Medsafe consultation submission

Guideline on the Regulation of Therapeutic Products in New Zealand - Part 8: Pharmacovigilance (Edition 2.0)

Name and designation	
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I would like the comments I have provided to be kept confidential: *(Please give reasons and identify specific sections of response if applicable)* (Reasons for requesting confidentiality must meet Official Information Act criteria)	☐ Yes ■ No
I would like my name to be removed from all documents prior to publication on the Medsafe website.	■ Yes ☐ No
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It would help in the analysis of stakeholder comments if you provide the information requested below.

I am, or I represent, an organisation that is based in:

☐ New Zealand ■ Australia ☐ Other (*please specify*):

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Please return this form to:

Email: medsafeadrquery@moh.govt.nz including 'Pharmacovigilance guideline' in the subject line

Or Post: Clinical Risk Management
Medsafe
PO Box 5013
Wellington 6145

Medsafe is seeking comments on:

Section 1: Legislation eg,

- Are the guidance documents appropriate?
- Are there other guidance documents that would be relevant to the conduct of pharmacovigilance in New Zealand?

Hospira agrees with the suggested recommended New Zealand legislation.

Will Medsafe also refer to any global legislation ie ICH, EU or TGA that they may be following?
Hospira notes that both ICH and European guidance on important medical events (www.eudravigilance.ema.europa.eu/human/textforIME.asp) are referred to in the reporting section and it may also be appropriate to reference the guidelines here.

Section 2: Roles and Responsibilities eg,

- Does the information adequately describe the roles and responsibilities of the various parties?
- Was the information appropriately presented?
- Was the information easy to find?
- Are there any changes you would like to suggest?

Hospira has no further comment on this section. The information provided is clear and self explanatory.

Please include additional pages if necessary.

Section 3: Reporting eg,

- Do you have any suggestions regarding the definitions and interpretations used in this section?
- Do the subsection headings appropriately and adequately describe each reporting circumstance?
- Is each reporting circumstance and the process involved adequately described and explained?
- Would it be easy to find the information you need in each particular reporting circumstance?
- Are there circumstances that are not in this guideline but should be? If yes, please provide more details.

Hospira has no comments with respect to the questions asked above however Hospira wishes to comment on the requirement outlined in Section 3.5.13 Media reports. Please see further attached comments.

Section 4: Signal Management Process eg,

- Does the content of each subsection adequately explain what the steps in the process involve?
- Do the subsections on the Early Warning System and Medicines Monitoring adequately explain how these tools can be used?
- Do you understand what the role of the sponsor is in these situations?

Hospira has no further comments on this section and understands the sponsor role in these situations.

Please include additional pages if necessary.

Section 5: Significant Safety Issues eg,

- Does the text in this section adequately explain what is required?
- Are there other pharmacovigilance-related safety issues or safety concerns about medicines that you consider should be included in this section?

Hospira has no further comment on this section. The information required has been sufficiently covered.

Section 6: Submission of Safety Monitoring Documents eg,

- Are there other suggestions or recommendations that could be included in this section?

Hospira has no further comment on this section. The information required has been sufficiently covered.

Please include additional pages if necessary.

Section 7: Safety Communications eg,

- Are there other suggestions or recommendations that could be included in this section?
- Is it appropriate to use the European template for safety communications?

Hospira has no further comment on this section. The information required has been sufficiently covered. It is appropriate to use the EU template for safety communications. Hospira agrees with this suggestion.

Additional Comments

- Is the order of the information presented in each section appropriate?
- Do you agree with the proposed structure of the guideline?
- Is the information easily understood?
- Is there any other information or subject that should be included in this guideline?

Hospira has no further comments. The only concern Hospira has is with regard to social media monitoring as detailed in Section 3.

Please include additional pages if necessary.

Section 3 Reporting – Hospira comments

Hospira would like to address and make comment regarding the requirement outlined in Section 3.5.13 Media reports.
"Sponsors should regularly monitor and review lay internet sites (such as chat rooms and discussion forums) for potential reports of suspected adverse reactions."

Hospira is concerned that compliance with the above requirement will not be feasible for any company and that attempts to comply will lead to a decline in the quality of PV reporting because:

- It is impossible to keep on top of any and all evolving and new sites, which makes it virtually impossible to comply with this requirement.
- Due to the "echo chamber effect" of the internet, the weight of reports becomes distorted (this is a well-recognized effect)
- Duplications (or more accurately multiplications by much larger factors) are the norm and are often impossible to distinguish
- Verification of reports and claims is usually not possible
- This requirement is inconsistent with that of other major regulators including the European Medicines Agency (EMA) and the Therapeutic Goods Administration (TGA)

Hospira proposes rewording of this section in line with EMA "Guideline on good pharmacovigilance practices (GVP) Module VI – Management and reporting of adverse reactions to medicinal products GVP Module VI" or the TGA "Australian requirements and recommendations for pharmacovigilance responsibilities of sponsors of medicines" as both require monitoring of media under the marketing authorization holder's management or responsibility only:

EMA Guideline on good pharmacovigilance practices (GVP) Module VI
VI.B.1.1.4. Information on suspected adverse reactions from the internet or digital media

Marketing authorisation holders should regularly screen internet or digital media under their management or responsibility, for potential reports of suspected adverse reactions. In this aspect, digital media is considered to be company sponsored if it is owned, paid for and/or controlled by the marketing authorisation holder. The frequency of the screening should allow for potential valid ICSRs to be reported to the competent authorities within the appropriate reporting timeframe based on the date the information was posted on the internet site/digital medium. Marketing authorisation holders may also consider utilising their websites to facilitate the collection of reports of suspected adverse reactions.

If a marketing authorisation holder becomes aware of a report of suspected adverse reaction described in any non-company sponsored digital medium, the report should be assessed to determine whether it qualifies for reporting.

Unsolicited cases of suspected adverse reactions from the internet or digital media should be handled as spontaneous reports. The same reporting time frames as for spontaneous reports should be applied. In relation to cases from the internet or digital media, the identifiability of the reporter refers to the existence of a real person, that is, it is possible to verify the contact details of the reporter (e.g., an email address under a valid format has been provided). If the country of the primary source is missing, the country where the information was received, or where the review took place, should be used as the primary source country.

Australian requirements and recommendations for pharmacovigilance responsibilities of sponsors of medicines Version 1.3, June 2014

Monitoring the internet or digital media

Sponsors should regularly screen internet or digital media under their management or responsibility, for potential reports of suspected ARs. This includes digital media that is owned, paid for and/or controlled by the sponsor. The frequency of the screening should allow for valid ARs to be reported within the appropriate reporting timeframe based on the date the information was posted on the internet site/digital medium. Sponsors may also consider utilising their websites to facilitate the collection of reports of suspected ARs.

If a sponsor becomes aware of a report of a suspected AR described in any non-company sponsored digital medium, the report should be assessed to determine whether it qualifies for reporting. If so, it should be reported according to the timeframes specified in this document.

In relation to cases from the internet or digital media, the identifiability of the reporter refers to the existence of a real person, that is, it is possible to verify the contact details of the reporter (e.g., an email address under a valid format has been provided).