Changes to the data sheet format and Part 10 of the GRTPNZ

Summary of consultation responses

Medsafe

November 2016

Contents

About Medsafe

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

Background

This project and consultation was initiated due to inconsistency in New Zealand data sheets. The most sought after information by healthcare professionals is often not near the beginning of the document, increasing the time it takes to locate desired information. In addition, the order of the sections is not consistent between sponsors, further adding to the time taken to locate information.

The data sheet provides information for healthcare professionals on how to use the medicine safely and effectively. A standardised format will assist healthcare professionals to access information quickly as there will be uniformity in the format of the data sheet as well as in the information that is included in each section. Placing clinically relevant information at the start of the data sheet will also bring New Zealand data sheets in line with overseas regulators.

The Therapeutic Goods Administration consultation on "Mechanisms to maintain the currency of approved Product Information (PI) and Consumer Medicine Information (CMI)" held in 2013 was considered to be a joint agency project, although the Australia New Zealand Therapeutic Products Agency is now not proceeding. Nevertheless, responses to that consultation were considered by Medsafe for New Zealand. Overall, submitters considered that standardisation to an international format was a good idea, as was placing critical and useful information at the beginning of data sheets.

Medsafe reviewed the US FDA's Product Information format and the European Summary of Medicinal Product Characteristics (SmPC) format and proposed that the European SmPC

format should be adopted, with minor adaptations to meet certain New Zealand legislative requirements.

To help with the reformatting, Medsafe proposed:

- a data sheet template (Word document, 1 page) based on the SmPC format
- guidance on preparing a data sheet in the Data sheet template explanatory guide based on the European guideline
- updates to part 10 of the Guideline on the Regulation of Therapeutic Products in New Zealand (GRTPNZ)
- an implementation timetable.

Introduction

The consultation ran between 12 February and 31 March 2016. Twenty eight submissions were received:

- 6 from healthcare professionals or their representative bodies
- 18 from industry (also referred to as pharmaceutical companies and sponsors) or their representative bodies
- 4 from government agencies or their affiliates.

These submissions have been carefully reviewed by Medsafe.

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

Format of the data sheet

There is currently no required format for data sheets. Medsafe proposed adopting the SmPC format. In total 18 submissions agreed with adopting the SmPC format; 8 responses disagreed with the proposal and in 2 responses the author's opinion was unclear.

There was agreement that it was desirable to have a single format and provide clear information for healthcare professionals.

All the submissions NOT in agreement with the proposal were from sponsors (both innovator and generic companies). The main reason cited for disagreement was a desire to provide product information in the same format in New Zealand and Australia. For some sponsors who disagreed with the proposal, it was noted that the SmPC format was generally acceptable. One sponsor suggested that a new format (agreed with Australia) should be adopted.

Response

The SmPC format will be used for data sheets.

Harmonisation with Australia

The advantages of harmonising regulatory processes and in particular the format of the data sheet/product information, between New Zealand and Australia was mentioned in 11 submissions (all from pharmaceutical companies). The Australian regulator is the Therapeutic Goods Administration (TGA).

Concerns were expressed that a lack of harmonisation would lead to increased regulatory burdens, problems for New Zealand obtaining medicines, increased costs, delayed submissions for approval of new medicines and confusion for healthcare professionals.

Response

Medsafe is always happy to work with the TGA and other regulators to harmonise regulatory requirements for sponsors. For these reasons Medsafe chose to adopt the format of another regulator for data sheets. Medsafe considers that the SmPC format represents current best practice in communicating information about medicines to healthcare professionals.

Data sheets are only required to be submitted electronically, whilst there is a small cost involved in maintaining product information in more than one format, all companies working internationally already do this. The comments citing increased cost appeared to be related to the provision of package inserts.

Package inserts

The TGA currently requires that a copy of the Australian Product Information (PI) is included in the package for all injectable products. Many of these products are provided jointly to both New Zealand and Australia. Medsafe allows the inclusion of the Australian PI as a package insert, providing it contains all relevant New Zealand specific information and is consistent with the data sheet.

Most sponsors provided comments on this topic and considered that having a New Zealand specific package insert would be a significant barrier to provision of medicines in New Zealand.

Response

Medsafe confirms that there is no change to the current situation. Companies can continue to use the Australian Product Information as a package insert, providing it is consistent with the approved particulars in New Zealand.

Implications of the abbreviated process

Pharmaceutical companies can choose to submit applications to Medsafe through an abbreviated process outlined in part 2 of the GRTPNZ.

Submissions indicated that sponsors believe that using the abbreviated process means that the original country approval must be adopted in full by Medsafe. Therefore, it was argued that the product information in the originator country is the source document and the data sheet should be the same as the source document.

Response

The abbreviated process allows overseas assessment reports to be used as an adjunct to Medsafe's evaluation. It is not obligatory that the originator approval will be adopted in full by Medsafe; part 2 of the GRTPNZ will be updated to clarify this.

Implementation

Timeline

The consultation proposed that.

- New Medicine Applications (NMAs) in evaluation should switch to the new format once the consultation was complete. NMAs which were complete but the data sheet had not been published should submit the new format within 10 days of consent being granted.
- For Changed Medicine Notifications (CMNs) in process the data sheets do not need to be updated until 1 Jan 2017. For new CMNs the new format should be used once the consultation is complete.
- A Self-Assessable Change Notification (SACN) to reformat all existing data sheets should be submitted by 1 Jan 2017. Unless changes are required when the correct CMN should be submitted.

It was also proposed that data sheets in the Australian format should be revised to the proposed format by 1 January 2017.

The majority of companies considered the 1 Jan 2017 deadline for completion too short to update all data sheets for existing medicines. Various alternate timelines were suggested.

Companies also considered that for NMAs it would be impossible to change the format after consent in time for publication (10 days). No problems were foreseen changing the data sheets for NMAs in evaluation.

Response

Medsafe agrees. The implementation start date will be 1 March 2017 and the completion date will be 28 Feb 2019 (2 years for completion of the change). All NMAs in evaluation at the start date will need to have a data sheet in the new format for publication on completion of the NMA evaluation process. In the unlikely scenario of NMAs which have been granted consent but no data sheet published, the current format will be accepted.

For existing data sheets CMNs may be submitted to change to the new format as soon as the outcome of this consultation is published. Notifications of changed data sheets will not be accepted after 1 March 2017 unless they are provided in the new format.

Fee waiver

Submitters commented that there should be the ability to submit changes that are only reformatting with a fee waiver and changes should only be required for marketed products. The CMN submission process should be by-passed with reformatted data sheets sent directly for publication.

Response

Sponsors can update their data sheets to the new format with no additional charge if the updated data sheet is submitted during routine CMNs and SACNs that include other charge categories. For updates of data sheets to the new format submitted in isolation from other changes then the normal administration fee will apply. The CMN forms will be updated to include this new category for the duration of the changeover (ie, until 28 February 2019).

The CMN/SACN process will not be bypassed as Medsafe will still need to record the changes in the regulatory file and monitor the progress of the changeover.

Proposed updates to part 10 GRTPNZ

In general submitters considered that the proposed updates simplified the guideline.

Reference product information

Generic companies responded that they do not generally use a core data sheet to generate product information. It was commented that Medsafe has expected that data sheets for generic products are consistent with the innovator. However, the source document is not always obvious in NZ when the innovator is no longer on the market.

Response

Medsafe has updated part 10 of the GRTPNZ to include information on suitable source documents for generic products. This review highlighted that more than one source document may be appropriate. For example the indications must be the same, or a subset, of the innovator product. The safety information may be better obtained from another source, if the innovator is no longer available in New Zealand.

Changing the status of 'not-available' products

It was proposed that 'approved but not marketed' medicines will be indicated by a 'not currently available' statement if the sponsor wishes the data sheet to be published. This status would be changed via a change medicine notification (CMN).

Submitters stated that it was not clear where this status will be indicated. It was proposed that a statement in the data sheet was redundant. In addition it was not clear if a self-

assessable change notification (SACN) can be submitted to change the status. From the proposed CMN forms a SACN would be acceptable but 2.13 (part 10) specifies that a SACN is not acceptable.

Response

If all formats/presentations of the product are not available, and the sponsor still wishes to publish the data sheet, it is acceptable to indicate this on the Medsafe website only (currently displayed on the data sheet search results page and the product application search). However, if there is a mixture of available and non-available formats/presentations this should be indicated in the data sheet. This is because not all unavailable formats/presentations will be linked to the data sheet and therefore availability will not be obvious on the data sheet search page.

To change the status, providing there are no other changes to the data sheet required, or not yet implemented when a product format/presentation becomes available, a completed product status change request is acceptable (see 4.8 of Part 2). Part 10 has been updated accordingly. The explanatory guide has been updated to indicate whether this information should be included.

Summary of changes at the end of the data sheet

The concept of including a method to highlight changes to data sheets was discussed in the 2013 TGA consultation.

In general, submissions from companies disagreed with the current proposal whereas government organisations wanted more information than was proposed.

Some companies proposed that Medsafe adopts a system similar to Health Canada, FDA and EMA; that is to maintain a running history of changes to the product information on the Medsafe website.

Response

Medsafe considered that the summary table should only highlight the difference(s) between the new version and previous version of the data sheet. Medsafe does not consider that there is a need to record all changes for all time either in the data sheet or on the website. When sponsors update the data sheet to the new format and if there are no other changes then the summary table should state: 'Format update only.'

The summary of changes table is intended to avoid using track changes in the data sheet which would make it difficult to read the information. The purpose is to highlight to healthcare professionals where the new information is so they can update their knowledge of the product. The inclusion of new information in the data sheet is not always accompanied by a Dear Healthcare Professional letter.

The explanatory guide has been updated with examples to help companies understand Medsafe's expectations.

Bookmarks and hyperlinks

Healthcare professionals considered that the use of bookmarks and hyperlinks should be encouraged. Sponsors proposed that hyperlinks could be used in data sheets to allow the healthcare provider to email the sponsor from the data sheet or there could be embedded links to ADR reporting forms.

Sponsors considered that it would be helpful to have information from Medsafe on what would be considered acceptable and what would be considered promotional.

One submission proposed that data sheets should be presented as html documents with a side-bar menu pane for ease of navigation. This could also be achieved in a pdf with a bookmark.

Response

The template provided has been formatted with headers which will automatically translate to bookmarks in pdf format. Part 10 of the GRTPNZ has been updated to encourage the use of bookmarks and explain which hyperlinks are acceptable. Sponsors should use the template or create headings in their own word documents. Conversion to pdf format will then automatically include bookmarks. Medsafe will not be moving back to the html format since this introduces more style and formatting issues than use of pdfs.

Other comments

- Concerns over the use of the word 'should' – may allow for non-inclusion of data that is available.

Response

A similar comment was made during the consultation on part 8 of the GRTPNZ. In response it was noted that the use of "should" and "must" would need to be reviewed for impact and applicability at an organisation wide level. In general, however, the word "should" is used in the absence of requirements in the legislation.

- Links to material safety data sheets would be helpful.

Response

Medsafe does not regulate material safety data sheets and has no remit to require such links.

- For Section 2.4 bullet point 3 a sponsor requested addition of 'strengths and formulations' added to second sentence.

Response

Medsafe agrees with this point. Part 10 of the GRTPNZ has been updated.

- Currently it is permissible to reference a data sheet of another company where the dose form or strength is not registered, it is requested that 2.4 bullet point 9 is revised to clarify the expectation.

Response

This is not the intent of this bullet point. It is allowed to reference other products but only by the International Non-proprietary Name (INN). No clarification is required.

- It was proposed that *in vivo* bioavailability data supporting interchangeability should be allowed.

Response

Medsafe disagrees; this information is not included in any jurisdiction.

- A requirement for separate data sheets for different dose forms etc must not become mandatory.

Response

Medsafe agrees.

- General requirements should also cover the use and acceptability of SI units and how they are written.

Response

Medsafe considers that companies should be allowed to retain flexibility to use the format that best reduces the risk of errors for their product. The need to use abbreviations only occurs when there are space restraints such as the product label. This is not expected to be a problem in the data sheet. Where space is limited Medsafe expects that mcg be used over µg, in line with FDA recommendations and the MHRA guideline best practice guidance on labelling and packaging.

- Regarding the declaration to accompany a data sheet submitted for publication. There is a contradictory question on the declaration.

Response

Medsafe has updated this form.

- Section 2.1 of Part 10 of the GRTPNZ states that data sheets are reviewed and approved, however this seems inconsistent with the SACN process.
- Section 2.7 submitting an approved data sheet for publication requires sponsors to supply Medsafe with an electronic copy within 10 days of confirmation of receipt, whereas 2.10.1 advises the electronic copy is provided once the SACN invoice has been paid.
- Part 10 clarification is requested as to whether it is now acceptable to produce electronic copies only with no paper submission.

Response

Medsafe considers the SACN to be an approval process, therefore by default the data sheet is also approved. The audit process is in place to identify problems.

Part 10 has been amended to resolve the confusion. Paper copies are still required to be submitted as part of the NMA or CMN, and only an electronic copy of the approved data sheet should be submitted at the end of the NMA or CMN process.

Content of the data sheet

Excipients and Residual substances

Healthcare professionals requested greater clarity about exposure of potentially harmful excipients to at-risk patients (eg, alcohol to neonates). One option suggested was to include quantitative information for a defined set of excipients that have been associated with toxicity.

Another submitter requested more detail on the meaning of 'excipients with known effect' (section 2 of the explanatory guide).

Healthcare professionals also suggested that the data sheet should include information on residual substances used in manufacture and other inactive ingredients not classed as excipients.

Sponsors noted that in section 6.1 it is indicated that any component of flavour and/or fragrance which are known to have a required action or effect should be included in the data sheet. Sponsors considered that this would not be possible where the formulation of such flavours and fragrance has been provided 'in confidence'.

Response

Medsafe notes that the excipient content of medicines and how this information is provided is of concern to both healthcare professionals and industry. Medsafe encourages sponsors to follow the EU excipient guideline.
(www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003412.pdf).

This guideline lists those excipients with known effect and outlines the different statements which are to be used for different concentrations of these excipients. In the case of alcohol the quantity should be provided in section 4.4 as per the explanatory guide.

Similarly with respect to residues Medsafe requests that sponsors use the EU vaccine guideline.
(www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003628.pdf).

Sponsors are expected to obtain information about excipients of concern from proprietary ingredient suppliers. Medsafe considers that such information does not disclose proprietary formulations.

The explanatory guide has been updated to include these recommendations.

Pregnancy and other special populations

It was noted in the submissions that the FDA has decided to eliminate pregnancy categories in the US product information. The FDA considers that pregnancy categories are often viewed as confusing and overly simplistic and don't effectively communicate the risk of the medicine in pregnancy. Pregnancy categories are not used in Europe or Canada.

Healthcare professionals stated that when a medicine is not approved for use in a specific group this should be stated clearly in the data sheet, for example pregnancy. Their experience in looking for this information in data sheets is that the information is often implied and difficult to find.

It was commented that section 4.1 (indications) states that a target population should be specified, the submitter queried whether this referred to a prevention indication or other indications as well.

Similarly another submitter stated that clarity is required on the definition of an adult patient some data sheets indicate 16 years and others 18 years.

Response

Medsafe notes that the FDA have moved away from a categorisation system and that including a pregnancy category is no longer considered to be best practice. Medsafe has removed the requirement for the pregnancy category from the explanatory guide. The company should include the information that supports the category as outlined in the explanatory guide. The company may include the TGA category if they wish.

Medsafe notes that pregnancy is an example of a special population with its own section (4.6) to provide information on the benefits and risks of use. This is similar to the situation for other special populations such as patients with renal impairment (information included in 4.4). If a medicine should definitely not be used in a special population this will be included in the contraindications section (4.3).

The text regarding section 4.1 is to ensure that the indication describes the clinical trial population, since this is the only population for which data on efficacy and safety are available. Similarly the age from which the medicine can be used should be stated in the indications and should be in line with the clinical study information.

Magnitude of the changes required from the existing formats

The currently approved data sheets do not contain all the information that Medsafe is recommending (in the SmPC format). The following sections were identified as requiring additional information or re-writing.

- Paediatric population dose. The current dosage section includes information on both adult and paediatric dosage, rewriting will be required to separate this information.
- Shelf life. It was commented that this is superfluous in a data sheet and should not influence prescriber choice and has the potential for confusion where multiple presentations have different shelf lives.
- Effects on ability to drive and use machines.
- Clinical Trials Information – currently the data sheet allows for substantial information regarding clinical trial data. This is particularly important for medicines with several indications.
- Undesirable effects – the proposed format includes a tabulated summary of adverse reactions, for some products it will require substantial resource to create this. Clarification was requested on adverse event information moving to frequencies from percentages. This information may vary between sponsors of the same active substance. It was proposed that the requirement is implemented for new data sheets only.
- Dosage and administration may need rewriting to separate this information into separate sections as per the SmPC template.

Another comment was that the guideline should be updated if it is acceptable to have data sheets with content which is non-compliant with the explanatory guide.

Response

Medsafe concurs that the changes in some cases are more than just a reshuffle of information. With respect to the specific points:

- If there is no paediatric dose because the medicine is not indicated in children this should not be included in the data sheet.
- Information such as shelf life should be the same as the Therapeutic Product Database Report (TPDR). The guideline has been updated to state that the data sheet information must be the same as that contained in the TPDR.
- The explanatory guide does contain some information on formulating the text for the driving warning. Further information has been included in the explanatory guide.
- Medsafe considers that for existing data sheets the current clinical trials information can be relocated to section 5.1 – clinical efficacy and safety, without any changes being made to the content. For new medicines approved after 1 Jan 2017 the text should comply with the explanatory guide.
- Medsafe agrees that for some medicines the undesirable effects section will need review and updating to the new format. Medsafe acknowledges that there are data

sheets that do not currently express the frequencies of adverse reactions. For some of these medicines this data will not be available. Companies should confirm in the CMN that this is the case. Medsafe also notes that frequencies may be different between different formulations for the same active. This is the situation currently and Medsafe expects it to continue.

- The rewriting of the dosage and administration should be feasible within the proposed time period.

Part 10 will not be altered to allow data sheets to be non-compliant as this defeats the purpose of a standard format. Medsafe has published a policy document to allow non-compliance in some parts of the SmPC format for existing products. Medsafe will provide information on these topics at the next industry meeting.

Other comments

- Inclusion of the antibiotic sensitivity table in section 5.2 could conflict with local guidance and misinform appropriate choice.

Response

This table is currently included in the checklist for a New Zealand format data sheet and therefore is incorporated in the proposed format. The table is intended as a guide. However, Medsafe expects the choice of antibiotic to be guided by sensitivity testing or local guidelines.

- Information on disposal of medicines according to the requirements of the Hazardous Substances and New Organisms Act would be very useful.

Response

The data sheet is not intended to replace local policies on disposal of medicines. If there are disposal considerations these should be included in section 6.6 of the SmPC.

- Section 2 of the explanatory guide states that full details of the qualitative and quantitative composition of the product needed to be known for correct use should be provided in section 2. However, later under the quantitative and qualitative declarations there is no mention of excipients.

Response

Excipients must only be mentioned in section 2 if this is relevant for correct use of the product. Otherwise they are described in other parts of the SmPC.

- In section 4.4 a warning is required for formulations containing ethanol – should this be cross referenced to section 2?

Response

Medsafe does not feel that a cross reference to section 2 is necessary given that a consistent format will mean that the information required by the reader should be in the same part of all data sheets and therefore easy to locate.

- Displacement values should be included in the section on powders for reconstitution prior to parenteral administration so healthcare professionals can reconstitute to known final concentration.

Response

This section includes the instructions for reconstituting the product according to the approved method recommended by the manufacturer. Medsafe cannot endorse the reconstitution at alternative concentrations as these have not been validated and are therefore considered 'off-label'. Where displacement values are required for reconstitution of the product they will be included.

- The provisional consent information is wrongly placed and should be in section 7, medicine schedule.

Response

Medsafe considered the position of this information prior to consultation and decided to keep the EU/SmPC positioning of equivalent information.

- Preparation and administration details. Information on the preparation or reconstitution of a product is required to be in section 6.6 not in section 4.2 –all information related to product preparation should be in a single section.

Response

The preparation/reconstitution information should all be contained in section 6.6 with reference from section 4.2.

- Clarification on dates was requested. In the new format date of preparation has been replaced with date of revision of the text. For new data sheets this includes the date of first approval of the data sheet. For SACN approvals the date will not always be known.

Response

In the proposed format the term "date of revision of the text" means the same as date of preparation. For the first data sheets for new products this date will be the same as the approval date, since the text will be revised with the approval date prior to publication. Approval dates are published in the New Zealand Gazette (https://gazette.govt.nz/) the data sheet should be provided within 10 days of gazettal (section 2.7 of part 10 of the GRTPNZ). SACN approval dates are the 'paid' date available on the Medsafe website.

- It is noted that the guidance discourages reference to herbal medicines. The prompt in the explanatory guide to refer to interactions with herbal medicines should be retained.

Response

Medsafe agrees. The interactions section (of the explanatory guide) has been updated using the term natural health products (including complementary medicines, dietary supplements and herbal remedies).

- The order of the information should be changed. Prescribers should consider the contraindications and warnings before they need to know the dose.

Response

Medsafe disagrees. If the SmPC format is to be adopted the order of the information cannot be changed. In the majority of cases, the contraindications will be on the same page as the dosing information and with a set format will be easy to locate.

- Healthcare professionals commented there should be reference to source documents for example for Medicines Adverse Reactions Committee (MARC)/Medsafe requests for changes to the data sheet. The references and/or clinical trial numbers for studies should be included. If the data is not published then data on file should be included. All data sheets should have a disclaimer that 'the studies cited are not all of the studies conducted. Prescribers are advised to undertake their own research literature searches'. There was concern that the efficacy data is not included in the SmPC format.

Response

The SmPC format specifically states that there should be no references. Medsafe will not be requiring that sponsors make reference to Medsafe or MARC reviews in data sheets. Important clinical trials will be referred to by name and are therefore easy to locate in the scientific literature or on clinical trials registers.

The data sheet is reviewed by clinically qualified staff at Medsafe to ensure that the information is correct. The data sheet is provided as a service to time-limited healthcare professionals so they do not need to research this information for every medicine they may need to prescribe or use. Healthcare professionals can choose to do their own research if they wish.

The efficacy data will continue to be included in the new format in section 5.1 under the subtitle clinical efficacy and safety.

- Synonyms are recommended in addition to the INN.

Response

Synonyms are not generally allowed in the data sheet as the product has one approved name to avoid confusion. The search functions on the Medsafe website allow you to search by synonyms. This information is also available in the New Zealand Universal List of Medicines (NZULM).

- Data sheets for discontinued products should remain available for an agreed period of time.

Response

Medsafe currently publishes data sheets for discontinued products until the sponsor informs Medsafe that there is no more product left in the market. Medsafe considers that it is not in the interests of safe medicine use to keep non-maintained data sheets on the website.

Future Name for the data sheet

The current medicines legislation mandates the use of the term "data sheet". However this term is confused with the hazardous materials data sheets (Material Safety Data Sheet) and is out of line with the terminology in other countries. Submitters were asked for their preference on the future terminology.

Two submissions preferred "SPC" or "NZSmPC" to reflect the revised format. Another submitter considered summary of product characteristics was rather verbose and tends to be abbreviated.

Eight submissions considered that the term "data sheet" should remain. The New Zealand Medical Association (NZMA) for example preferred data sheet whilst the New Zealand Nurses Organisation (NZNO) wanted anything but data sheet. The main reason for preferring this term was for continuity.

Twelve submissions considered "product information" should be used as this aligns with the Australian terminology.

"Prescribing Information" was considered an acceptable alternative to product information by three submitters. It was noted in other submissions that "Prescribing Information" is less than ideal because information contained in the data sheets is used for activities other than prescribing.

Response

Medsafe has noted these responses and also considers that "therapeutic product information" (TPI) could be an alternative name. This information will be considered in the development of new legislation.

Use of technology

The consultation asked how the expansion of e-information might contribute to patients' safety. This question was intended to help Medsafe understand future directions and start preparing for different ways of working.

Instructional videos and educational materials

Healthcare professionals considered that instructional videos would be helpful to detail correct reconstitution/administration techniques of medicines. How-to-use videos may be able to impart some information more effectively. Subtitles on videos may be required. Electronic information provides opportunities to provide access to information for patients who are unable to read printed instructions. E-information should help to reduce delay, error and duplication.

The EMC website has a section for risk minimisation materials. This approach adopted for New Zealand context would be very useful.

Risks of e-technologies include inappropriate use to replace relationships between healthcare professionals and consumers, lack of training to use them properly, if only marginal benefits are delivered, may be commercialised, may cause or exacerbate inequity. Consideration must also be given to any disadvantage this may confer to those for whom access to electronic information is limited.

It is important to maintain standards and ensure the information is kept up-to-date. This may require an additional regulatory framework.

Consumers should be directed only to accurate information consistent with the Medsafe approved document. This could be achieved by the websites where the information is located being under the control of the local sponsor.

Consideration about independent information sources as opposed to drug company sponsored sources is important.

Response

The provision of educational materials is mentioned in section 7 of part 8 (pharmacovigilance) of the GRTPNZ. Medsafe will use this information in future projects.

Use of QR codes

QR codes in data sheets could be used to provide links to consumer medicines information. The information sourced through these tools should be in a legally approved format. This information needs to be regularly updated to ensure best practice.

Sponsors noted that the option of including QR codes as a replacement for the need to provide printed package inserts is of interest. This would enable access to current information. This is appropriate particularly for prescription or high technology products where use is controlled by healthcare professionals.

Introduction of this technology would require a compliance framework and should be optional.

The TGA has specific guidelines on use of QR codes weblinks etc which may prove problematic for shared packaging. Other barriers to implementation include the time needed to maintain another set of data, small pack sizes limiting the space to fit QR codes.

It would be encouraging for sponsors if Medsafe holds an open view on the adoption and partners with industry on how this should be regulated.

Response

Medsafe acknowledges the helpful comments provided and will keep an open view on adoption of the technology. The use of QR technology will be investigated as part of the review of the therapeutic products legislation.

Using technology to reduce the administrative burden

Medsafe should adopt the use of technology to facilitate the electronic distribution of data sheets. Currently and in the proposed guidelines sponsors are required to submit an approved data sheet to Medsafe for publication in a separate email for each data sheet. In Australia a single centralised repository is used which distributes documents to a number of government agencies, publishers and industry associations.

Response

This request will be considered during future projects.

Other comments

- It may be useful to consider incorporating SNOMED terminology into the data sheet to enable interoperability with electronic systems.

Response

MedDRA is the standard terminology used in medicines regulation, as mandated by ICH and outlined in the explanatory guide.

- Data apps may be the way of the future, Medsafe should develop an app for healthcare providers to provide medicines information and reduce the use of paper.

Response

Medsafe also asked about the use of apps in a *Prescriber Update* survey. There appeared to be no enthusiasm for the use of apps.

Information for Medical devices

Two questions were posed during the consultation regarding making information on devices available on the Medsafe website.

The majority of submitters who responded were in favour of some information being provided on medical devices. It was noted that instructions for use (IFU) are more appropriate than a data sheet and are already produced. IFU documents include information on

- Description of the device
- Indications or intended purpose
- Contraindications
- Precautions or warning information
- Directions for use
- Storage conditions

There were several different opinions about which devices it be useful to publish the IFU for. For example the need for information for devices only used in a surgical setting or lower risk devices was considered to be low.

Response

This information will be fed into the new legislation project.

Other general comments

Submitters were also provided with the opportunity to provide any other comments. In some cases these comments related to issues already discussed above. Other comments related to Consumer Medicine Information (CMI) which is outside the remit of this project. These comments will be considered in the future.

Medsafe website

We would like to see increased functionality and improved appearance of the Medsafe website to facilitate fast and efficient navigation. It would be helpful to have a similar layout searching and document navigation to the electronic Medicines Compendium (eMC). Links out to other trusted sources of medicines information would also be useful.

The search function for data sheets on the Medsafe website should cover trade and generic names by default. Links to data sheets and CMIs should be on the same page.

Response

Medsafe will be updating the data sheet search page. It should be noted that the Medsafe website contains more information than the eMC and is therefore more difficult to arrange in a fashion that suits everyone.

Understanding of medicines regulation

Comments were made by healthcare professionals regarding the reliance by Medsafe on data provided by companies. Clarification was sought on what safeguards are in place to ensure that complete information is used.

Response

There appears to be a misunderstanding of the provision/production of medicines and the role of the regulator. These comments suggest that Medsafe should undertake some educational activities with healthcare professionals on the role of the regulator.