September 2012

Dear Stakeholder

**Processing adverse reaction reports received in New Zealand**

Pharmacovigilance in New Zealand is conducted jointly by the Centre for Adverse Reactions Monitoring (CARM) and Medsafe. The two organisations work closely together to identify possible safety issues with medicines in a timely manner. CARM is part of the New Zealand Pharmacovigilance Centre and is contracted to collect and analyse adverse drug reaction (ADR) reports submitted in New Zealand, and to provide this information to Medsafe.

Medsafe is the medicines regulator in New Zealand. As part of this responsibility Medsafe monitors the safety of medicines in New Zealand and will take regulatory action when required to improve the safety of medicines in use in New Zealand. CARM and Medsafe regularly communicate about possible safety issues that have been identified and share data and expertise to help in the investigation of these issues. This information includes details of clinical studies conducted, information received from other organisations, and the details of ADR reports received in New Zealand. Sharing of ADR report details between CARM and Medsafe is currently done on an ad hoc basis when potential safety issues are being investigated. In sharing reports for this purpose CARM has ensured that the anonymity of both the patient and reporter were maintained. This has typically involved editing the original report or recapturing the non-identifiable elements of the original report.

When ADR reports are submitted to CARM, medical assessors review the reports and make a determination with regard to whether the medicine may have contributed to the reaction or whether other factors may have contributed to the event. The medical review includes consideration of the medicines involved, the reaction(s) experienced, and other patient details such as current and previous medical history. In many cases, further information is sought in order to improve the accuracy of this assessment.

CARM and Medsafe have been reviewing pharmacovigilance processes and concluded that routine sharing of ADR report details will further facilitate the conduct

of pharmacovigilance and patient safety in New Zealand. This is in keeping with international practice as Pharmacovigilance Centres are usually part of the Regulatory Agency. Therefore as of **1 November 2012** the provision of case details of ADR reports received in New Zealand will move from being shared with Medsafe on an ad hoc basis to one that is routine. Whilst CARM will continue to anonymise reports where possible, usually electronic versions, this may not be possible with all hardcopies.

In the interests of maximum transparency, CARM and Medsafe wish to notify all stakeholders of this change.

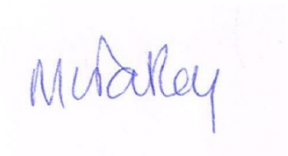
In implementing this change CARM and Medsafe wish to reassure stakeholders that, as is the case now, all patient and reporter details will remain confidential. Prior to notification of this change advice was sought by CARM and Medsafe from the Office of the Privacy Commissioner. It is important to remember that Medsafe is responsible for the regulation of medicines. Medsafe does not regulate medical practice; therefore Medsafe is not concerned with the details of the reporter, only the details of the suspected adverse reaction(s). The reporting of adverse reactions to medicines remains “no-fault”.

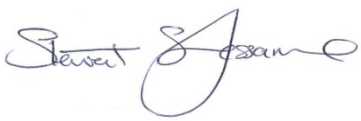
There are no changes to the way in which suspected ADRs should be reported. As is the case now, healthcare professionals, consumers and industry are encouraged to continue to report all suspected adverse drug reactions to CARM in the usual way. Further information about how to report adverse reactions in New Zealand is available on either organisations website.

Questions or points of clarification about this change should be directed to CARM on (03) 479 7247 or Medsafe at (04) 819 6800.

Thank you for your assistance in continuing to report your suspicions of adverse reactions experienced in New Zealand. This change will increase the efficiency in the way CARM and Medsafe work together to monitor and maintain the safety of medicines in New Zealand.

Yours sincerely





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