

The Ministry of Health And The Pharmacy Council

Information Sharing Memorandum of Understanding

Purpose

This Memorandum of Understanding documents the commitment between the Parties to work with each other to share information relating to pharmacists, to maximise the ability of each to contribute to ensuring all New Zealanders are able to access safe and appropriate services from pharmacies and pharmacists.

Legal Authority

The Legal Authority for this agreement is established:

- Under the Privacy Act 2020 and Health Information Privacy Code 2020; and
- The Health Practitioners Competence Assurance Act 2003; and
- In alignment with the public safety intent of the regulatory frameworks administered by the Parties, including the Medicines Act 1981 and the Misuse of Drugs Act 1975, and the respective regulations.

Date Valid from:
1 March 2021

THIS MEMORANDUM OF UNDERSTANDING (MOU) is made this 1st day of March 2021.

Between Her Majesty the Queen in Right of Her Government in New Zealand acting by and through the **MINISTRY OF HEALTH**

And **The Pharmacy Council**

1. Purpose of this MOU

1.1 This MOU relates to the sharing of relevant information between the Pharmacy Council and the Medsafe business unit of the Ministry of Health (**MOH**). This MOU documents the commitment between the parties to work with each other to share information relating to pharmacists, to maximise the ability of each to undertake their statutory responsibilities to protect the health and safety of members of the public by:

- ensuring pharmacists are competent and fit to practise their profession;
- ensuring all New Zealanders can access safe and appropriate services from pharmacies and pharmacists.

1.2 The information to be shared is set out in Appendix A and includes:

- regulatory information (for example pharmacist registration and pharmacy licensing information);
- pharmacist and pharmacy practice information (including conduct and competence); and
- health information about identifiable individuals

(together defined as **Information**).

1.3 Information may be shared both formally and informally.

1.4 The purpose of the MOU is to set out the relevant Information and the controls in place to ensure that any Information is shared, used and handled responsibly within the parameters of the legal limitations set out below in Section 3.

1.5 The parties agree that this MOU is not legally binding and does not create legal relations between the parties.

2. Background

2.1 The MOH's role is to improve, promote and protect the health of New Zealanders. The MOH is the Government's principal advisor on health and disability support services policy. Medsafe is the authority responsible for the regulation of therapeutic products in New Zealand through its role in administering most aspects of the Medicines Act, Misuse of Drugs Act and their associated Regulations. Medsafe's mission is to enhance the health of New Zealanders by regulating medicines and medical devices to maximise safety and benefit. Medicines Control, a branch of Medsafe, regulates the supply chain of medicines and controlled drugs, including the licensing framework for the operation of pharmacies.

2.2 The Pharmacy Council is established under the Health Practitioners Competence Assurance Act 2003 (**HPCAA**). The principal purpose of the HPCAA is to protect the health

and safety of members of the public by providing for mechanisms to ensure that health practitioners are competent and fit to practise their professions. The Pharmacy Council has a duty to protect the public and promote good pharmacist practice. Relevant functions of the Pharmacy Council include authorising registration of pharmacists; considering applications for annual practising certificates; reviewing and promoting competence; and ensuring pharmacists are fit to practise their profession.

- 2.3 The Ministry of Health and the Pharmacy Council believe they will be better able to meet their statutory purposes of protecting the health and safety of the public by sharing relevant Information in a timely manner.

3. Legal Framework

- 3.1 The Information may be shared both formally and informally, but always within the parameters of lawful disclosure under the privacy legislation, medicines legislation, and the HPCAA.

- 3.2 To that end, the parties confirm their commitment to working together in a spirit of good will and ensuring that they will each act in a manner consistent and compliant with the legislation governing the parties, including:

- The Health Act 1956;
- The New Zealand Public Health and Disability Act 2000;
- The Health Practitioners Competence Assurance Act 2003;
- The Medicines Act 1981 and Medicines Regulations 1984;
- The Misuse of Drugs Act 1975 and the Misuse of Drugs Regulations 1977;
- The Privacy Act 2020 (**Privacy Act**) and Health Information Privacy Code 2020 (**HIPC**);
- The Official Information Act 1982; and
- Any further relevant legislation.

- 3.3 For the avoidance of doubt, the parties acknowledge the terms of this MOU **do not supersede the Privacy Act 2020 and/or Health Information Privacy Code 2020** or their obligations under the HPCAA or Medicines legislation. In particular:

- Information should be **obtained** from the pharmacist concerned unless one of the exceptions in Information Privacy Principle 2 apply or any other statutory provision applies;
- Information will be **disclosed** to the other party only where the disclosure is lawful under Information Privacy Principle 11 or any other statutory provision.

- 3.4 Further, the parties acknowledge this MOU does not override the following specific statutory limitations on the Information that can be shared or disclosed:

- No information, statement or admission that is disclosed or made by a pharmacist in the course of, or for the purposes of, a competence review, competence programme or recertification programme that relates to the conduct of that pharmacist may be used or disclosed by the Pharmacy Council under this MOU (section 44(4) HPCAA); and

- The Pharmacy Council may provide any determination of a Professional Conduct Committee to Medsafe for the purpose of Medsafe determining whether an applicant for a license to operate a pharmacy is a fit and proper person or of good repute as provided for under section 51(1A)(b) of the Medicines Act.
- 3.5 In accordance with its obligations under the legal framework Medsafe confirms it will act in accordance with the requirements under section 34(1) and section 45(2) of the HPCAA.
- 3.6 Operational guidance is followed to assist the parties in determining whether a statutory limitation applies to any information it proposes to share under this MOU.

4. Purpose and Provision of Information

- 4.1 Relevant Information is being shared between Medsafe, a business unit of the MOH, and the Pharmacy Council under this MOU for the purposes set out in the MOU and to ensure the relevant party has information necessary for it to perform its statutory functions.
- 4.2 The purposes for which this Information will be shared under this MOU are to:
- ensure protection of the public when accessing services from pharmacists and pharmacies, for example through the early identification of potential public safety issues with pharmacists or pharmacies;
 - support maintenance of the pharmacy licensing framework in the Medicines Act 1981, for example in relation to pharmacists who operate pharmacies, and those who conduct pharmacy practice;
 - support the mechanisms to ensure pharmacists are competent and fit to practise their profession;
 - avoid prejudice to the maintenance of the law by Medsafe, including the prevention, detection, investigation, prosecution and punishment of offences.
- 4.3 The parties acknowledge that the collection, use and disclosure of Information under this MOU must come within the authority provided for such collection, use and disclosure under the law and in particular must comply with:
- Information Privacy Principle/Rule two (source of personal information);
 - Information Privacy Principle/Rule three (collection of information from subject);
 - Information Privacy Principle/Rule five (storage and security of information);
 - Information Privacy Principle/Rule ten (limits on use of personal information);
 - Information Privacy Principle/Rule eleven (limits on disclosure of personal information);
 - Section 44 of the HPCAA - Confidentiality of information;
 - Section 51(1A)(b) of the Medicines Act - Licensing authority may take into account determinations of professional conduct committees;
 - Section 83 of the HPCAA - Restriction on use and disclosure of information obtained by Professional Conduct Committees.
- 4.4 The Information that may be shared between MedSafe and the Pharmacy Council is set out

in Appendix A. The parties have resolved that the Information referred to in Appendix A is necessary to meet the purposes for which the Information will be shared.

4.5 The parties recognise the benefits of early intervention, open communication and a collaborative working relationship. The parties therefore acknowledge that Information may be shared both formally and informally, as is required by the circumstances and the particular purpose. Informal disclosure of Information may occur in a number of different circumstances including:

- Meetings between Medsafe and the Council; and
- Telephone discussions.

4.6 Relevant Information may be shared informally during meetings and/or telephone discussions for the purposes of determining the relevant authority to attend to any matter of concern about public safety relating to a pharmacist's competence, conduct or fitness to practise.

5. Disclosure, collection and use of Information

5.1 The parties may **collect** Information other than directly from the individual concerned where the parties reasonably believe that any of the exceptions in Information Privacy Principle 2 of the Privacy Act or Rule 2 of the HIPC applies. In particular:

- it is not reasonably practicable in the circumstances of the particular case to collect the Information from the individual concerned (Information Privacy Principle 2(2)(f) and Rule 2(2)(d)) and/or;
- the Information is publicly available (for example, Information available on the Pharmacy Council's public register) (Information Privacy Principles 2(2)(d) and Rule 2(2)(f)); and/or
- the pharmacist authorises the collection of the Information directly from a party to the MOU (Information Privacy Principle 2(2)(c) and Rule 2(2)(a)); and/or
- collecting the Information from the pharmacist would prejudice the purposes of the collection (Information Privacy Principle 2(2)(b) and Rule 2(2)(c)(ii));
- collection is necessary to avoid prejudice to the maintenance of the law including the prevention, detection, investigation, prosecution and punishment of offences (Information Privacy Principle 2(2)(e)(i), and Rule 2(2)(h)(i)); and

5.2 The parties may **disclose** relevant Information where any of the exceptions in Information Privacy Principle 11 of the Privacy Act or Rule 11 of the HIPC applies, or where a notification made in good faith is provided for under the HPCAA. In particular:

- the disclosure is one of the purposes in connection with which the Information was obtained (Information Privacy Principle 11(1)(a) and Rule 11(1)(c)); and/or
- the Information is publicly available and it would not be unfair or unreasonable to disclose the Information (Information Privacy Principle 11(1)(d) and Rule 11(1)(d)); and/or
- disclosure of the Information is authorised by the pharmacist concerned (Information Privacy Principle 11(1)(c) and Rule 11(1)(b)); and/or
- disclosure is necessary for the maintenance of the law including the prevention,

detection, investigation, prosecution and punishment of offences (Information Privacy Principle 11(1)(e)(i), and Rule 11(2)(j)(i)); and/or

- where the person making the disclosure is a registered health practitioner and makes the disclosure under section 34 of the HPCAA (notification that practice below required standard of competence); and/or
- where the person making the disclosure has reason to believe that the pharmacist is unable to perform the required functions of his or her profession due to a mental or physical condition under section 45 of the HPCAA; and/or
- Where Medsafe has notified the Pharmacy Council of a concern under section 34 of the HPCAA (that a pharmacist may pose a risk of harm by practising below the required standard of competence), Council must inform Medsafe whether it has decided to conduct a review of the competence of the pharmacist (section 36(3A)).

Use of Information

5.3 The Information will be used by the parties to:

- assist the Pharmacy Council in deciding whether to make enquiries into the competence, fitness to practise, or conduct of pharmacists in order to protect the health and safety of the public;
- assist Medsafe in deciding whether any action, or further action is necessary in relation to a pharmacy to ensure the safety of the public.

5.4 The authority upon which the parties rely for the use of Information obtained under this MOU is found in the Privacy Act, HPIC and HPCAA. Specifically, the Party obtaining the Information from the other Party will use the Information for the purpose(s) for which the Information was obtained unless the Party has reasonable grounds to believe that any of the exceptions in Information Privacy Principle 10 or Rule 10 of the HIPC applies. In particular:

- the use of the Information is directly related to the purpose for which the Information was obtained by that party (Information Privacy Principle 10(1)(a) and Rule 10(1)(b)); and/or
- use for another purpose is authorised by the individual concerned (Information Privacy Principle 10(1)(c) and Rule 10(1)(a)(i)); and/or
- the Information is publicly available and it would not be unfair or unreasonable to disclose the Information (Information Privacy Principle 10(1)(d) and Rule 10(1)(c)); and/or
- the use of the Information for a purpose other than the purpose the Information was obtained is necessary for the maintenance of the law (Information Privacy Principle 10(1)(e), Rule 10(1)(f)).

General conditions of disclosure and use

5.5 The Information is being supplied on the conditions:

- that it will only be disclosed to those persons who need to see it to achieve the purpose(s) for which it has been supplied;

- that it will only be used for a purpose set out in this MOU;
 - that, prior to disclosing Information, the disclosing party will take such steps as are reasonable in the circumstances to confirm the Information is accurate, up-to-date, complete and relevant as at the date of disclosure. Future operational Information matching not directly related to the MOU purpose(s), or outside the timeframes authorised by this MOU is prohibited; and
 - it will be managed and maintained so that each party will be able to be fully compliant with any request for access to the Information or correction of the Information by any identified individual for Information about themselves (and agree to promptly transfer the request to the other party within the relevant statutory timeframe where appropriate).
- 5.6 Where the Information is intended to be used in a form which does not identify the individual concerned, the disclosing party will have the opportunity to review the output prior to it being finalised to ensure the likelihood of re-identification is low. Publications of any findings or analysis resulting from this MOU will take into consideration suppression of small values or findings that have the potential to identify any individual.
- 5.7 Both parties will comply with the conditions regarding the Information set out in Appendix A, including Information security.

6. Responsibility for Acts and Omissions of Employees

- 6.1 Each party will be responsible for the acts and omissions of its employees, contractors and agents, and in particular will:
- ensure access to Information is not available to any employee, contractor or agent who is not covered by Appendix A;
 - keep those employees informed of all obligations concerning security and confidentiality of Information including the requirements of the Privacy Act and the Official Information Act 1982;
 - ensure they are adequately trained to perform agreed tasks, and
 - ensure that they comply with all the requirements of this MOU.

7. Costs

- 7.1 Each party will be responsible for their own costs incurred under this MOU.

8. Security and confidentiality

- 8.1 Each party must comply with its obligations under Privacy Act and HIPC, in particular obligations under Information Privacy Principle/Rule 5 (storage and security).
- 8.2 Each party must ensure that the Information (and any product of the use of that Information) is protected from unauthorised access, use and / or disclosure.
- 8.3 *A party must as soon as reasonably practicable notify the other party in writing of any actual*

or suspected unauthorised use or disclosure of any Information supplied by either party pursuant to this MOU. The parties must investigate any actual or suspected unauthorised use or disclosure of Information.

- 8.4 Where it is reasonable to believe that a breach has caused, or is likely to cause, serious harm to an affected individual or individuals, the party concerned **must** comply with its obligations relating to a **notifiable privacy breach** under the Privacy Act 2020, including notifying the Privacy Commissioner as soon as practicable, and notifying the individual or individuals concerned unless an exception set out in section 115 of the Privacy Act 2020 applies.
- 8.5 If either party has reasonable cause to believe that a breach of any security provision in this MOU has occurred or may occur, that party may undertake such investigation as it deems necessary. Where an investigation is undertaken under this clause, the other party will provide the investigating party with reasonable assistance, and the investigating party will keep the other party informed of progress.
- 8.6 If there has been a security breach, either party may suspend the operation of this MOU by notice in writing, to give the other party time to remedy the breach.

9. Dispute Resolution

- 9.1 In the case of any dispute, the parties will attempt in good faith to resolve the dispute through negotiation, and will promptly escalate the dispute to an appropriate level of seniority within each party if necessary.
- 9.2 The parties will continue to fully comply with their obligations under this MOU despite the existence of any dispute.

10. Term

- 10.1 This MOU shall commence when signed by both parties and will remain in force until either terminated by agreement between the parties, or by the planned expiry date, two years from the date of this MOU, whichever occurs first.

11. Termination and Suspension

- 11.1 This MOU may be terminated at any time by one month's notice in writing given by one party to the other.
- 11.2 Where there is a dispute and the dispute resolution procedure above has not produced an outcome satisfactory to both parties, either party may terminate this MOU by giving five days' notice in writing to the other party.

12. Destruction of Information

- 12.1 Information will be securely destroyed by both parties once it is no longer required for the purposes set out in this Memorandum, subject to the requirements of the Public Records Act 2005.

13. Assignment and Sub-Contracting

13.1 Neither party shall assign, transfer, subcontract or otherwise dispose of any benefits, rights, liabilities or obligations under this MOU or any part of this MOU, except has set out in this MOU.

14. Intellectual Property

14.1 Where any intellectual property rights exist in any Information disclosed in accordance with this MOU, the parties acknowledge that the existing intellectual property rights of each party and any third party will be unaffected by this MOU.

15. Variations

15.1 This MOU may only be varied with the agreement of both parties and any such variation shall be set out in writing and signed by both parties.

16. Contact Persons

16.1 The parties designate the following person as their representative for the administration of this MOU, provided that the name and/or contact details listed below can be changed by written notification to the other party, provided that the replacement employee is at an equivalent level to that of any individual being replaced.

For the Ministry of Health	For the Pharmacy Council
<p>Role: Manager, Medicines Control</p> <p>Phone: +64 4 816 2579</p> <p>Email: medicinescontrol@health.govt.nz</p>	<p>Role: Registrar</p> <p>Branch: N/A</p> <p>Phone: +64 4 495 0330</p> <p>Email: enquiries@pharmacycouncil.org.nz</p>

17. Reviews

17.1 The parties Contact Persons will undertake an initial review of this MOU six months from the commencement date, and thereafter on an annual basis. The review will address:

- Whether any additional security safeguards are required, and what they might be; and
- Whether it is appropriate for the MOU to continue.

17.2 This MOU may also be reviewed and amended at any time with the joint written agreement of both parties.

18. Definitions and interpretation

18.1 In this MOU, the following terms have the following meanings:

Term	Meaning
Medicines Act	The sections of the Medicines Act 1981 administered by Medsafe
Misuse of Drugs Act	The sections of the Misuse of Drugs Act 1975 administered by Medsafe
Notifiable Privacy Breach	Under section 116 of the Privacy Act 2020 a notifiable privacy breach is defined as: (a) means a privacy breach that it is reasonable to believe has caused serious harm to an affected individual or individuals or is likely to do so (see section 113 for factors that must be considered by an agency when assessing whether a privacy breach is likely to cause serious harm); but (b) not include a privacy breach if the personal information that is the subject of the breach is held by an agency who is an individual and the information is held solely for the purposes of, or in connection with, the individual's personal or domestic affairs
Health Practitioners Competence Assurance Act	The Health Practitioners Competence Assurance Act 2003
Pharmacy	A physical premises specified on a Licence to Operate Pharmacy, issued by Medsafe
Pharmacist	A health practitioner registered by the Pharmacy Council (including intern pharmacists).

19. Signatures

Signed for and on behalf of
HER MAJESTY THE QUEEN IN RIGHT OF HER GOVERNMENT IN NEW ZEALAND (acting by and through the Ministry of Health)
 by:

 Authorised Signatory

Position Group Manager, Medsafe.....

Date 1 March 2021.....

Signed for and on behalf of
THE PHARMACY COUNCIL by:

 Authorised Signatory

Position: Chief Executive

Date 1 March 2021.....

Appendix A

Description of Information Sharing Process

1. Information and format

1.1. The Information to be supplied by Medsafe:

- Pharmacy Indicator Report which includes information relating to licensed pharmacy premises. The HPI of named pharmacists with effective control is part of this report. An updated version will be provided monthly; and
- Where Medsafe has reason to be concerned about the competence or fitness to practise of a pharmacist, Medsafe may communicate this concern to the Pharmacy Council. The purpose of this communication is to assist Medsafe in determining whether there is a sufficient risk to public safety that a formal notification to the Council is required under ss34 or 45 of the HPCAA.

1.2. The Information to be supplied by the Pharmacy Council:

- An electronic copy of the Pharmacy Council's public register. An updated version will be provided monthly;
- Where either party identifies that there is reason to be concerned that the competence or fitness to practise of a pharmacist may pose a risk of harm to the public, the Pharmacy Council may provide relevant Information to Medsafe. This may include by way of initial discussions, to assist Medsafe make an informed decision about the risk of harm and to undertake their regulatory functions;
- Determinations of professional conduct committees that relate to pharmacists with effective control of a pharmacy (Medicines Act, section 51(1A)(b)); and
- Notification to Medsafe as to whether the Pharmacy Council has decided to conduct a review of the competence of a pharmacist that Medsafe notified to the Council under section 34 of the HPCAA.

1.3. Initial discussions or communications may occur between the parties when there is reason to believe a pharmacist may pose a risk of harm to the public and it is not reasonably practicable to collect the Information from the pharmacist concerned (Information Privacy Principle 2(2)(f)). As an example, this may be because the pharmacist is not contactable, or the Information, or detail of the Information, required is not held by the pharmacist. If neither this exception, nor any other exception in Information Privacy Principle 2 applies, Medsafe should seek the Information directly from the pharmacist concerned, or seek the pharmacist's authorisation to obtain Information directly from the Pharmacy Council.

1.4. Under Information Privacy Principle 11(1)(a), and in accordance with clauses 13, 14 and 15 the Pharmacy Council's Privacy Statement, the Pharmacy Council may provide relevant Information to Medsafe in order for Medsafe to carry out its legislative functions to ensure the health and safety of the public. This includes:

- Information relating to criminal proceedings or an investigation into the pharmacist or an intern pharmacist under the HDC Act or HPCAA, and the pharmacist or intern

pharmacist is registered (or holds a licence) with Medsafe (Privacy Statement clause 13);

- When the Council is taking formal action or formal action is pending against a pharmacist because of competence or fitness to practise concerns, Council may share relevant Information relating to these concerns and actions with Medsafe (Privacy Statement clause 14):
- Where the Information is related to protecting the health and safety of the public and the Information is relevant to Medsafe carrying out its functions of licencing a pharmacist with effective control of a pharmacy (Privacy Statement clause 15).

1.5. In addition to the above, and as set out in this MOU, the parties may, at any time where they have reason to believe the conduct or practise of a pharmacist or pharmacy may pose a risk to public safety, share relevant Information with the other party, where the collection or disclosure of the information is permitted under privacy or official information legislation, or any other statutory authority.

2. Staff involved

2.1. Each party will ensure that all personnel who are working with the Information are aware of and comply with their responsibilities under this MOU including the requirements to protect the Information from unauthorised access, use and / or disclosure.

3. Data security

3.1. Information will be transferred via a secure data platform The Information transferred between the parties will be securely stored within each parties' respective computer network with access limited to the parties' personnel who are approved to work directly with this Information.

3.2. Individual PCs will be secured by standard security for each party respectively, including password and firewall protection and ensuring only the approved users under this MOU are able to access the drives containing the Information.

3.3. Any matched dataset obtained solely as a result of this MOU will be kept and maintained in an environment separate from the recipient's standard operating systems to ensure that the Information in the dataset is only used for the purpose of aggregated analysis as agreed and is not used in any other manner etc.

3.4. Where the parties are sharing information informally (e.g. by telephone, zoom or in meetings) information will be shared using appropriate security safeguards.

3.5. The Data Security Provisions will remain in force notwithstanding the termination of this MOU.

4. Unique Identifiers

4.1. The Pharmacy Council assigns pharmacists unique identifiers for the Health Provider

Index (HPI), the national database administered by the Ministry of Health. The principal purpose of the HPI is to uniquely identify health practitioners and to hold that information in a central, national database. The HPI will be used under this MOU for the purpose of ensuring information used or disclosed under this MOU is correctly linked to the relevant pharmacist to avoid incorrect identification of pharmacists.