is available on the Medsafe website and from Lozamed Pharmaceuticals Ltd.

Data Summary
A phase III double-blind randomised placebo controlled study conducted in 3,000 patients in the United States has recently been completed. The study was designed to investigate the efficacy of Noxuout in Shift-Work Sleep Disorder. Initial analysis of the study indicates an increased risk of seizure in patients taking Noxuout: adjusted OR 2.2 (95% CI 1.5-9.3). A meta-analysis of clinical study data for the insomnia indication also revealed an increased risk of seizure adjusted OR 1.8 (1.3-2.5).

In addition, four reports of seizure in patients taking Noxuout have been reported to CARM.

What action is Medsafe taking?
Medsafe considers that the high risk of seizures in patients who are otherwise well means that the benefits of this medicine may not outweigh the risks. Consequently, Medsafe has suspended the approval for this medicine to be supplied in New Zealand. Medsafe is seeking the advice of the Medicines Adverse Reaction Committee (MARC) on whether this medicine should remain available for use or should be removed from the New Zealand market.

How to report

Phone	+ 64 3 479 7247 to speak to a Medical Assessor
	From your iPhone using the ADR online app
Online	Submit a report
	General Practitioners can submit using the online reporting tool available in patient management software
Yellow Card	A completed Yellow card can be submitted to CARM via email, fax or mail (address is on the card)
Email	carmnz@otago.ac.nz
Fax	+64 3 479 7150

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Early Warning System

Alert Communications

Lowklot (finagrel) - No increased risk of cancer identified

Related Information

- MARC meeting minutes

14 February 2013

Healthcare professionals and consumers are advised that there is no evidence of an increased risk of cancer associated with the blood thinning medicine Lowklot (finagrel). This advice comes following a full safety review conducted by Medsafe in conjunction with the Medicines Adverse Reactions Committee (MARC). This potential risk was first highlighted by the results of an observational study published in the BMJ.

Products Affected

This alert applies only to Lowklot, the trade name for finagrel, manufactured by Mormedz Ltd. Lowklot is a medicine used to thin the blood (an anticoagulant) and help prevent strokes and heart attacks. These tablets are only available on prescription from a doctor for use in adults.

Information for Consumers and Caregivers

- No evidence of an increased risk of cancer has been found in patients taking Lowklot.
- If you have any concerns or questions about this information please discuss these with your doctor, pharmacist or nurse.
- Report any problems you experience with medicines to the Centre for Adverse Reactions Monitoring (CARM); see below for how to report.
- Medsafe cannot give advice about an individual's medical condition. You are strongly encouraged to talk with a healthcare professional if you are concerned about a possible adverse event associated with a medicine.

Information for Healthcare Professionals

- In Jan 2012 the BMJ published the results of an observational study showing an association between use of Lowklot and an increased risk of cancer were published.
- The manufacturer provided Medsafe with additional safety information including: results of preclinical studies, a meta-analysis of randomised controlled trials and two further observational studies conducted in the USA and UK.
- There was no evidence that Lowklot had mutagenic activity in pre-clinical studies.
- The meta-analysis did not find a significant increased risk of cancer: Odds Ratio 1.2 (95% CI 0.8-1.5) in patients taking Lowklot compared to placebo.
- Two observational studies were conducted. A small increased risk was noted in the study comparing patients exposed to Lowklot with unexposed patients Hazard Ratio 1.32 (95% CI 1:04- 1.45). In the study comparing Lowklot with clopidogrel, no increased risk of cancer was noted Hazard Ratio 1.05 (95% CI 0.89-1.12).
- Medsafe and the MARC concluded that there is no increased risk of cancer in patients taking Lowklot (finagrel).

Data Summary

In the original paper conducted using the General Practice Research Database (GPRD), an increased risk of cancer, Hazard Ratio 1.5 (95% CI 1.1-1.9), was seen in patients taking Lowklot compared to patients unexposed to Lowklot. This safety concern was further investigated by the manufacturer. A review of previously conducted studies investigating the mutagenicity and carcinogenicity of Lowklot were negative. The company conducted a meta-analysis of phase II to IV clinical studies for Lowklot. In total 17 studies including 3,587 patients exposed to Lowklot and 3,289 patients taking placebo were included in the meta-analysis. There was a slight imbalance in baseline risk factors for cancer favouring the placebo group. The risk of cancer found in the meta-analysis was an Odds Ratio 1.2 (95% CI 0.8-1.5) in patients taking Lowklot compared to placebo. The MARC considered that this analysis did not support an increased risk of cancer. Two further observational studies were conducted. In the first study conducted using a claims database in the USA, patients exposed to Lowklot were compared to unexposed patients. A small increase in cancer risk was noted, similar to the GPRD study: Hazard Ratio 1.32 (95% CI 1:04- 1.45). It was noted during the review of this study that there was the potential for residual confounding which may have accounted for the observed association. In the second study, conducted using The Health Improvement Network (THIN) database patients taking Lowklot were compared to patients taking clopidogrel, a medicine with a similar mechanism of action. This comparison was used to try to reduce bias in the study. No difference in cancer risk was noted between the two groups: Hazard Ratio 1.05 (95% CI 0.89-1.12). Overall Medsafe and the MARC consider that the evidence does not support an increased risk of cancer in patients taking Lowklot.

What action is Medsafe taking?

No action is being taken, please continue to report any suspicions of adverse reactions to Lowklot to CARM.

How to Report

Phone	+ 64 3 479 7247 to speak to a Medical Assessor
	From your iPhone using the ADR online app
Online	Submit a report
	General Practitioners can submit using the online reporting tool available in patient management software
Yellow Card	A completed Yellow card can be submitted to CARM via email, fax or mail (address is on the card)
Email	carmnz@otago.ac.nz
Fax	+64 3 479 7150

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Early Warning System

Alert Communications

Speediwiz wheelchairs: Elevated failure rates of brake mechanism

Related information

- Recall: Speediwiz wheelchairs (Models XC-XE)
  1 March 2013

1 March 2013

Consumers, health professionals and retailers are advised that Speediwiz Manufacture Pty Ltd (SMPL), after consultation with Medsafe, is recalling some models of the Speediwiz wheelchair to correct the brake mechanism.

Investigations by SMPL in conjunction with Medsafe have found that the brake mechanism can fail when there is inadequate air pressure in the rear tyres. The recommended air pressure of the rear tyres is 40 – 50psi.

While no injuries have been reported, failure of the brake mechanism during use could result in serious injury.

All Speediwiz wheelchairs manufactured since July 2012 have a redesigned brake mechanism and are not affected by this issue.

Products Affected
The affected model numbers are:

- 10908 - Speediwiz wheelchair XC (manufactured between July 2008 – July 2012)
- 10909 - Speediwiz wheelchair XD (manufactured between July 2008 – July 2012)
- 10910 - Speediwiz wheelchair XE (manufactured between July 2008 – July 2012)

The listed Speediwiz wheelchair models can be identified from the manufacturer plate stamp which is located on the underside of the chair.

Information for Consumers

- If you have a Speediwiz wheelchair from one of the affected models, you can return it to the place of purchase or rental for a replacement wheelchair whilst SMPL replaces the brake mechanism.
- Alternatively, you can call the SMPL toll-free customer service line on 0800 000 000 between 8:30am and 5:30pm to arrange the return of the affected product and a replacement.
- If you think you may have a Speediwiz wheelchair from one of the affected models but cannot confirm the details, phone the SMPL customer service line.
- Report any problems to Medsafe; see how to report below.
- Medsafe cannot give advice about an individual's medical condition. You are strongly encouraged to talk with a healthcare professional if you are concerned about a possible adverse event associated with a medical device

Information for Healthcare Professionals and Retailers

- If you have a Speediwiz wheelchair from one of the affected models in stock, do not sell, rent or provide them to consumers. Check all stock, including storerooms and hire pools and isolate any products from the affected models.
- SMPL has written to retailers outlining the process for returning affected models and obtaining replacement stock.

Additional Information

Medsafe has received four reported failures of the brake mechanism not holding the wheelchair on a sloped surface.

The models that were found to be affected were manufactured between 2008 and 2010, with failures presenting between two and four years after manufacturer. During the investigation it was found the failures were occurring when the air pressure in the rear tyres was less than 25psi. The recommended air pressure of the rear tyres is 40 – 50psi.

How to report

Post	Compliance Management Branch, Medsafe, PO Box 5013, Wellington 6415
Online	Submit a report
Email	devices@moh.govt.nz
Fax	+64 4 819 6806

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Early Warning System

Alert Communications

Germzoff (kilzamycin)- Not to be Used in Patients With Severe Renal Failure

Related Information

- Dear Healthcare Professional letter

7 March 2013

Healthcare professionals and consumers are advised that Germzoff (kilzamycin) should not be used in patients with severe renal failure. Information supplied by Kwalimed Ltd shows that exposure to Germzoff in patients with creatinine clearance less than 30ml/min was double to that in patients with normal renal function. Higher blood concentrations of Germzoff have been associated with an increased risk of serious skin reactions and liver disorders.

Products Affected

This alert applies only to Germzoff, the trade name for kilzamycin, manufactured by Kwalimed Ltd. Germzoff is a new broad spectrum antibiotic used to treat infections such as pneumonia. This medicine is only available on prescription from a doctor in tablet, injection or liquid suspension for use in adults and children.

Information for Consumers

- Patients with severe kidney problems should not take Germzoff. Your doctor will have informed you if you have this problem.
- Report any problems you experience with medicines to the Centre for Adverse Reactions Monitoring (CARM); see below for how to report.
- Medsafe cannot give advice about an individual's medical condition. You are strongly encouraged to talk with a healthcare professional if you are concerned about a possible adverse event associated with a medicine.

Information for Healthcare Professionals

- A pharmacokinetic study conducted by the manufacturer showed exposure to Germzoff in patients with creatinine clearance less than 30ml/min was double that in patients with normal renal function.
- Despite reducing the dose of Germzoff from 100mg daily to 25mg daily, plasma levels in patients with **severe** renal failure remained high.
- Two patients with severe renal failure participating in the study experienced adverse effects: one developed an exfoliating skin reaction and the other experienced jaundice.
- In patients with **moderate** renal failure a dose reduction to 50mg resulted in acceptable plasma levels .
- Medsafe concluded that the lack of information on safe dosing of Germzoff in patients with severe renal failure and the adverse reactions noted in the study means that Germzoff should not be used in these patients.
- Report any suspected adverse reactions to the Centre for Adverse Reactions Monitoring (CARM); see below for how to report.

Data Summary

Kwalimed Ltd performed a pharmacokinetic study of Germzoff in patients with mild, moderate and severe renal failure. The study was designed to test whether target plasma levels of Germzoff could be achieved with dose reductions predicted from previous pharmacokinetic studies. The results are shown in the table below.

Degree of Renal Failure	Dose of Germzoff	Mean $AUC_{(0-24)}$ (percentage difference to patients with normal renal function)	Mean C_{max} (percentage difference to patients with normal renal function)
Mild (>50-<80ml/min)	100mg	2.4µg hr/ml (25%)	312ng/ml (33%)
Moderate (30-50ml/min)	50mg	1.8µg hr/ml (-9%)	221ng/ml (-6%)
Severe (<30ml/min)	25mg	3.9µg hr/ml (102%)	421ng/ml (80%)

The predicted dose adjustment required for patients with moderate renal failure was successful. However in patients with severe renal failure the predicted dose adjustment was not successful. In addition, two patients in this group experienced serious adverse events: skin exfoliation and jaundice.

What action is Medsafe taking?

The data sheet is being updated to reflect this new information. In addition, the company have sent a letter to all healthcare professionals advising them of these changes.

How to Report

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Alert Communications

Reliachex Blood Glucose Strips- Do Not Store in the Fridge

7 March 2013

Consumers and health professionals are advised not to store the blood glucose test strips used in the Reliachex Blood Glucose Monitor in the fridge.

Investigations by the Medihealthchex Technologies Ltd in conjunction with Medsafe into reports of unusual blood glucose readings with the Reliachex blood glucose monitoring system found no quality issues with the product and that the strips had been stored incorrectly in the fridge. Incorrect storage can lead to false or inaccurate blood glucose readings.

While no adverse outcomes were reported, unreliable blood glucose test results could result in a patient taking too much or too little insulin which poses a significant health risk.

Healthcare professionals and consumers should follow the storage conditions outlined in the instructions for use and on the labelling of the product which specify the test strips for the Reliachex Blood Glucose Monitor should be stored out of direct sunlight, in a dry place at room temperature below 30°C.

Products Affected

This alert applies to the blood glucose test strips that are used in the Reliachex blood glucose monitoring system made by Medihealthchex Technologies Ltd.

Information for Consumers and Caregivers

- Store Reliachex blood glucose test strips out of direct sunlight, in a dry place at room temperature below 30°C as per the manufacturer's instructions.
- Reliachex blood glucose test strips that have been stored in the fridge should be discarded.
- Report any problems you experience with medical devices to Medsafe; see below for how to report.
- Medsafe cannot give advice about an individual's medical condition. You are strongly encouraged to talk with a healthcare professional if you are concerned about a possible adverse event associated with a medical device.

Information for Healthcare Professionals

- Advise patients to store Reliachex blood glucose test strips out of direct sunlight, in a dry place at room temperature below 30°C as per the manufacturer's instructions.
- Advise patients to discard any unused strips that have been stored incorrectly in the fridge.
- Report any problems with medical devices to Medsafe; see below for how to report.

Data Summary

Medsafe has received a total of four reports from healthcare professionals and consumers regarding this problem. The investigation by Medihealthchex Technologies Ltd and Medsafe found that in each case the patient had stored the glucose test strips in the fridge, along with their insulin. The reporters noticed that the results of their glucose test were higher or lower than expected and when the reporters retested using strips not stored in the fridge; a different result was obtained. In accordance, with the manufacturer's instructions the test strips for the Reliachex Blood Glucose Monitor should be stored out of direct sunlight, in a dry place at room temperature below 30°C.

During the investigation, a series of quality control tests were performed on retained test strip samples from the same batch numbers. All the tested strips passed and were within the expected range. There were no quality issues identified with the product.

What action is Medsafe taking?
No action is being taken.

How to Report

Post	Compliance Management Branch, Medsafe, PO Box 5013, Wellington 6415
Online	Submit a report
Email	devices@moh.govt.nz
Fax	+64 4 819 6806

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Alert Communications Archive

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14 Feb 2013	Medicine	Lowklot (finagrel) and risk of cancer – No increased risk identified
1 Mar 2013	Device	Speediwlz wheelchairs and risk of intermittent brake problems
6 Mar 2013	Medicine	Germzoff (kilzamycin) – Not to be Used in Patients with Severe renal Failure
7 Mar 2013	Device	Reliachex Blood Glucose Monitoring System – Do not store the test strips in the Fridge

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