Medsafe consultation submission

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

Name and designation	
Company/organisation name and address	Roche Products (New Zealand) Limited 98 Carlton Gore Road, Newmarket, Auckland
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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:

☒ 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 No specific comments about this section.
Section 2: Roles and Responsibilities No specific comments about this section.

Please include additional pages if necessary.

Section 3: Reporting

Section 3.1: Introduction

We would like to suggest that it is made clear that for spontaneous reports, where the reporter (either HCP or consumer) has explicitly stated that the event is unrelated to the medicine, and the sponsor agrees with this assessment, that the case does not require reporting to CARM. This section seems to indicate that this is the expectation, but it is not clear. We would also suggest that this information is included either under section 3.2.1 or 3.3.2.

Section 3.2: What should be reported

Regarding the following statement: *"approved medicines in a blinded study, after the identity of the suspected medicine has been determined."* Could this sentence be clarified to confirm whether the case report should only be submitted to CARM once all medicines in the case have been unblinded, i.e. for case reports where there is more than one suspect medicine.

Section 3.3.3: Follow-up of reports

We would like to suggest that the example given in this section (a report of death/sudden death), which should not be reported to CARM until further information is received, is removed from this section and discussed under section 3.3.2 instead. This example seems to be about what reaction terms make the case valid. We would suggest that if there are particular instances when a reaction is not considered valid that this is discussed in greater detail under section 3.3.2. The *EU GVP Module VI, section VI. B. 2. Validation of reports* contains useful information in this regard. We would suggest something similar is documented in the Medsafe guideline.

Regarding the following sentence in this section which states: *"If incomplete information is received directly from a consumer, sponsors should make attempts to contact the consumer directly or obtain consent to contact a nominated healthcare professional for further information";* whereas in section 3.5.1 it states *"Sponsors should seek and document permission from consumers to allow contact with their primary healthcare professional to obtain additional relevant medical information."* The first sentence implies sponsors can contact the consumer OR obtain consent to contact their healthcare professional for further information; whereas the second sentence states the sponsor should contact the healthcare professional only (after consent is provided from the consumer). Please clarify who the sponsor should be contacting, as these two sentences seem to contradict each other.

We would like to request that examples are given for what is considered to be *"significant additional information".* Could it also be clarified in this section that when further information is received which is considered to be non-significant, that this therefore does not require reporting to CARM.

Section 3.4: Reporting timeframes for adverse reaction reports

Where significant additional information will be available *"shortly after 15 calendar days"* could it be clarified whether there is a maximum timeframe for delay.

Section 3.5.4: Lack of efficacy

Could it please be clarified whether the requirement is indeed for all lack of therapeutic efficacy cases for all medicines to be reported to CARM, or only lack of efficacy cases for vaccines, contraceptives or medicines used in critical conditions or life-threatening situations? We would like to suggest that *EU GVP Module VI guideline, section VI.B.6.4.* is followed which states that lack of efficacy cases should not normally be reported, but in certain circumstances (such as have been given in this section), that these should be reported within 15 calendar days.

Section 3.5.13: Media reports

Regarding the following sentence: *"Sponsors should regularly monitor and review lay internet sites (such as chat rooms and discussion forums) for potential reports of suspected adverse reactions."* We do not consider that this requirement is feasible. We would like to request that Medsafe follows

the *EU GVP Module VI guideline, section VI.B.1.1.4.* This states that sponsors should regularly screen internet or digital media under their management or responsibility only, for potential reports of suspected adverse reactions. If sponsors become aware of a report described in any non-company sponsored digital medium then this should be assessed to determine whether it qualifies for reporting and handled as a spontaneous report. There is no requirement in the *EU GVP Module VI guideline* requiring sponsors to monitor non-company sponsored digital media.

Section 3.5.15: Suspected adverse reactions related to quality defect or falsified medicine

We request further clarification regarding this section. Could it please be defined what is considered a quality defect? Does Medsafe want to receive adverse reactions associated with any product quality complaint received by a sponsor?

Please note that there may be occasions when a lack of efficacy report is considered by the reporter to be due to a product quality issue, which is then investigated as a product quality complaint by Roche. According to this section this would need to be reported to Medsafe and not to CARM, which contradicts section 3.5.4. Please clarify whether these types of reports should indeed be sent to Medsafe and not to CARM.

Section 4: Signal Management Process

No specific comments about this section.

Please include additional pages if necessary.

Section 5: Significant Safety Issues

Section 5.2: What are significant safety issues

Regarding the issues for which sponsors are considering sending Dear Healthcare Professional (DHCP) letters; please clarify whether this means that sponsors are required to notify Medsafe within 72 hours that we intend to send a DHCP letter, and then subsequently send Medsafe the draft DHCP letter to review, if this is ready outside of the 72 hours. This seems to overlap somewhat with section 7.2 on DHCP letters.

Section 6: Submission of Safety Monitoring Documents

Section 6.2: Submission of PBRERs

Please define what Medsafe means by a biological. Is this referring to complex proteins such as monoclonal antibodies, or to blood products? Please add the definition to the glossary section.

Please include additional pages if necessary.

Section 7: Safety Communications

Section 7.4: Other educational materials

Further clarity is requested for this section. Is this section referring to those educational materials which are considered as "additional Risk Minimisation Activities" in Risk Management Plans? Stating that this is "desirable" presumably means that sponsors are not obliged to provide copies of materials.

Additional Comments

Section 8: Glossary

The glossary is missing definitions for RMPs and DHCP letters. In addition, please define here what Medsafe means by "biologicals".

General Comments

Overall we found this to be a well-structured and easy to read document, which will be a valuable resource in ensuring that we meet Pharmacovigilance requirements in New Zealand.

Please include additional pages if necessary.