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

Medsafe Communication with Therapeutic Products Industry

Workshop Summary Document

Medsafe

November 2013

MINISTRY OF HEALTH
MANATU HAUORA

New Zealand Government

Contents

Background

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*. Communication is critical to achieving this mission.

In 2012 Medsafe initiated a communication strategy to enhance the quality, efficiency, effectiveness and timeliness of internal and external communications. The strategy provides framework for detailed action plans that will result in the implementation of well documented policies and procedures designed to enable Medsafe to meet clear communications objectives and monitor performance against these objectives.

Introduction

The first phase of Medsafe's strategy to improve communications with external stakeholders is to engage with the therapeutic products industry. The focus of improving communication with industry will be to:

'improve transparency, collaboration with stakeholders and use of available technologies to expand and enhance communication with the pharmaceutical and medical device industry sectors'.

A workshop was held at Medsafe on 24 September 2013. The objective of the workshop was to give representatives from the therapeutics industry the opportunity to provide input on communication with Medsafe. The workshop allowed all parties to take stock of current communications between Medsafe and the therapeutic products industry, provide suggestions for improvement and prioritise the changes required.

This document summarises the comments and the themes identified by participants at the workshop.

Participants were asked to:

- provide advice on the effectiveness of current communications,
- provide advice on the best methods of communication,
- provide advice on implementation of recommended changes to communication,
- provide advice on the priority of suggested changes.

The overarching themes of the workshop were a wish to move towards a more collaborative approach, more use of electronic systems and more guidance from Medsafe.

Face to Face Communication

Medsafe currently hosts two forums in which members of the therapeutic products industry meet Medsafe representatives. These are the 'Industry Liaison Group' (ILG) and the Regulatory Technical Meeting. In addition representatives from New Zealand Self-Medication Industry Association (NZSMI) and Medicines New Zealand meet with the Group Manager of Medsafe every month.

Industry Liaison Group

This meeting occurs around every six months and is held at Medsafe. The ILG includes representatives from the pharmaceutical industry and the medical device industry. Medsafe branch managers provide an update on performance and strategy. Current consultations and projects are discussed.

The following themes were identified:

Overall, participants agreed that these meetings are valuable and having this kind of high level consultation with Medsafe is beneficial. Holding these meetings in Wellington is considered useful as it enables greater input from Medsafe.

Suggestions for potential improvements included:

- increasing the frequency of ILG meetings to three times per year, in preparation for the Australia New Zealand Therapeutic Products Agency (ANTZPA),
- expanding the reach of the ILG meetings to include groups such as: New Zealand Therapeutic Products Manufacturers Association (NZTPMA), and Natural Products New Zealand,
- making meeting material available in advance to promote discussion,
- making minutes available on the Medsafe website (though it was noted that comments regarding budgets should be excluded)

Regulatory Technical Meeting

This meeting occurs around every six months and includes representatives from NZSMI and Medicines New Zealand. The meeting is usually held in Auckland. Medsafe's Product Regulation Branch provides an update on performance regarding approval of medicines. Current consultations and projects are discussed. Industry representatives can request topics to be included in the agenda.

The following themes were identified:

Participants agreed that the meetings are useful and were satisfied with the venues used in Auckland.

Suggestions for potential improvements included:

- alternating a meeting in Auckland with a meeting in Wellington every six months to allow a wider range of Medsafe staff to present. Some participants thought that Medsafe should present at each meeting, and that there should be an effort to improve the balance between Medsafe and industry proposed discussion topics,
- including workshops within meetings and/or small group discussions. Industry would like to be involved in proposing topics,
- using webinar formatting and/or letting ARCS Australia Ltd facilitate the meetings,
- opening the meetings up to the medical device industry, though there was discussion whether this would dilute the relevance of topics. Separate meetings were also proposed as another option to avoid the issue of dilution,
- attendees not limited to Medicines New Zealand and NZSMI in order to expand the reach of the meetings,
- publishing agenda items, minutes, and actions arising on the Medsafe website in the 'For Industry' section.

Group Manager Meetings with NZSMI and Medicines New Zealand

These meetings take place around once a month. The purpose of the meeting is to provide an update on the progress of ANZTPA.

The following themes were identified:

Participants agreed that these meetings are helpful and informative. The informal nature of the meetings is seen as very valuable and they are described as "providing a good steer". It was also mentioned that they likely save Medsafe time by reducing the need to repeat the same message to different parties.

Participants discussed whether these benefits could be improved on by inviting a wider audience- recognising that this would likely affect the informality of the meetings and possibly reducing their value. Thus tension was further reflected in the suggestions proposed around more meetings. The issue of diluting relevance to different industry sectors is the other potential downside to this.

Other suggestions included:

- preparing an agenda and recording action points for circulation to distribute to a wider audience. It was pointed out that there is no acknowledgement of these meetings on the Medsafe website. One participant commented that one of the major benefits of these meetings was being able to speak freely and therefore did not support recording minutes. However, a short bullet point list of outcomes and important points to consider may be useful
- attendance at these meetings should also be available for the MTANZ and NZTPMA

- moving forward, medical devices will become more important so information about them needs to be communicated. Members from this industry could be invited to these meetings.

Individual company technical meetings

These meetings have been held on an ad hoc basis between representatives of Medsafe and companies to consider technical issues. Examples of issues that may be discussed include requirements for application to market a new medicine in New Zealand. There is currently no procedure for arranging or conducting these meetings. There is currently no charge for these meetings.

The following themes were identified:

Participants described these meetings as extremely useful for contentious, complex issues and for resolving safety concerns that can't be effectively communicated by other means. In particular, this is most valuable for innovative companies looking to sponsor new chemical entities. Some participants commented that these meetings are much less frequent now than five years ago, when Medsafe was considerably more accessible. However, it is understood that these meetings are often resource intensive- hence the change.

Suggestions for potential improvements included:

- establishing some guidelines and meeting principles such as: an agenda; meeting objectives; time limits; and agreed actions or action points. It was noted that the TGA have published guidelines, however representatives recommend that these could be simplified,
- incorporating the option for industry to propose or request Medsafe attendees,
- ensuring the right people attend these meetings. Certain criteria were suggested such as: the evaluator(s) attending; limiting the total number of attendees; and monitoring the ratio of industry to Medsafe staff,
- video conferencing should be utilised where possible.

It was agreed that Medsafe should re-initiate these meetings, with some (but not too extensive) guidelines, and with clear criteria to justify the need for these meetings.

Medsafe response

Medsafe will consider the frequency and attendance of ILG meetings. Medsafe agrees that an agenda and meeting papers should be circulated to attendees in advance. Medsafe agrees that actions points/recommendations from these meetings should be published on the Medsafe website. Presentations can also be published on the Medsafe website, with the author's permission.

Medsafe considers that the format of the regulatory technical meeting should be updated and will form a project team to investigate how these meetings can be

improved. The new format will be trialled and refined based on feedback from participants.

Medsafe agrees to publish any action points/ recommendations from the Group Manager meetings. Medsafe considers that these meetings should not be widened but additional meetings can be held with other bodies if necessary.

Medsafe agrees that there is a need for technical meetings with industry. A project team will be formed to produce criteria and guidelines for these meetings. The project team will consult with industry before these are finalised.

Written Communications

Medsafe generally communicates formal decisions by letter and via the completion of forms. Email may be used for more informal communication. Recently, companies have been given the opportunity to provide submissions in electronic format. Some submissions, for example WAND notifications, can only be made electronically.

Letters

Many of the formal letters generated for medicine approval activities are templates populated from the Medsafe regulatory database, SMARTI. Other letters are produced according to the Ministry of Health communication standards. In some situations a formal paper document is required in New Zealand, although it is recognised that this may lead to delays.

The following themes were identified:

Participants were happy with the current standard format used in letters and agreed that Medsafe letters were generally clear and easy to understand. Industry participants prefer emails to physical letters and would appreciate clarity regarding whether an email response is sufficient, or if paper notifications are still required. Participants stated that email acknowledgment letters and invoices are sufficient and the timing of these is fine.

Some more specific points for improvements included:

- consistent use of confirmation emails regarding new medicine applications (NMA),
- changed medicine notification (CMN) consent letters to be emailed. Participants noted that this was most critical after approval of an application requiring datasheet changes,
- an increased capacity for Medsafe to receive larger files via email,
- more guidance on how to submit information to post-market surveillance is required.

Forms

Medsafe has produced a number of forms to be submitted with various applications. There are 26 different forms currently published on the Medsafe website.

The following themes were identified:

Participants provided positive feedback regarding the location of the forms; all being in one place.

Suggestions for improvements included:

- limiting the use of macro-enabled forms as they have difficult functionality, depending on the software being used. The macro-enabled new medicine

application form was highlighted as being much more difficult to use than the previous version
- clearly communicating any changes that have been made to forms. Version numbers would assist with clarification
- compliance forms should be located in the same place as the rest of the forms. Some guidance instructions should be included for completing compliance forms,
- guidance for forms could include good and/or bad examples and provide more useful information,
- making applications simpler- possibly using cover letters and response templates for consultations,
- it was agreed in general that the fewer number of forms, the better,
- providing more guidance on selecting the correct CMN type,
- participants highlighted the approach taken by the Therapeutic Goods Administration (TGA). The A, B, C approach was recommended as a method of reducing the difficulty of finding the correct form. The TGA also includes a comprehensive list of changes that have been made to forms,
- providing a guidance document for choosing the type of self-assessable change notification like the TGA does.

Consultations

Medsafe consultations tend to be conducted through written submissions. Consultations are published on the Medsafe website.

The following themes were identified:

Participants stated that the current timeline of six weeks for consultation is about right. Participants also agreed that industry is satisfied not to consult on everything; however, they would like to be kept up to date with what Medsafe is currently working on.

Suggested improvements included:

- creating a form for responding to consultations,
- providing a description of how topics for consultation are chosen,
- while publication of the consultation document is fine, the outcome is not adequately published. There should be an effort to improve on this,
- introducing separate consultations for TGA/Medsafe and ANZTPA.

Email correspondence and broadcasts

More informal communication between Medsafe and industry is often conducted via email. This correspondence is usually with individuals regarding particular product based issues.

Medsafe also sends out a broadcast email to subscribers. This email outlines changes that have been made to the Medsafe website, since the last broadcast. These emails are generally sent fortnightly.

The following themes were identified:

A major theme was the need for a platform that would allow companies to self-update their contact details. Participants agreed that it is the responsibility of companies to keep Medsafe up to date with their details, however, no current system makes this easy to do. A website-based contact database was suggested, in which companies are able to log-in at any time and update their information.

A similar web-based system for subscribing to notifications was also proposed. In order to reduce the amount of searching through irrelevant information, participants were keen to introduce the ability to choose areas of interest, to thereby receive only posts relating to those selected areas. Another suggested option is to modify the format of notification emails to include hyperlinks. Participants also stated that the formatting should be 'modernised' to improve the visual appeal of those emails. A return to including gazette notices (since they stopped in June 2013) was also popularly voiced.

In relation to formal letters, it was agreed by industry members that a printed email containing a signature should be considered an acceptable equivalent of the original paper copy. This was based on the notion that other entities (PHARMAC, IRD) accepted this as standard practice.

Some participants commented that they had technical problems with the secured PDF attachments sent by Medsafe staff. It was suggested that Medsafe staff change their security settings on PDFs.

Medsafe response

Some submissions can already be provided electronically, Medsafe expects that there will be an expansion in the use of electronic submissions as part of the move to ANZTPA. Medsafe is investigating a software upgrade to ensure that pdf documents are useable. Medsafe agrees that forms should all be located in one place on the website and will incorporate this task into the ongoing website improvements.

Medsafe notes that the guidance on choosing the correct CMN has been designed to allow pragmatic decisions to be made. Medsafe notes that macro enabled forms are not helpful.

Medsafe notes the comments on consultations and will create templates for consultations and foreshadow consultations where possible.

Any significant changes to processes will be discussed at ILG and/or a regulatory technical meeting.

Oral Communication

Oral communication involves both formal presentations and more informal telephone calls. Medsafe has a number of advisory committees whose recommendations can be important to the therapeutic product industry.

Presentations

Medsafe staff occasionally provide formal presentations at conferences, for example ARCS and the MTANZ congress.

The following themes were identified:

- presentations should be posted on the Medsafe website
- presentations should be tailored
- presenters should undergo presentation skills training
- presentations should be more formal, but still simple. There should be a concerted effort to reduce the amount of information on each presentation slide
- where possible, presentations at local meetings should be revealed in advance and an option for questions to be submitted made available.

Telephone calls

Medsafe staff may phone industry contacts to ask informal questions and seek urgent clarification on issues. In addition, stakeholders may need to phone Medsafe to obtain clarification or advice. If a Medsafe staff member is not available the caller is directed to leave a message.

The following themes were identified:

Participants offered plenty of positive feedback regarding telephone contact with Medsafe. Medsafe staff members are described as courteous, helpful and professional when answering queries. Conversations are normally very solution-focused and effective.

Another positive comment was the way that Medsafe staff would answer phone calls for other staff members who were away from their desk.

Participants felt there was a need to provide a full Medsafe contact list with information to industry so that they were better informed and knew who to call in what situation.

Advisory Committees

Medsafe provides the secretariat for three Ministerial advisory committees. The minutes of the Medicines Classification Committee (MCC) and the Medicines Adverse Reactions Committee (MARC) are published on the Medsafe website. Submissions for MCC agenda items are also welcomed from all stakeholders.

The following themes were identified:

MARC: The overall view was that the MARC minutes are accessible and the hyperlinks to specific agenda items are helpful. Formatting the recommendations in bold was also seen as helpful. However, it can be difficult to identify the minutes for specific items on the Medsafe website.

Medicines Assessment Advisory Committee (MAAC): Participants felt that there was a lack of communication to industry regarding the MAAC. Recognition of commercial sensitivity of information was discussed. Certain participants believed that with greater transparency internationally with evaluation reports, there is less justification not to publish MAAC minutes. Other suggestions for improvement included:

- publishing the recommendations on the Medsafe website if publishing the entire minutes is not possible
- providing communication about the MAAC observer pilot
- the MAAC establishing an industry rep, to align with the MCC.

MCC: Participants offered positive feedback on the MCC minutes. They were described as easy to read and the hyperlinks to company submissions were popular. Industry participants also stated that the observer status at meetings is excellent. Concerns were raised as to whether some of the MCC recommendations were leading to a divergence with Australia and also whether the minutes could be published in a timelier manner.

Medicines Review Committee (MRC): The general consensus from participants was that it is great to have the MRC and the fact that it does not get used is a sign that the other committees are working effectively.

Medsafe response

Medsafe notes the comments on presentations; there is a section on the Medsafe website available to publish these (http://www.medsafe.govt.nz/publications/presentations.asp).

Medsafe notes the comments on contact details. However, to avoid problems when staff are on leave or sick, Medsafe considers that it is better if companies use the generic contact emails. Queries received through these emails are passed to the correct staff member as soon as possible.

With regard to the MAAC, the communication on the observer pilot will be reported as previously agreed. Medsafe will investigate the best method of communicating MAAC recommendations.

The minutes for MCC are subject to review and sign off by the Minister's delegate and this dictates the time scale for publication.

Medsafe notes that it would be helpful to have some information about the Medicines Review Committee on the website.

General Publications

Medsafe provides general information through the *New Zealand Regulatory Guidelines* and the Medsafe website. Medsafe also publishes *Prescriber Update* which is intended for healthcare professionals but provides some general information on post-marketing activities in New Zealand.

Guidelines

The New Zealand regulatory guidelines for therapeutic products are published on the Medsafe website. These guidelines provide an interpretation of the New Zealand legislation.

The following themes were identified:

Participants described the guidelines as very useful and felt that the formatting is suitable. They appreciated that changes made to guidelines are apparent but felt they could be made clearer.

Comments on guidelines included:

- certain policy statements (eg, 'divisibility of tablets' and 'validation of method transfer') have disappeared from the Medsafe website,
- Part 1 of the guidelines have been revised but not yet implemented. Questions were raised about this and communication is required,
- the status of the recall guidelines was highlighted. Communication is required on this,
- many of the guidelines are "under preparation" and have been for some time. This is not a desirable situation,
- it is difficult to find your way through current medicines guidelines, the previous guideline was preferred,
- the recent Medsafe website improvements were helpful for the use of guidelines,
- interim supplements used to be good, communication as to what has happened to them is required. A question and answer section would make a suitable alternative or addition,
- there is a mix of old and new links and many of these links are broken,
- there is a mismatch between Pharmacovigilance guidelines and informal CARM guidance,
- having two sets of guidelines is confusing for those that are unfamiliar with them.

Suggestions for improvement included:

- introduction of a revision history, providing details of what changes have been made to the guidelines and when each change was made. A consistent notification of changes is required,

- greater clarity is required for the devices industry. Definitions are required and perhaps a catalogue. Examples of how borderline substances have been defined would be helpful,
- the addition of regulatory affairs consultants with knowledge of dietary supplements to the current list,
- providing training for significant updates eg, electronic submissions. These could be in the form of webinars, and include question and answer sections,
- the introduction of joint Medsafe-industry training sessions for new international guidelines and how they impact New Zealand.

Website

The Medsafe website provides general information on Medsafe activities. The website was recently updated with the aim of making it easier to use and more visually attractive.

The following themes were identified:

Participants from industry felt that the website is easy to use and that the recent updates were a significant improvement. The products and application search provides good visibility of information. However, many felt that the website could be utilised more and provided the following suggestions:

- a platform on the website to enable companies to log-in and update their contact details was reiterated,
- a company log-in could also be used to pre-populate forms downloaded (with address details, product details etc.) from the Medsafe website. An alternative would be to use cookie recognition although this could cause difficulties as many people have cookies disabled,
- improving the search function, for example by introducing an advanced search with additional options to produce more specific results and make it simpler to find specific items on the website,
- introduce an alphabetical topic guide index, similar to the one present on the TGA website to provide another way of searching for information,
- making it clearer where forms are located on the website. Participants explained it is easy once you know, but if you haven't used them before, it can be difficult,
- registration forms should include hyperlinks to the relevant guideline,
- electronic submissions for registrations should be made available,
- any changes to guidelines should be notified clearly on the Medsafe website,
- the application search should be refined so that you can search the latest CMNs separately from all CMNs,
- establishing an electronic platform for companies to submit information required for post-market vigilance activities,
- the 'Other Useful Links' box covers parts of the Medsafe website and takes up space in some browsers. This should be moved or an option to hide it added,

- there are issues regarding datasheets for non-marketed products that are part of a family. It is unclear which strengths are marketed and which ones are non-marketed,
- the product application search shows only the latest regulatory action. It used to show everything, which was preferred to the current search,
- introduce training video links (eg, for Good manufacturing practice (GMP) training). The US Food and Drug Administration (FDA) has several that videos that could be linked to on the Medsafe website,
- there should be a move to increase the number of electronic application forms available as the organisation heads towards ANZTPA,
- the Medsafe and TGA websites should be standardised, also in anticipation for ANZTPA,
- WAND is not publicly searchable.

Prescriber Update

Prescriber Update is published every three months and is aimed at healthcare professionals. It provides some general information on Medsafe's post-market activities in New Zealand.

The following themes for improvement were identified:

- producing a search function within the Prescriber Update section on the Medsafe website to make it possible to find specific articles relating to particular substances or companies
- sponsors would like a notification or forewarning before publication of an article that includes their product. They should be provided with 24 hours to comment on the content
- articles should be published on the Medsafe website before they are published on paper.

Medsafe response

Medsafe notes that the policy statements are still published on the website (http://www.medsafe.govt.nz/medicines/policy-statements.asp). Forms are located at http://www.medsafe.govt.nz/regulatory/forms.asp

Medsafe notes that the guidelines for therapeutic products are not complete. These guidelines will be completed as part of the ANZTPA programme. Medsafe agrees that having a revision history and highlighting changes would be helpful.

Medsafe will publish determinations on whether products are devices or medicines when possible.

It is not Medsafe's intention to expand the list of regulatory consultants.

The need for training will be considered in the project investigating the format of the regulatory technical meetings.

The group's comments with regard to the Medsafe website were noted and will be incorporated into the ongoing improvement project, where possible. However, Medsafe notes that the application search only includes the latest CMN for space reasons – the database would not function if all CMNs were included.

Medsafe has changed the search function and added the ability to show hide the side links. Medsafe is investigating the feasibility of a platform for companies to provide contact details. Medsafe will also investigate a search function for Prescriber Update articles.

Medsafe notes the comments on WAND. The data contained in WAND is partial and in some cases inaccurate and has not been assessed or approved by Medsafe. Therefore Medsafe considers that there is little benefit to making this publically available.

Post-Meeting Comments

Comments provided to Medsafe after the meeting included:

The complaints procedure was not discussed and this appears to have disappeared from the website

Medsafe and Industry should have joint developments of guidelines and joint training where possible.

The ILG meeting should include all members of the Medsafe Board.

Could the website be configured to send out a notification immediately any change is made on the website?

It would be useful to receive RFIs in word format rather than pdf

There may be a need for wider discussion and clarification about what is consulted on and to whom. It is important that all groups have the opportunity to respond to consultations.

Medsafe response

The complaints procedure is still on the Medsafe website in the report a problem section (http://www.medsafe.govt.nz/safety/report-a-problem.asp).

Development of guidelines and training will be considered for inclusion in the new format of the Reg Tech meetings, by the project team.

It is not Medsafe's intention to include the board in the ILG meetings.

Medsafe's website is changed on a daily basis, which would result in subscribers receiving notifications every day. Important announcements will be sent to relevant parties and the intention is to improve the frequency of the website update email.

Medsafe will investigate upgrading its software to enable the security settings in pdfs to be changed.

Changes to the consultation process will be discussed in Reg Tech meetings and/or ILG meetings.

Appendix 1: In Attendance

Alison Quesnel	(Natural Products NZ)
Vicki Wilson	(MTANZ)
Faye Sumner	(MTANZ)
Nancy Yopp	(MTANZ)
Philippe Robertson	(MTANZ)
Teresa Taylor	(MTANZ/NZSMI/Medicines NZ)
Sharyn Roberts	(MTANZ)
Matt Taylor	(Medicines NZ)
Pasquale Gargiulo	(Medicines NZ)
Philippa Davies	(Medicines NZ)
Mike Thompson	(Medicines NZ)
Elizabeth Joshi	(Medicines NZ)
Roger Smart	(NZSMI)
Terri Kong	(NZSMI)
Lizann Woodin	(NZSMI)
Maureen Roberts	(NZSMI)
Deborah Owen	(NZSMI)
Colin Robertson	(NZTPMA)
Maurice Parlane	(NZTPMA)