Memorandum of Understanding

PARTIES TO THE MEMORANDUM

New Zealand Medicines and Medical Devices Safety Authority (Medsafe)

133 Molesworth Street

Wellington 6011

AND

Pharmac - Te Pātaka Whaioranga

Level 9, 40 Mercer Street

Wellington 6011

Contents

1. Rationale

The New Zealand Medicines and Medical Devices Safety Authority (Medsafe), and Pharmac - Te Pātaka Whaioranga (Pharmac) are both committed to facilitating New Zealanders' access to safe and effective pharmaceuticals.

This Memorandum of Understanding (Memorandum) is intended to formally record how the parties will work together. Medsafe and Pharmac have a long-standing constructive and effective working relationship. The formulation of this Memorandum is motivated by a desire to maintain that constructive relationship and to ensure that the parties continue to work together effectively for the benefit of all New Zealanders.

2. Fundamental principles

The principles that underpin our relationship under this Memorandum are as follows:

- we are committed to a long term, cooperative and collaborative relationship
- we will act towards each other with honesty and in good faith
- we will work in a constructive manner, recognising each other's viewpoints and respecting differences
- we will communicate openly with each other on a regular basis
- we recognise that we are both guided by our respective statutory objectives, but that we have in common a desire to promote positive health outcomes for New Zealanders through access to safe and effective pharmaceuticals and devices.

Notwithstanding our common interests and desire for a cooperative relationship, Medsafe and Pharmac are independent entities, with unique relationships with stakeholders, and different statutory objectives. This Memorandum will not cause any erosion of this independence.

Medsafe and Pharmac acknowledge that each entity receives certain information and makes decisions in confidence, and in certain instances it may not be appropriate to share sensitive or commercial information.

We will endeavour to resolve any disputes or disagreements between us constructively and expeditiously. However, in cases of differing agency functions where differences of opinion cannot be resolved to a single point of view, the agencies will respect each other's opinion and continue to work together in a professional manner to the benefit of New Zealanders.

3. Roles

Medsafe

Medsafe is a business unit of the Ministry of Health (the Ministry). The Ministry leads New Zealand's health and disability system and has overall responsibility for the management and development of

that system. The Ministry's regulatory responsibilities within the health and disability system include administering health legislation and associated regulations, including the Medicines Act 1981 (Medicines Act).

Medsafe administers the Medicines Act and associated legislation on behalf of the Ministry. Medsafe is the authority responsible for the regulation of therapeutic products in New Zealand. Medsafe's responsibilities include:

- to the extent provided for under the Medicines Act, regulating products used for a therapeutic purpose, by ensuring they meet the safety, quality and efficacy requirements of the Act
- in accordance with the Medicines Act, applying a framework of controls, through pre-market approvals and post-market surveillance, designed to ensure that the therapeutic products available in New Zealand are safe and efficacious for New Zealanders
- for avoidance of doubt, the Medicines Act does not provide for pre-market assessment of medical devices. However, provision is made in the Act for Medsafe to take certain actions in relation to the safety of medical devices in the market.

Pharmac - Te Pātaka Whaioranga

Pharmac is a Crown entity whose statutory objective is to secure for eligible people in need of pharmaceuticals, the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided.

Pharmac's core functions are set out in section 69 of the Pae Ora Health Futures Act 2022 (the Pae Ora Act). In carrying out its core functions, Pharmac is guided by the Pae Ora Act health sector principles.

4. Exchange of Information

To give effect to this Memorandum, Medsafe and Pharmac both commit to:

- exchange information about various matters where such information is relevant to the performance of each party's statutory functions, unless that information is subject to restrictions such as confidentiality or privacy considerations (see section 5 below)
- ensure each other is kept informed of matters and developments that are relevant to the other party in a timely manner, to ensure that the parties can coordinate their responses to matters of mutual interest, including those outlined in Schedule One. Schedule One is a list including, but not limited to, examples of interactions between the two agencies
- meet regularly as required, but at least once every quarter of a year, to discuss operational matters of mutual interest.

Key relationship contacts

This section identifies key personnel at each agency who are responsible for implementing the Memorandum and facilitating effective lines of communication between the parties.

Medsafe / Ministry	**Pharmac**

• Manager, Product Regulation Branch, Medsafe • Group Manager, Medsafe	• Manager, Pharmaceutical Funding • Manager, Procurement & Contracts • Director, Pharmaceuticals • Manager, Medical Device Funding • Director, Medical Devices • Chief Executive

It is expected that most communication arising from this Memorandum will be between Managers, with the Group Manager, Medsafe and the Pharmac Directors or Chief Executive being escalation points.

5. Confidentiality and Privacy Considerations

In carrying out the purpose of this Memorandum, the parties to this Memorandum will comply with the law, including provisions of the Privacy Act 2020 and the Official Information Act 1982 (OIA). For the avoidance of doubt, this Memorandum does not require either party to disclose information where such disclosure may:

- be in breach of statutory obligations
- give rise to liability for defamation
- give rise to liability for breach of confidence
- give rise to public disclosure of commercially sensitive information or any other information that would otherwise be refused or withheld under the OIA
- give rise to civil liability for any other reason
- would otherwise be unlawful.

6. Resolving issues

Medsafe and Pharmac agree that issues or disputes that arise between the parties or in connection with this Memorandum will be resolved in the first instance by personnel of each party directly involved with the issue.

If the issue is unable to be resolved in this manner, the matter can be referred for discussion at the next regular operational Medsafe-Pharmac meeting. If the matter is urgent, either party may request an ad-hoc or urgent meeting to address the issue.

Issues can be escalated, as required, to the Group Manager, Medsafe and the Chief Executive, Pharmac.

7. Review and Renewal or Termination

The parties agree to review this Memorandum three-yearly to ensure that this Memorandum remains current and attuned to changing conditions.

The parties further agree that this Memorandum may be terminated at any time by either party giving a notice in writing to terminate this Memorandum to the other party.

8. No Legal Effect

This Memorandum is not intended to create legal relations between the parties and is of no binding legal effect. However, the parties agree to apply their best endeavours to implement this Memorandum in good faith. Where parties share information under this Memorandum they do so as representatives of their respective organisations.

Schedule One: matters of mutual interest

The following is a non-exhaustive list of actions in which the actions of one agency have an impact on the other or in which Medsafe and Pharmac commonly interact.

- Ensure communication and, where necessary, consultation in relation to potential stock shortages resulting from quality issues that may impact supply.
- Provide information when necessary where events may disrupt supply.
- In relation to the progress of applications for consent and/or funding, exchange information and advice where appropriate.
- It is expected that any decision to supply and funding of unapproved (unconsented) medicines is discussed and agreed as the only viable option.
- New funding proposals where the medicine concerned has not yet received regulatory approval will be discussed between the parties prior to public communication or consultation, with best endeavours from each party to reach mutual agreement on the timing of public communications and consultation.
- Collaborate on information provided publicly and that may affect or be of interest to the other party. This to include educational / information material for the industry, health care professionals and the public.
- Provide information and advice about the requirements of the relevant legislation, when requested.
- Collaborate on issues of mutual concern where a consistent approach is necessary.
- Collaborate on public statements where both organisations have an interest to ensure consistency and acceptable timing.
- In relation to medical devices, and in recognition that pre-market assessment is not required, communicate and collaborate on stock and quality issues where appropriate.

Execution

Ministry of Health

Name: Chris James

Title: Group Manager, Medsafe

Date: 06 May 2024

Signature: 

Pharmac - Te Pātaka Whaioranga

Name: Sarah Fitt

Title: Chief Executive

Date: 19 April 2024

Signature: Sarah Fitt