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
I would like for my name not to be included within the list of submissions published on the Medsafe website.	■ Yes ☐ No

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:

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☐ Health professional – *please indicate type of practice*:			
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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?

It would be helpful to include a reference to the relevant guideline/guidance for medical device safety reporting requirements for sponsors in this section.

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?

No comments.

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.

3.5.9 and 3.5.10 (page 18) - MERP:
Is it a requirement that sponsors report cases of medication error (with or without an adverse event) through MERP or is this voluntary? The current wording of 3.5.9 and 3.5.10 suggests this is voluntary.

3.5.13 - Media Reports:
Page 19 states "sponsors should regularly monitor and review lay internet sites (such as chat rooms and discussion forums) for potential reports of suspected adverse reactions". We appreciate that if an adverse event is identified in such sites by chance, that it should be captured in our safety database for assessment. We regularly monitor digital media sites for which Novo Nordisk is responsible or involved. However we note that the European legislation (GVP module VI) does not require marketing authorisation holders (MAH) to routinely monitor digital media sites which are not under the MAH's management or responsibility (referred to as "any non-company sponsored digital medium"). We respectfully request Medsafe to reconsider the requirement to regularly monitor and review lay internet sites (such as chat rooms and discussion forums) for which the sponsor is not responsible. We would suggest that section 3.5.13 of the proposed guideline be re-worded to clarify that routine review of non-company sponsored digital medium is not mandated, but that should the sponsor become aware of any suspected adverse events described in such medium, the sponsor should assess the information to determine whether it qualifies for reporting.

3.5.15 - Suspected adverse reactions related to quality defect or falsified medicine (page 19)
This section states that sponsors should notify Medsafe (not CARM) with 72 hours of any adverse reactions associated with suspected or confirmed adulterated, contaminated, counterfeit or tampered medicines. Does this apply to non-serious adverse reactions or just serious adverse reactions? We note that the TGA requirement is that sponsors are required to report serious adverse reactions associated with a suspected or confirmed quality defect of a medicine for which they are the sponsor, including a suspected or confirmed

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?

No comments.

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?

No comments.

Section 6: Submission of Safety Monitoring Documents eg,

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

Page 28: PBRERs
With regard to the routine submission of PBRERs, we would suggest that specific definitions be included in the glossary for "biologicals" and "biosimilars".

It would also be useful to provide details in this section on the practicalities around reporting these documents. ie:
- How to report them.
- Who to report them to.
- Should they be reported six monthly or annually?
- Should they be reported electronically or in paper format?
- ...Or confirmation that these details/instructions will be specified in the approval letter.
- Are PBRERs required for all biologicals, biosimilars and vaccines which already have consent for distribution or is it only for new biologicals, biosimilars and vaccines granted consent after the effective date of this new guideline?

Page 29: RMPs
In the event that RMPs are requested, are the European RMPs acceptable?
Does a New Zealand-specific document or annex need to be developed?

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?

Dear Healthcare Professional Letters:
Section 7.2 (page 30) states "Common examples of changes that have to be communicated are the imposition of new warnings, precautions, contraindications, a limitation or indication, or restriction on use". We respectfully request Medsafe to reconsider whether Dear Healthcare Professional letters in these situations are mandatory as the proposed wording suggests. If not mandatory, we would suggest that wording be altered to state that DHCP letters in these situations are 'encouraged'. We note that the European requirements (GVP Module XV) advise that a Dear Healthcare Professional letter should be considered for these situations. GVP Module XV confirms that throughout the module, legal obligations are identified by the modal verb 'shall' (e.g 'the marketing authorisation holder shall...'). When guidance is provided on how to implement legal provisions, the modal verb 'should' is used (e.g. 'the marketing authorisation holder should...').

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?

Glossary:
1) We suggest that a definition for "biologicals" be included in the glossary (including confirmation of whether Medsafe is referring specifically to biological medicines).
2) We suggest that a definition for "biosimilars" be included in the glossary.
3) We suggest that a definition for "Solicited report" be included in the glossary.

No further comments. We appreciate the value of this updated guideline for providing further detail and clarity around pharmacovigilance requirements for sponsors in New Zealand. Thank you.

Please include additional pages if necessary.