



# Pharmacy Regulatory Quality Improvement Project

**Version 1.0 (22 November 2021)**

Medicines Control Branch

## Overview

Medsafe is the New Zealand Medicines and Medical Devices Safety Authority, responsible for the regulation of therapeutic products in New Zealand. Medicines Control is the branch of Medsafe responsible for regulating the supply chain of medicines and controlled drugs in New Zealand, including pharmacy practice activities under the Medicines Act 1981.

Te Pou Whakamana Kaimatū o Aotearoa | Pharmacy Council of New Zealand (Council) is responsible for the regulation of pharmacists in New Zealand. The Council is responsible for protecting the health and safety of the public through mechanisms that ensure pharmacists are competent and fit to practise under the Health Practitioners' Competence Assurance Act 2003.

In order to assess compliance with regulatory requirements, and ensure public safety, Medsafe conducts audits of individuals and organisations holding a regulatory instrument (licence), including pharmacy premises.

Medsafe has implemented a risk-based pharmacy quality audit framework, including the establishment of a sector response group. This group contributes to the implementation and support of quality improvement initiatives on behalf of the pharmacy sector, and is comprised of representatives from Medsafe, Council and key stakeholders including DHBs, the Pharmaceutical Society and pharmacy sector agents.

Quarterly trend updates are published to the pharmacy sector for audits conducted in the pharmacy quality audit programme. Recent updates have highlighted the need for significant improvement in the quality of pharmacy services being provided from pharmacies.

These trends have identified a need for Medsafe (the regulator of pharmacy practice) and the Pharmacy Council (the regulator of pharmacist practice) to collaborate on a project to support the sector to identify, develop and implement effective quality improvement initiatives. This contributes to pharmacy services being provided in a safe and appropriate manner to the public.

This document outlines the key Regulatory Quality Improvement Activities contributing to the project, as identified by Medsafe and the Pharmacy Council. It is expected that this document will evolve to include sector quality improvement initiatives.

A successful outcome will be evidenced by an improvement in the reported trends, particularly those relating to significant and serious non-compliances, and the percentage of full attainment in audit findings.

## Regulatory Quality Improvement Activities

The following table outlines the pharmacy regulatory quality improvement activities that Medsafe is actively progressing as part of the pharmacy regulatory quality improvement project.

Activity	Description	Rationale	Lead	Prerequisites (if applicable)	Anticipated completion date	Actual completion date	Status
Pharmacy Licensing	Publication of an extract of the pharmacy licence register on the Medsafe website. The register is published in accordance with the intent of the Medicines Act 1981 (section 55) and will be updated monthly.	<ul style="list-style-type: none"> <li>To enhance access to Medsafe regulatory information relating to pharmacy licences.</li> <li>To increase the visibility of pharmacies that have additional operating conditions imposed on pharmacy licences.</li> </ul>	Medsafe	N/A	December 2021	-	In progress
	Enhancement of the Medicines Control Case Manager platform to support active monitoring of licence holders with additional operating conditions that require reporting to Medsafe.	<ul style="list-style-type: none"> <li>There are an increasing number of licences that have additional operating conditions imposed that require the licence holder to undertake regular reporting to Medsafe.</li> <li>Existing processes were designed to manage small volumes and include maintaining manual records in discrete contact event cases.</li> <li>A semi-automated enhancement in Case Manager will enhance the ability of Medsafe to monitor compliance and directly contribute to the public safety intent of the licensing framework.</li> </ul>	Medsafe	N/A	January 2022	-	In progress
	Develop and publish regulatory guidance on responsible persons specified on a pharmacy licence.	<ul style="list-style-type: none"> <li>To provide clarity of the expectations and requirements of individuals who apply to be listed as responsible persons on a pharmacy licence.</li> </ul>	Medsafe	N/A	April 2022	-	To be commenced
	Develop and implement updated application forms for pharmacy licences.	<ul style="list-style-type: none"> <li>To enhance the awareness and accountability of individuals who are nominated to be responsible persons on a pharmacy licence.</li> </ul>	Medsafe	N/A	April 2022	-	To be commenced

Activity	Description	Rationale	Lead	Prerequisites (if applicable)	Anticipated completion date	Actual completion date	Status
<b>Insights &amp; Intelligence</b>	Implement data analytics to link Medsafe licensing and audit data with registered pharmacists. Factors may include, but are not limited to, pharmacy practice experience, age, training and additional APC conditions.	<ul style="list-style-type: none"> <li>To explore potential risk factors related to the standard of pharmacy practice, with a view to inform improvement in the pharmacy sector.</li> </ul>	Medsafe & Pharmacy Council	<ul style="list-style-type: none"> <li>Access to specific subset of pharmacist registration data held by the Pharmacy Council.</li> <li>Privacy Impact Assessment.</li> </ul>	January 2022	-	In progress
	Implement data analytics to link Medsafe licensing and audit data with other Ministry of Health datasets (for example dispensing volumes and contracted services).	<ul style="list-style-type: none"> <li>To explore potential risk factors related to the standard of pharmacy practice, with a view to inform improvement in the pharmacy sector.</li> </ul>	Medsafe	N/A	January 2022	-	To be commenced
	Implement data analytics to link ACC Notification of Harm reporting relating to pharmacy practice with Medsafe licensing and audit data.	<ul style="list-style-type: none"> <li>To explore potential risk factors related to the standard of pharmacy practice, with a view to inform improvement in the pharmacy sector.</li> <li>To enhance risk profiling of pharmacies within the pharmacy quality audit framework, contributing to the public safety intent of the licensing framework.</li> </ul>	Medsafe	<ul style="list-style-type: none"> <li>Ensure Medsafe is consistently receiving ACC notification of harm reporting.</li> </ul>	November 2021	-	In progress
	Investigate and assess if there is a link between pharmacies engaged in existing quality improvement programmes, such as 'Safety in Practice', and the standard of pharmacy practice.	<ul style="list-style-type: none"> <li>To explore potential risk factors related to the standard of pharmacy practice, with a view to inform improvement in the pharmacy sector.</li> </ul>	Medsafe & Pharmacy Council	<ul style="list-style-type: none"> <li>Engagement with and access to information held by the 'Safety in Practice' project.</li> </ul>	February 2022	-	To be commenced
	Develop a Pharmacists' Quality of Care Measurement Report which canvasses the 1) size and characteristics of pharmacist-related harm and benefits and; 2) how the quality of care provided can be routinely and sustainably measured (e.g. quality metrics).	<ul style="list-style-type: none"> <li>To provide key partners (e.g. DHB Funding &amp; Planning, HQSC, ACC, etc) with key insights by which to inform, prioritise and support more precise patient safety improvement and monitoring across whole-of-system.</li> </ul>	Pharmacy Council	N/A	October 2021	-	In progress

Activity	Description	Rationale	Lead	Prerequisites (if applicable)	Anticipated completion date	Actual completion date	Status
<b>Regulatory Tools to Support Pharmacy Practice</b>	Increase pharmacy and pharmacist access to regulatory resources available in the Medicines Control Online System (MCOLS) by continuing to roll-out MCOLS access to all registered pharmacists.	<ul style="list-style-type: none"> <li>To contribute to pharmacies and pharmacists being able to readily access Medsafe regulatory information relating to pharmacy practice.</li> </ul>	Medsafe	N/A	February 2022	-	To be commenced
	Optimise Pharmacy Council regulatory tools (e.g. standards, qualifications, accreditation, recertification, registration, competency reviews).	<ul style="list-style-type: none"> <li>To support and ensure pharmacists have and can demonstrate clinical governance, quality improvement and other competencies necessary for safe care.</li> </ul>	Pharmacy Council	<ul style="list-style-type: none"> <li>Community Pharmacists' Quality of Care Measurement Report</li> </ul>	August 2022	-	In progress
	Continue to support the development and implementation of electronic controlled drugs registers in pharmacies.	<ul style="list-style-type: none"> <li>To reduce the administration effort within pharmacies to maintain controlled drugs registers.</li> <li>To enhance the accuracy of controlled drugs register records.</li> </ul>	Data & Digital with Medsafe support	N/A	[Ongoing at this time]	-	In progress
	Development and publication of case studies.	<ul style="list-style-type: none"> <li>An educative tool to support pharmacy practice by raising awareness of regulatory process and response to specific non-identifiable scenarios identified in pharmacies.</li> </ul>	Medsafe	N/A	June 2022	-	To be commenced

Activity	Description	Rationale	Lead	Prerequisites (if applicable)	Anticipated completion date	Actual completion date	Status
<b>Sector Engagement</b>	Engagement with Pharmacy Sector Organisations in relation to pharmacy and pharmacist practice.	<ul style="list-style-type: none"> <li>Provide information on the pharmacy regulatory quality improvement project, including pharmacy trend information, to facilitate the sector organisations implementing actions to drive improvement in the pharmacy sector, contributing to public safety.</li> </ul>	Medsafe & Pharmacy Council	N/A	November 2021 (initial engagement)	-	To be commenced
	Engagement with HQSC in relation to pharmacy and pharmacist practice.	<ul style="list-style-type: none"> <li>To identify and better understand the risk factors related to the standard of pharmacy practice, which will be used to drive improvement in the pharmacy sector.</li> </ul>	Medsafe & Pharmacy Council	N/A	February 2022 (initial engagement)	-	To be commenced
	Engagement with HDC in relation to pharmacy and pharmacist practice.	<ul style="list-style-type: none"> <li>To identify and better understand the risk factors related to the standard of pharmacy practice, which will be used to drive improvement in the pharmacy sector.</li> </ul>	Medsafe & Pharmacy Council	N/A	February 2022 (initial engagement)	-	To be commenced