New Zealand Pharmacovigilance Centre
University of Otago
PO Box 913, Dunedin 9054, New Zealand

4 September 2023

Dear CARM Reporter

Re: Processing of adverse reaction reports received in New Zealand

- **There are some changes happening to the collection of reports of suspected adverse reactions in New Zealand with the completion of a new database**
- **The Centre for Adverse Reactions Monitoring will continue to assess serious reports and enter Medical Warnings**
- **The changes will improve our medicine safety monitoring capacity**

Pharmacovigilance in New Zealand is conducted jointly by the Centre for Adverse Reactions Monitoring (CARM) and Medsafe. CARM is part of the New Zealand Pharmacovigilance Centre within the University of Otago and is contracted to collect and analyse adverse drug reaction (ADR) reports submitted in New Zealand, and to report this information to Medsafe.

The CARM systems and database were established by the University of Otago in 1965. New Zealand was one of ten founding members of the WHO Programme for International drug monitoring.

Medsafe is the medicines regulator in New Zealand, with the responsibility for monitoring the safety of medicines in New Zealand. CARM and Medsafe regularly communicate about possible safety issues and share data and expertise to help in the investigation of these issues.

A database containing details of all ADR reports received in New Zealand is critical to the work that CARM and Medsafe do. An ageing database and advancing technology resulted in CARM and Medsafe working together to develop a new state-of-the-art digital solution. An early version of the new system came online in December 2022, supporting the processing of ADRs for the COVID-19 and Mpox vaccines. With work now complete, CARM and Medsafe are transitioning the collection and storage of adverse reaction reports to the new database and will retire the old system.

The new digital technology also presents the opportunity to transform our joint process and improve the efficiency and overall effectiveness of medicine safety monitoring. To achieve this, CARM and Medsafe are implementing changes to the processing of ADRs. The database and initial processing will be centred in Medsafe, and the CARM experts will focus on the valuable role of medical assessment of non-routine reports.

CARM will continue to respond to those reports they review and advise if an alert has been entered in the national Medical Warning System. Importantly, the reporting of adverse reactions to medicines remains “no fault”.

These technology changes will improve the turnaround time for processing reported ADRs and also mean pharmacovigilance staff at Medsafe and CARM will be able to focus more time on the analysis of reports, contributing to improved signal detection and overall medicine safety monitoring.

CARM and Medsafe are also working to preserve the valuable information contained in the current CARM database. This information includes details of clinical studies conducted and information received from other organisations, along with the details of all ADRs received in New Zealand.

CARM holds the historical data in the old database and shared the data with Medsafe as required. In sharing historical data, CARM has been responsible for privacy and maintaining confidentiality of the patient and reporter.

In November 2012, CARM, Medsafe and the Privacy Commissioner reviewed pharmacovigilance processes and concluded that routine sharing of ADR details between CARM and Medsafe would facilitate the conduct of pharmacovigilance. Routine sharing has been in place since 1 November 2012.

With the retirement of the current CARM system, CARM and Medsafe are advising stakeholders that, subject to your feedback and with supporting advice from the Privacy Commissioner, all historical data pre-November 2012 will then be migrated into the new digital solution.

CARM and Medsafe wish to reassure all stakeholders that, as is the case now, all patient and reporter details will remain confidential. Medsafe maintains confidentiality of data received from other parts of the health sector in accordance with the Privacy Act 2020. CARM and Medsafe have received advice from the Privacy Commissioner as part of this work.

CARM and Medsafe are happy to answer questions, provide more information about this change and receive feedback. Please contact CARM on (03) 479-7247 or Medsafe on (04) 819-6800, or by email to carmreport@health.govt.nz by Friday 29 September 2023.

We would like to take this opportunity to thank you for your assistance in continuing to report your suspicions of adverse reactions to medicines. CARM and Medsafe are confident these changes will increase the effectiveness and efficiency of medicine safety monitoring in New Zealand.

Yours sincerely

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