

DRAFT FOR CONSULTATION



# Operating Policies and Procedures Manual (2026)



## Introduction

Pharmac's Operating Policies and Procedures Manual (the Manual) provides guidance on the way Pharmac carries out its statutory role and functions. It is referenced in all Pharmac's contractual listing agreements with suppliers.

The Manual comprises five sections.

Section one includes:

- Pharmac's objectives and functions
- consultation and engagement
- the strategies Pharmac employs to achieve its statutory objectives
- Pharmac's decision-making framework the Factors for Consideration, and
- the role of expert advice, equity, the handling of information, responsible use initiatives and research.

Section two concerns the [Pharmaceutical Schedule](#) (the Schedule) that records most of Pharmac's listing decisions, and details products available for reimbursement. It also considers how Pharmac might implement decisions outside of the Schedule.

Section three focuses on funding. This includes funding applications, funding criteria, funding exceptions, and the implementation of funding decisions.

Section four concerns commercial processes. This includes contracting, competitive procurement processes, bundling, and rebates.

Section five focuses on how Pharmac reimburses pharmacies and other organisations for the cost of pharmaceuticals used in the health sector. This includes both subsidies and restrictions on reimbursement.

# Section one

## 1 Pharmac

### 1.1 *About Pharmac's Operating Policies and Procedures Manual*

The Operating Policies and Procedures Manual provides a high-level overview of the way Pharmac carries out its statutory role and functions. Further information is detailed in operational policies that are in place, under development, or undergoing review as specified in timeframes contained in the policy.

### 1.2 *Pharmac's objectives and functions*

Pharmac is a Crown entity<sup>1</sup> governed by a Board. The Board is accountable to government policy directed by the Minister of Health or designated Minister. Pharmac's objectives, as set out in the Pae Ora (Healthy Futures) Act 2022 (the Act) are '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'.<sup>2</sup> In this context, pharmaceutical means a medicine, therapeutic medical device, or related product or related thing.<sup>3</sup>

Pharmac's functions include:

- maintaining and managing the Schedule<sup>4</sup>
- managing incidental matters relating to the Schedule, including providing subsidies for pharmaceuticals not on the Schedule in exceptional circumstances<sup>5</sup>
- engaging in research to meet our objective<sup>6</sup>
- promoting responsible use of pharmaceuticals.<sup>7</sup>

Pharmac must carry out its functions within the amount of funding provided, in accordance with its Statement of Intent and any directions given under the Crown Entities Act (2004).<sup>8</sup>

Pharmac makes decisions in accordance with its objective and functions, consistent with its legal obligations. Pharmac works within the New Zealand health system to deliver on its objectives and fulfil its functions.

The Crown Entities Act prescribes processes and conditions for delegation (and sub-delegation) of Board functions and powers. Pharmac's delegations are outlined in the [Delegated Authority Policy](#).

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<sup>1</sup> Section 7 of the Crown Entities Act 2004.

<sup>2</sup> Section 68 of the Pae Ora (Healthy Futures) Act 2022.

<sup>3</sup> Section 4 of the Pae Ora Act.

<sup>4</sup> Section 69 1 A of the Pae Ora Act.

<sup>5</sup> Section 69 1 B of the Pae Ora Act.

<sup>6</sup> Section 69 1 C of the Pae Ora Act.

<sup>7</sup> Section 69 1 D of the Pae Ora Act.

<sup>8</sup> Section 69 2 of the Pae Ora Act.

### **1.3 Consultation and engagement**

Consultation and engagement are central to Pharmac's purpose. Section 70 of the Act states that Pharmac must consult when it considers it appropriate to do so in implementing its objectives and performing its functions.<sup>9</sup> Pharmac's obligation to consult may stem from either a legislative requirement, Te Tiriti o Waitangi commitments, a contractual obligation, or where there is a legitimate expectation of consultation in certain circumstances. In some cases, Pharmac may need to consult for a combination of these reasons.

In addition to our general engagement work, Pharmac will also generally formally consult on specific proposals or transactions before it makes a final decision. Input and engagement may happen at multiple points during the consideration of a funding proposal. There is no set timeframe for consultation.

As with consultations, under its legislation Pharmac must, when it considers appropriate to do so, take measures to inform the public, groups, and individuals of its decisions concerning the Schedule.

### **1.4 Factors for Consideration**

Pharmac uses a decision-making framework, the [Factors for Consideration](#), throughout its whole assessment and decision-making process. It is used for both decisions relating to treatments being listed (or delisted) on the Schedule, and for decisions for individual patients with exceptional clinical circumstances through Pharmac's Exceptional Circumstances Policy.

The Factors for Consideration are used to determine whether a proposal or decision helps Pharmac to achieve its statutory objective of securing best health outcomes within the funding provided.

### **1.5 Pharmac's Commercial Strategies**

Pharmac may adopt a range of strategies to achieve its statutory objectives and in pursuit of its functions. For further clarity, some descriptions of strategy examples are found in section five. In addition to standard commercial practices, including competitive processes, specific strategies adopted by Pharmac may include:

- contracting and contract management
- reference pricing
- parity pricing
- risk sharing
- cross-deal and bundling arrangements; and
- annual tender.

Pharmac is not bound to pursue any particular strategy and may modify or depart from a strategy previously adopted, including not applying the strategy the same way in all situations, or adopting new strategies.

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<sup>9</sup> Section 70 of the Pae Ora Act.

When adopting a new strategy, Pharmac will comply with its public law obligations, and any decision will be consistent with Pharmac's statutory objectives.

### **1.6 Expert Advice**

Pharmac has statutory advisory committees and a range of specialist advisory committees that provide expert advice on many topics.<sup>10</sup> Section 86 of the Act notes that in making appointments to a committee of a Board of an organisation, the Board must endeavour to ensure representation of Māori on the committee.

The Pharmacology and Therapeutics Advisory Committee (PTAC) is the primary advisory committee. It provides objective clinical advice to ensure Pharmac makes the best possible funding decisions. It also provides and promotes critical appraisal of the strength and quality of evidence for funding applications. This is applied rigorously, systematically and consistently across all clinical areas.

Pharmac has 21 further specialist advisory committees (SACs) which provide Pharmac with objective specialist knowledge and expertise within specific clinical areas such as cancer, diabetes and mental health and devices. Pharmac also receives advice from consumers.

Pharmac also works with advisory groups who give targeted advice on specific issues. These advisory groups meet specific needs as and when they arise. This allows Pharmac to move quickly and flexibly to respond to any possible changing landscape. Pharmac is not limited to seeking advice from its statutory advisory committees and may establish any additional means of obtaining advice.

### **1.7 Equity**

Pharmac's [Equity Policy](#) notes its commitment to improving health equity by focusing on those with the greatest health needs. This includes people living with severe conditions, those experiencing multiple co-morbidities, individuals residing in areas of high deprivation, and those facing overlapping forms of disadvantage.

### **1.8 Handling of Information**

As a Crown Entity and a public sector agency, Pharmac endeavours to be transparent in its work and decision-making, in accordance with its obligations under the Official Information Act 1982) and Privacy Act (2020). Transparency is facilitated through proactive releases on Pharmac's website, public consultations, and an enhanced awareness of staff towards embedding a culture of information availability.

Pharmac carefully balances its commitment to transparency with public law duties of protecting confidential, commercially sensitive, or personal information.

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<sup>10</sup> Section 71 of the Pae Ora Act.

### **1.9 Responsible use initiatives**

Pharmac can undertake a range of activities to support its statutory function to promote the responsible use of pharmaceuticals,<sup>11</sup> for example population health activities.

Population health activities are developed in response to evidence-based analysis and identified unmet needs and aim to improve access and promote responsible use of pharmaceuticals.

### **1.10 Research**

Section 69 of the Act notes that one of the functions of Pharmac is to engage as it sees fit, but within its operational budget, in research to meet the objectives.<sup>12</sup>

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<sup>11</sup> Section 69 (1)(d) of the Pae Ora Act.

<sup>12</sup> Section 69 (1)(c) of the Pae Ora Act.

# Section two

## 2 The Pharmaceutical Schedule

### 2.1 *The Schedule records most of Pharmac's listing decisions*

Pharmac maintains and manages the Schedule. This is Pharmac's primary mechanism for recording and implementing national funding, procurement and reimbursement decisions. Pharmac is also responsible for determining access criteria for listed pharmaceuticals. The process for determining access criteria is outlined in Pharmac's [Access Criteria Policy](#).

The Schedule lists the pharmaceuticals (medicines, vaccines, medical devices, and related products) that are publicly funded in New Zealand within Pharmac's scope of responsibility, including pharmaceuticals that are:

- dispensed by a community pharmacy,
- administered in general practice
- provided in a public hospital.

In addition to containing various lists of pharmaceuticals, the Schedule also contains:

- specific restrictions, limitations or requirements for individual pharmaceuticals (outlined further in the following sections)
- general rules, which outline the general parameters for pharmaceuticals that are funded by Pharmac and/or to be used within Health New Zealand hospitals, and provide context and meaning to any specific restrictions, limitations or requirements.

The Schedule can also include multiple categories of pharmaceuticals, each under different stages of management by Pharmac, such as:

- procurement
- procurement and funding
- procurement, funding and reimbursement.

As a result, different sets of Schedule rules may apply to different sections of the Schedule, and the effect of being listed on the Schedule (or not) may also be different. That is, being in the Schedule (or not) means different things to different types of products.

### 2.2 *Pharmac might implement decisions outside of the Schedule*

Although the Schedule is Pharmac's primary mechanism for giving effect to decisions, Pharmac may need to implement decisions in an alternative way. This may include:

- decisions relating to named individuals
- decisions relating to specific pharmaceuticals
- decisions given effect through means other than the payment of subsidy payments.

### **2.3 Amending the Schedule**

Pharmaceutical suppliers, clinicians, consumers, Ministry of Health, Health New Zealand, and any other interested parties may approach Pharmac to suggest possible amendments to the Schedule, using the process described in the relevant funding application guidelines.

Pharmac may amend the Schedule as it considers appropriate, including initiating amendments of its own accord. Possible amendments to the Schedule include (but are not limited to):

1. listing new pharmaceuticals
2. changing the terms on which a pharmaceutical is listed including:
  - a. changing guidelines or access criteria on prescribing and dispensing
  - b. changing the subsidy levels of pharmaceuticals as a result of Pharmac adopting one of the strategies set out in section 1.5 or by any other means
  - c. delisting pharmaceuticals or delisting part or all of a therapeutic group or sub-group
  - d. changing packaging sizes and brand names
  - e. changing the indications, formulations, presentations, or any other feature of a listed pharmaceutical.
3. amending the basis on which pharmaceuticals are classified into therapeutic groups and sub-groups
4. publishing of information or requirements relating to the implementation of contracts for supply to public hospitals or Health New Zealand.

# Section three

## 3 Funding

Pharmac makes decisions about which pharmaceuticals will be publicly funded in New Zealand, being decisions about both:

- which pharmaceuticals will be funded, and
- the circumstances under which those pharmaceuticals will be funded.

This includes decisions made both on a population level and those for named individuals. All decisions are supported by relevant application and evaluation, and decision-making processes.

Pharmac does fund some medical devices in community setting however the funding arrangement for hospital medical devices is outlined in section 3.5 below.

### 3.1 Funding applications

It is possible for anyone to make a funding application, however most applications come from pharmaceutical suppliers. The [Guidelines for funding applications to Pharmac](#) provide information on how to submit a funding application to Pharmac for proposed amendments to the Pharmaceutical Schedule.

Work on each funding application falls into three broad assessment areas: health need, health benefit, costs and savings and suitability.

Pharmac's health economists assess new funding proposals and run the [prioritisation process](#) where Pharmac ranks its current funding options and develop and maintain tools for managing and assessing the proposals.

Pharmac's Health Technology Assessments (HTA) inform funding choices. HTAs support a decision rather than estimate the exact value of everything. The focus is on incremental gains and costs, and on showing whether a proposal is cost-effective and good value for money. As prioritisation ranks proposals in order, analysis needs to focus on relative value for money.

### 3.2 Funding criteria

Pharmac may consider it appropriate to apply criteria or other restrictions to the funding of a pharmaceutical. This helps to ensure that funding can be targeted and enables Pharmac to maximise the benefits of its available funding. This may include:

- limiting funding to specific indications and/or clinical circumstances
- requiring the recommendation of a particular prescriber type, and/or
- limiting the amount of a pharmaceutical that is funded for an individual.

The most common form this takes is targeting funding through the use of tools that relate to particular indications or clinical circumstances, including:

- disease or condition targeted
- staging or severity of disease, or
- a requirement to have tried other treatments.

Pharmac may implement such targeting in different ways, as it considers appropriate for the situation. The most common form is a Special Authority restriction, which requires prescribers to certify that a patient meets the specific criteria outlined in the Schedule before the patient could receive funding for that pharmaceutical.

### **3.3 Funding exceptions**

#### *Exemptions*

Pharmac may provide for situations where a broad exemption is provided for other pharmaceuticals to be funded, beyond the funding decisions recorded in the Schedule. In these situations, we may allow for individual clinicians or Health New Zealand hospitals to make decisions about whether a treatment should be funded for a patient.

The Exceptional Circumstances Framework does not limit Pharmac's ability to consider any application for funding treatments outside of the Named Patient Pharmaceutical Assessment (NPPA) Policy or any other exceptional circumstances processes, at its discretion.

#### *Exceptional circumstances*

Pharmac's role includes considering whether to fund pharmaceutical treatments for people in exceptional circumstances when those treatments are not currently available for them on the Schedule. The [Exceptional Circumstances Framework](#) outlines the ways Pharmac generally considers these funding decisions including funding for individual cases through waivers and NPPA.

Waivers are used in cases where an individual falls outside of the restrictions of a Special Authority (or analogous restriction in a hospital setting) but fall within the intended population so should be able to access treatment. In such cases Pharmac can waive the restriction for these individuals.

In cases where a person's situation falls outside funding criteria or where Pharmac does not fund the treatment at all, the case may be considered under the NPPA policy. The policy has three core principles:

- it provides a pathway to consider those whose clinical circumstances cannot be met through the Pharmaceutical Schedule at a given point in time
- it complements the Pharmaceutical Schedule and the Schedule decision-making process
- it is designed for individual assessment.

Like all funding applications NPPA applications are evaluated against the Factors for Consideration. However, prior to this a determination is made by first evaluating the application against the principles of the NPPA policy.

### **3.4 *Implementing funding decisions***

Pharmac manages the implementation of its funding decisions. Pharmac determines an appropriate approach to implementing each funding decision it makes. Pharmac liaises with others in the sector with similar responsibilities for implementation (for example, the Ministry of Health in respect to changes to the National Immunisation Schedule). This can include support for consumers, Health New Zealand, prescribers, pharmacists and other clinicians, and consideration of distribution and funding arrangements.

### **3.5 *Hospital medical devices***

Pharmac and Health New Zealand are working together to strengthen a more coordinated, transparent, and value-driven national approach to hospital medical device evaluation and procurement.

In September 2025, the Government announced changes to how hospital medical devices are procured. Under this joint approach, Pharmac and Health New Zealand share responsibility, with each organisation focusing on the areas that best align with its expertise and capabilities.

Hospital medical devices are not funded by Pharmac. Health New Zealand is the funding authority for hospital medical devices, with decisions informed by agreed priorities and evidence-based advice from Pharmac.

# Section four

## 4 Commercial processes

Pharmac also undertakes commercial processes for pharmaceuticals, either to augment its funding decisions, or as a standalone function to cover off individual commercial arrangements that do not augment funding decisions as such. For example, the annual tender, distribution, and storage activities. Most pharmaceuticals listed on the Schedule are supported by a supply agreement between Pharmac and the relevant pharmaceutical supplier, following a procurement process.

In general, securing commercial terms acceptable to Pharmac is necessary to support a funding decision.

### 4.1 Contracting

Pharmac has standard terms of listing for pharmaceuticals, for example the [medicines standard terms and conditions](#).

A listing agreement details the terms of listing of a pharmaceutical on the Schedule, including an agreed price. Listing agreements may also include special terms for certain pharmaceuticals, including, but not limited to, rebate arrangements, agreed access criteria, protection against delisting or subsidy reduction, minimum shelf life, decommissioning and disposal, service and maintenance services. Any special terms in an agreement depend on the commercial arrangement Pharmac negotiates with the supplier.

Contracts may be for a single pharmaceutical or may include multiple pharmaceuticals from the supplier's portfolio, in order to seek best health outcomes from within the funding provided.

### 4.2 Competitive procurement

Pharmac occasionally undertakes competitive procurement processes for the supply of funded pharmaceuticals, subject to the Government Procurement Rules.

Pharmac will consider the procurement outcome to best meet its needs for the relevant pharmaceutical(s), which can:

- result in a single principal supplier or multiple suppliers being awarded contracts (subject to procurement exceptions as described below)
- be for an existing market or a currently unfunded pharmaceutical
- relate to a single pharmaceutical or a class of pharmaceuticals; or
- vary in any other way that Pharmac considers necessary.

Pharmac issues an annual Invitation to Tender for the supply of funded pharmaceuticals to community pharmacies and Health New Zealand hospitals.

### **4.3 Procurement exceptions**

Pharmac's competitive procurement processes can result in a single principal supplier of a funded pharmaceutical (or class of pharmaceuticals) or, two or more preferred suppliers.

Pharmac can permit alternative pharmaceuticals to be funded to ensure that the needs of all patients are able to be met. Suppliers are not guaranteed exclusivity, but the certainty of a particular level of market share (either individually or collectively). Pharmac might choose to implement this funding through:

- the listing of an alternative pharmaceutical on the Schedule
- approving an alternative pharmaceutical for named individuals; or
- by permitting a general discretion through the Schedule rules.

### **4.4 Rebates and other pricing arrangements**

Pharmac and pharmaceutical suppliers can agree on the use of rebates as part of a supply agreement. Rebates are payments from pharmaceutical suppliers to Pharmac that reduce the overall expenditure incurred in funding a pharmaceutical.

Rebates can be used for a variety of purposes, including:

- enabling the net price paid by Pharmac to be kept confidential
- allowing Pharmac to secure a net price lower than in other markets
- to manage Pharmac's risk around total expenditure for a pharmaceutical.

Rebate arrangements can take a range of forms, but are typically structured to either:

- reduce the net price per unit paid by Pharmac – for example, a percentage rebate for all units subsidised by Pharmac, or
- limit the overall expenditure incurred by Pharmac – for example, a percentage rebate for all expenditure over a certain threshold.

Pharmac can also agree to other alternative expenditure management arrangements with pharmaceutical suppliers, including discounts and two-part or tiered pricing arrangements.

# Section five

## 5 Reimbursement

Through the Schedule and other means, Pharmac reimburses pharmacies and other organisations for the cost of pharmaceuticals used in the health sector (excluding devices).

### 5.1 Reimbursement arrangements

Most reimbursement by Pharmac occurs through the payment of pharmaceutical subsidies. The Schedule records the subsidy payable by Pharmac for a pharmaceutical, providing that all other Schedule rules and restrictions are met, and claimants submit reimbursement claims through to Pharmac's payment agent for processing.

Pharmac can choose to reimburse pharmacies or other claimants directly, rather than through the regular subsidy claiming process. In other cases, Pharmac can purchase pharmaceutical stock from a pharmaceutical supplier or other distributor.

#### 5.1.1 Pharmaceutical subsidies

In most cases, the subsidy in the Schedule will reflect the price at which the pharmaceutical is sold by the pharmaceutical supplier (the ex-manufacturer cost). However, Pharmac can also set a subsidy that is lower than the ex-manufacturer cost, meaning that the pharmaceutical is partially subsidised and therefore carries a surcharge.

Pharmac can also choose to implement other subsidy arrangements, including having no fixed subsidy for a pharmaceutical, with claimants reimbursed according to their purchase price.

#### *Reference pricing*

Pharmac sometimes classifies pharmaceuticals into different therapeutic sub-groups. A therapeutic sub-group is a set of pharmaceuticals that, in Pharmac's opinion, produce the same or similar therapeutic effect in treating the same or similar condition or conditions.

Pharmac can use reference pricing to set pharmaceutical subsidies. Where reference pricing is applied, all pharmaceuticals within a therapeutic sub-group are subsidised at the level of the lowest-priced pharmaceutical in that sub-group.

#### *Parity pricing*

Pharmac can use parity pricing to set pharmaceutical subsidies. Parity pricing involves reducing the subsidy for a pharmaceutical in a particular therapeutic sub-group to the level of a subsidy for a pharmaceutical in any other sub-group.

## **5.2 Restrictions on reimbursement**

Pharmac might limit how and where pharmaceuticals are reimbursed, including:

- whether a pharmaceutical is reimbursed for supply through Health New Zealand hospitals, community pharmacies, general practice or other service types
- whether a subsidy must be pursuant to a prescription and/or through other means, such as supply order
- the manner in which a prescription can be filled across one or more dispensings, and
- whether payment of subsidies is contingent on particular processes being followed, or required information being provided.

## **5.3 Reimbursement exceptions**

Pharmac can exercise its discretion to waive or modify any of the requirements in this section for an individual dispensing, for a patient or in any other way, which may include:

- paying a subsidy or total payment above that prescribed by the Schedule
- paying a claim for a dispensing either made or submitted outside of the prescribed timelines
- making a reimbursement payment in a different manner, or
- allowing a funded dispensing to occur in a different setting.

## **Review period**

Pharmac will review this document once Pharmac's medical devices work programme is further developed to ensure alignment. Following that Pharmac will review this document three-yearly.