Summary of Changes Made to GRTPNZ Part 8: Pharmacovigilance Edition 2.2

The pharmacovigilance guideline has been updated as part of the review of Medsafe's quality system documents. The following changes have been made.

Section	Summary of changes
Cover page	Month and year, and Edition number updated to June/July 2020, Edition 2.2.
Throughout	Hyperlinks to web documents in the text have been updated. Edition number in the footnote updated to Edition 2.2. Minor grammatical and formatting changes. "Healthcare professional" changed to "health care professional" following Ministry of Health communications standard.
2.3	Changed "…expert advice on medicines' safety issues…" to "…expert advice on medicine safety issues…" Added nursing to the list of MARC expertise.
2.5.2	Updated the Medsafe email address.
2.6	"...withdrawal of consent to distribute..." has been changed to "...revocation of consent to distribute..." "conditions may be imposed on the sale or supply..." has been changed to "... the sale of the medicine may be prohibited, or conditions imposed on supply..."
3.2	Clarification added that sponsors are expected to report valid case reports to CARM for medicines that are dispensed or purchased in New Zealand.
3.2.1	Clarification added that reports of cases occurring outside New Zealand do not have to be reported unless the sponsor is aware that the medicine was dispensed or purchased in New Zealand.
3.2.4	Removed capitalisation of "Unsolicited" in the heading. Added "those" to the final sentence of the section: "Stimulated reports, such as *those* following media coverage…"
3.5.3	Replaced "efficacy" with "therapeutic effect" throughout this section. The reason for this is because a lack of efficacy is something that would be determined from a clinical trial, whereas a lack of therapeutic effect is something that may be observed in an individual patient and therefore reported as an adverse event. Removed requirement for reporting a lack of therapeutic effect for medicines used for off-label purposes. Clarification added that only a lack of therapeutic efficacy for medicines that is considered serious should be reported. Example of consequence of a lack of therapeutic effect given for antibiotics and a lack of prophylactic effect given for vaccines.
3.5.6	Added a comma to the heading to distinguish between medicines supplied under section 25 (which can include both approved and unapproved

	medicines), and medicines supplied under section 29 (unapproved medicines). Clarification that ICSRs detailing serious unexpected suspected adverse reactions to medicines supplied under section 25 or 29 should be reported to CARM.
3.5.6.1	New subsection - addition of information about medicinal cannabis products.
3.5.7	Clarification made that if consent to distribute a new medicine is granted while a clinical trial involving the new medicine is still in progress, adverse reactions from that clinical trial should continue to be reported to Medsafe until the trial is over. Clarification made that where a clinical trial involves an approved medicine and an unapproved medicine, adverse reactions to the approved medicine should be reported to CARM, while adverse reactions to the unapproved medicine should be reported to Medsafe.
3.5.8	Clarification made that reporting all valid ICSRS of serious adverse reactions to CARM should occur within 15 calendar days.
3.5.9	Removed references to MERP (Medication Error Reporting Programme). This programme has closed.
3.5.10	Removed references to MERP (Medication Error Reporting Programme). This programme has closed.
3.5.11	Changed “after the event” to “after the suspension or revocation of consent” in relation to the withdrawal of a medicine, to avoid confusion with an adverse event.
3.6	Changed the order of the contact details. Updated the address for online reporting to CARM
3.7	Removed telephone number and fax number for reporting adverse reactions associated with quality defects or falsified medicines to Product Safety. Changed the order of the contact details. Updated the email address for reporting (address to be confirmed with CARM).
3.8	Added “If more information is required about case reports identified using SMARS, contact CARM.” Removed postal address and telephone number. Enquiries on using SMARS should be submitted to Medsafe by email. Updated the email address for enquiries.
4.2.1	Rephrased the final sentence to replace “periodicity of the signal detection activity” with “how often the signal detection activity is undertaken”
4.3	Added a new bullet point: “communication to health professionals”.
4.5	Changed title of this section from Early Warning System to Medsafe safety communications.

	Changed occurrences of Early Warning System in the text to safety communication. This section is revised to provide more information about what sponsors should do when a safety communication about a medicine is published.
4.6	This section has been removed as the Medicines Monitoring programme has been replaced by Medsafe Safety Communications. Some of the information in the previous section 4.6 has been retained and moved into section 4.5 Medsafe safety communications.
5.2	Changed “a lack of efficacy” to “a lack of therapeutic effect”.
5.4	Removed postal address, telephone and fax number. Significant safety issues should be reported to Medsafe by email. Updated the email address for reporting significant safety issues.
6.2	Re-ordered the listing of products for which PBRERs are required. Added instruction for vaccines that are not on the routine National Immunisation Schedule and are funded only for a small group of patients.
6.5	Removed the postal address and updated the email address for submitting PBRERs or RMPs. Added information about using Medsafe’s electronic file transfer system if documents are too big to submit by email.
9	Minor grammatical correction made to the information on Adverse event (AE). Clarification provided that many reports of a similar adverse event associated with a medicine may indicate a potential signal, not an indication of causality.