Memorandum of Understanding

PARTIES TO THE MEMORANDUM

New Zealand Medicines and Medical Devices Safety Authority (Medsafe) on behalf of:

Ministry of Health

133 Molesworth Street

Wellington 6011

AND

Pharmaceutical Management Agency (PHARMAC)

Level 9, 40 Mercer Street

Wellington 6011

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1. Rationale

The New Zealand Medicines and Medical Devices Safety Authority (Medsafe), on behalf of the Ministry of Health (the Ministry), and the Pharmaceutical Management Agency (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.

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

The Ministry of Health (the Ministry) / Medsafe

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, a business unit of the Ministry, 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.

Pharmaceutical Management Agency (PHARMAC)

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 does this by:

- maintaining and managing the Pharmaceutical Schedule, which records the PHARMAC determined eligibility and criteria for public funding of pharmaceuticals
- managing DHB spending on pharmaceuticals within a fixed budget.
- managing incidental matters, including in exceptional circumstances providing for funding for pharmaceuticals not available via the Pharmaceutical Schedule.
- managing the funding and supply of all government-funded vaccines.
- promoting the responsible use of pharmaceuticals.

PHARMAC's role is expanding to include managing medical devices used by DHB hospitals. In time, this will mean that PHARMAC will perform the same activities set out above in relation to medical devices.

PHARMAC's objective and functions are set out in the New Zealand Public Health and Disability Act 2000 (NZPHD Act).

4. Exchange of Information

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

- 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 confidentiality or privacy considerations (see section 5 below)
- to 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
- to 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 of Operations • Chief Executive

It is expected that most communication arising from this Memorandum will be between Managers and the Director of Operations, with the Group Manager, Medsafe and the Chief Executive, PHARMAC 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 1993 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 the relevant privacy legislation
- 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 before the end of the first 12 months of this Memorandum. Thereafter, the parties further agree to commit to review the substance of this Memorandum at the end of each three years' term 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.
- In relation to the supply and funding of unapproved (unconsented) medicines, exchange information and advice where appropriate.
- 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 joint public statements 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: 04 June 2020

Signature: 

Pharmaceutical Management Agency (PHARMAC)

Name: Sarah Fitt

Title: Chief Executive

Date: 17 June 2020

Sarah Fitt

Signature: