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# Supplier Onboarding

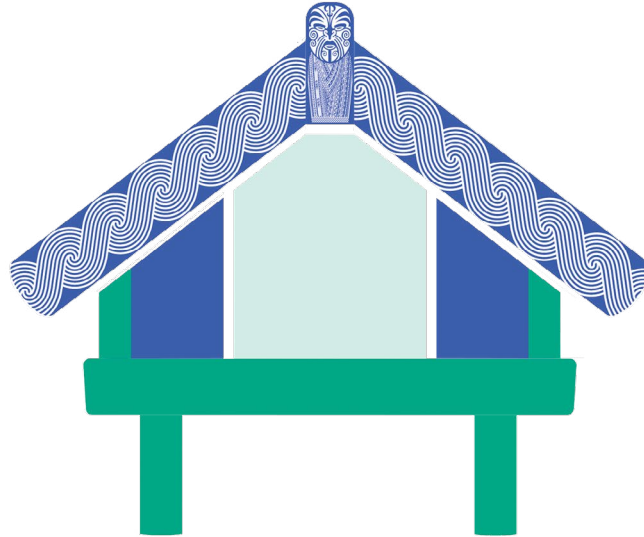
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PHARMAC  
TE PĀTAKA WHAIORANGA

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### **Te pātaka (The storehouse)**

Haere mai, uru mai ki Te Pātaka Whaioranga. Welcome to Pharmac.

Te Pātaka Whaioranga, 'the storehouse of wellbeing', sums up the part we play in managing and safeguarding something that is valuable to all New Zealanders – the pursuit of wellbeing. For us at Pharmac the concept of the pātaka symbolises a solid and reliable structure safeguarding the continuous flow of supplies – such as medicines and medical devices – and it is our role to keep the flow constant and maintain availability for the benefit of all New Zealanders.

## Letter from Chief Executive

This booklet outlines who we are, how we work and the values we embrace. As a new supplier of medicines or medical devices to New Zealand, we want to engage with you in a collaborative relationship. Many suppliers may be more familiar with other funding models – I would encourage you to familiarise yourselves with Pharmac, our values and our processes. The information provided in this booklet will guide you through our processes and help you to get the most out of our ongoing relationship.

The relationship Pharmac builds with suppliers is a key component for our success in ensuring the best health outcomes for New Zealand. Our primary purpose at Pharmac is to achieve the best possible health outcomes from New Zealand's investment in medicines and medical devices, and we anticipate this strongly aligns with what you as a supplier wish to achieve as well. While our agreements set out contractual obligations for both parties, I wish to reiterate that we want to work collaboratively with you to build a successful and productive relationship.

Pharmac has established five core values that ground our behaviour and guide our thinking, helping us make decisions that create better health outcomes for New Zealanders. We also consider our commitment to Te Tiriti o Waitangi in all of our decision making and encourage our suppliers to familiarise themselves with the principles set out in this document to better understand the special relationship that exists between the Crown and Māori.

Pharmac's work is more important now than ever in a post COVID-19 world, as we work to ensure uninterrupted access to funded medicines and medical devices for New Zealanders. We played a key role in responding to this global pandemic, and our success is reliant on a cohesive relationship with suppliers.

I would like to thank you for engaging with us to supply these vital medicines and medical devices to New Zealand. We value our partnerships with suppliers and want to ensure you are getting the most out of your arrangement.

We would like to see you add value to our organisation and encourage you to engage with your Contract Manager to have an open line of communication – this is the best way you can provide input for how we can improve our own processes, as well as advising of potential supply issues you may be facing. Our Contract Managers are facilitators – analytical, responsive risk managers with access to clinical advice, and can be of great help to you as a supplier.

Once more, thank you for joining us in our ongoing efforts to provide the best possible health outcomes for New Zealanders.

Ngā mihi nui



**Sarah Fitt**  
Chief Executive  
Te Pātaka Whaioranga – Pharmac

## Introduction to Pharmac

### What is Pharmac?

Pharmac is a Crown Entity that makes decisions on which medicines, vaccines and related products, and medical devices are publicly funded to get the best health outcomes within the available funding. This includes:

- Receiving funding applications for new medicines and eligibility criteria
- Contracting medical devices used by public hospitals
- Seeking clinical advice
- Applying health economics
- Following procurement guidelines
- Managing the Pharmaceutical Schedule (including maintaining the Schedule of medical devices, which Health New Zealand | Te Whatu Ora hospitals can purchase under the agreed terms and conditions).

We do not make, buy, or sell medicines or medical devices, nor do we manage their distribution (although we do buy vaccines and manage their distribution as part of the National Immunisation Schedule).

### We don't make a profit.

We manage a budget set by the Government in collaboration with Health New Zealand and we invest all of it on making sure New Zealanders can access medicines.

Our priority is improving health outcomes for all New Zealanders. An important part of this is ensuring New Zealanders can equitably access suitable medicines and medical devices.

Medsafe is the regulator responsible for assessing the safety and efficacy of medicines. **Medsafe operates independently of Pharmac.** You can find information on Pharmac's relationship with Medsafe in our recently updated [Memorandum of Understanding](#).

## How does the New Zealand market work?

Pharmac manages the Pharmaceutical Schedule. This schedule is split into three sections:

- Medicines
- Vaccines and related products, and;
- Hospital medical devices

The Pharmaceutical Schedule also lists (where applicable):

- Eligibility criteria for patients, and;
- Funding rules related to dispensing of that pharmaceutical

The [Pharmaceutical Schedule](#) is separated into sections that relate to medicines, special foods, vaccines, extraneously compound products, and devices.

The majority of products listed are supplied and/or funded under the terms of agreements with suppliers. Many of these agreements have come about as a result of competitive processes that follow [National Procurement Rules](#). This includes our annual multi-product Tender and Requests for Proposals (RFP).

Pharmaceuticals (medicines, vaccines and vaccine-related products) that are successful in these bids are often awarded a period of market exclusivity. Medicines that are funded outside of a competitive process, such as those under patent, are subject to agreements directly negotiated between Pharmac and suppliers.

Market exclusivity means that there is only one brand funded by Pharmac and the supplier is responsible for ensuring supply for the entire market for that medicine or vaccine with their brand. This approach may differ to other markets, such as Australia, where frequently there are multiple brands funded. Pharmac uses defined terms such as Principal Supply Status, Sole Supply, and Hospital Supply Status in agreements to describe these arrangements.

Market exclusivity means that suppliers benefit from being the only brand funded, and can plan accordingly, including stock levels and lead times, without the challenges of managing market-share.

A direct contract, rebate scheme or market share arrangement exists between Pharmac and a supplier to provide medical devices at an agreed price to Health New Zealand hospitals.

These arrangements can be very beneficial for suppliers but still contain the obligations that all our Contractual Agreements employ, such as the need to inform Pharmac if there is likely to be an issue with supply.

## What is the Pharmaceutical Schedule?

The Pharmaceutical Schedule is a list of all the medicines and therapeutic products that Pharmac has approved for funding. The Schedule lists more than 4,500 medicines that are dispensed in the community or contracted to be given in public hospitals at specified prices, and a growing list of approximately 200,000 hospital medical devices that may be ordered at a specified price.

In the Schedule you'll find:

- The list of funded medicines in the community
- The list of funded medicines that can be used in public hospitals
- The rules for dispensing or giving medicines
- The price and subsidy (the amount that it is funded) for each medicine
- Any rules or limits on access to funding for specific medicines or groups of medicines
- The list of Health New Zealand hospital devices with national contracts.

More information on the [Pharmaceutical Schedule](#) and our guide to use.

## Official Information Act

As a Crown Entity and part of New Zealand's Public Sector, Pharmac is subject to the Official Information Act 1982 (OIA). Under that Act, members of the public may write to Pharmac to get access to official information. While there are some grounds to withhold information, the general rule is that official information held by Pharmac is subject to the principles of availability and transparency.

For suppliers, this means that –

- information provided by suppliers to Pharmac becomes official information and must be dealt with under the OIA. Pharmac's duty to act lawfully will supersede other duties Pharmac may owe to the supplier.
- Suppliers may request official information held by Pharmac, just like any other member of the public.

Where Pharmac is asked to disclose information which was provided by a supplier (or may otherwise affect suppliers), Pharmac may ask the relevant supplier for feedback before deciding how to respond to the request. Even where lawful grounds to withhold information are available, Pharmac will still consider whether it is in the public interest to make that information available.

Pharmac's decisions on information requests under the OIA are subject to a right to make a complaint to the Office of the Ombudsman.

[Pharmac's OIA team](#) will be available to assist and provide guidance on related questions. Suppliers are also welcome to raise any OIA questions with their contract managers or TGMs.

## Our Values



Our values ground our behaviour and guide our thinking. They help us make decisions that create better health outcomes for New Zealanders.

It is important for our suppliers to learn and understand these values, as these make up Pharmac's identity as an organisation and forms the basis for how we engage with our partners within the health sector in New Zealand and abroad.

### Our values and how they relate to our organisation.

#### **Te Tiriti o Waitangi**

The text of Te Tiriti o Waitangi is the enduring foundation of the Crown's commitment to Māori, and as citizens of New Zealand we endeavour to respect the principles that Te Tiriti represents.

At Pharmac, this outlines our continuing pursuit of excellence in addressing the best health outcomes possible for Māori and as a supplier we expect and encourage cooperation as we look to improve the lives of Māori as well as other groups experiencing health inequality.

During our ongoing supply partnership, if you, as a supplier, identify inequity in New Zealand, we would strongly encourage you to reach out to your Contract Manager to advise whether you could provide value in this area.

Pharmac acknowledges the special relationship that exists between the Crown and Māori. We uphold the articles of Te Tiriti, advancing Māori health and aspirations: Tino Rangatiratanga, Partnership, Active Protection, Options, and Equity. In the context of supply chain and pharmaceutical supply, this includes:

- Working with whānau, hapū, iwi and Māori communities when developing responses to supply issues with significant impact on these groups.
- Ensuring Māori enjoy the same access to medicines as non-Māori and that changes acknowledge and safeguard Māori cultural concepts and values.
- Encouraging Māori participation in problem solving, especially when issues significantly impact whānau, hapū, iwi and Māori communities.

Read [Te Whaioranga](#) for more information.



## How do we work with medicines and medical device suppliers?

We work with pharmaceutical companies to secure medicines for New Zealanders. Our scope has expanded to also include negotiating contracts for hospital medical devices:

- Pharmac manages a fixed budget set by the Government and decides which pharmaceuticals will be funded. We also oversee national contracts for hospital medical devices.
- We must make difficult decisions about which pharmaceuticals we will fund – there will always be more pharmaceuticals we want to fund than we can afford. Our decisions are informed by evidence, our Factors for Consideration, internationally recognised assessment methods and expert advice.
- We also use commercial tools (such as competitive procurement) to get as much value from the budget as possible so that we can fund more products for more New Zealanders. We do not make, buy, or sell pharmaceuticals. We don't make a profit. We are given a budget by the Government, and we invest all of it on making sure New Zealanders can access treatments.
- Pharmac negotiates contracts with suppliers to provide hospital medical devices and related products for Health New Zealand hospitals. They include a range of options to support local requirements, such as how equipment is managed and maintained. They include terms and conditions to support the ongoing use of hospital medical devices.
- Once terms are finalised, the hospital medical devices are then added to the Hospital Medical Devices List.
- *Caveat: In future, hospital medical devices will need to be listed in the Hospital Medical Devices List for Health New Zealand to be able to use them. Medical devices don't need to be contracted to be added to the Hospital Medical Devices List. Over time, anything of significant value (financial or clinical) will be contracted.*
- Currently, both Pharmac and Health New Zealand manage contracts for hospital medical devices. Health New Zealand holds and manages national contracts for hospital medical devices that Pharmac has not yet contracted.
- Pharmac's hospital medical device contracts supersede all national, regional, and local Health New Zealand contracts for the same hospital medical device (with the same supplier). The contract terms and conditions include the responsibilities of Health New Zealand, suppliers, and Pharmac.

Most hospital medical devices, used by Health New Zealand hospitals, will be under Pharmac contracts in 2025.

## **How do we work with Health New Zealand?**

Health New Zealand holds the funding to deliver most publicly financed health services, including public hospitals and the medical devices they use.

We work closely with clinicians and procurement staff when making decisions about hospital medical devices.

## **How do we work with Medsafe?**

Medsafe decides which medicines, related products, and medical devices are safe and effective for New Zealanders to use. They check that these products meet standards of quality, safety, and efficacy.

We can consider a medicine or related product for funding before approval by Medsafe.

## **We are establishing national contracts for medical devices.**

In most cases, we agree on a supply contract with the company to ensure they continue to supply the contracted medicines or medical devices. These arrangements are generally 'ever-green', which means there is no specified end date for supply.

Every medicine and medical device supplier with an active agreement is assigned a Contract Manager. Contract Managers are generally contactable via phone or email, however in some instances written notification is required (such as when you experience, or may experience, a supply issue).

## The Pharmac / Supplier Relationship

At Pharmac we consider the professional relationship with our suppliers to be a “two-way street”. Here are the key things to keep in mind after you’ve entered into an Agreement for supply with Pharmac:

### **Ensure you’re aware of the terms of your contract**

Please read through the agreement and become familiar with the Terms of the Agreement. If you have any questions, please contact your Contract Manager. Generally, agreements include separate sections for the standard terms and for the terms specific to the Agreement.

### **Continuity of supply is our priority**

We understand that sometimes supply issues happen. It is important however that we’re advised as soon as possible. This allows us to help you resolve the issue and develop plans to reduce the impact on patients.

Supplier performance in responding to supply issues, including timely communications and working to a resolution that mitigates the impact on patients, may be a factor that Pharmac considers as part of its procurement process for future Agreements.

### **Contract Managers should be your first point of contact for product changes**

Pharmac is responsible for making decisions on what is listed in the Pharmaceutical Schedule, therefore we need to be made aware of any changes to the listed products. Chances are that patients, pharmacists, distribution chains, hospital staff or any number of interested parties will reach out to us with questions – it’s helpful for everyone if we’re given a heads-up first.

### **Before you first list a pharmaceutical on the Pharmaceutical Schedule**

Pharmaceuticals are listed on the Pharmaceutical Schedule with unique identifiers for brands, presentations, and pack sizes. The Pharmaceutical Schedule uses Pharmacodes and NZMT CTPP codes. You are required to apply for both a Pharmacode and NZMT CTPP codes for all of your products.

Pharmacodes are issued by the [Pharmacy Guild of New Zealand \(PGNZ\)](#). There is a fee applied for each Pharmacode by PGNZ. At least one month before your listing due please do the following:

- Set up an account with PGNZ (so you can apply for Pharmacodes)
- Apply for a Pharmacode for each of the products and pack sizes you have a listing Agreement for. PGNZ will provide you with

NZMT CTPP codes are issued by New Zealand Universal List of Medicines ([NZULM](#)). These codes are free.

As soon as you have both codes for each brand/presentation/pack, complete and submit a [Notification of Product Change \(NOPC\)](#) form. More information on the [NOPC process and timings](#).

In order to list a hospital medical device on the Pharmaceutical Schedule, you will need to provide a supplier code unique for each device and where available, a GTIN code. We use GTIN codes as part of our partnership with Health New Zealand's Health System Catalogue (HSC) team and GS1. We encourage you to provide information to the HSC and in the future, GTIN codes will be required to list medical devices on the Pharmaceutical Schedule.

### **Notify us with significant product changes and changes to regulatory status.**

Depending on what the change is, we may need to seek advice from industry experts on the impact. It's important that we're given enough notice to do this and consider whether additional communications are required.

If regulatory activity may impact supply continuity, please let us know. While we expect you to maintain marketing approvals (and with medical device contracts it is an obligation to do so), we may seek feedback from Medsafe on pathways that mitigate patient impact. Note again that we operate independently of Medsafe and engage with them on an advisory basis only.

### **Keep agreements and the Schedule up to date.**

We will action any necessary amendments to our Agreement and align the Pharmaceutical Schedule with the changes (such as list new Pharmacodes for medicines and product codes for devices). It's important that the Schedule reflects the codes of the available product. The market cannot access funding for any medicine which does not have a Pharmacode listed.

## **Communicate any discontinuations of supply - immediately.**

Medicine and Medical Device continuity for patients is critical. We understand that events happen which need to be managed - including discontinuations. We would expect that the notice period (lead-time) would be sufficient to enable alternative products (clinical suitability) for the ongoing supply be arranged so that patients can continue receiving treatment without interruption.

A discontinuation of a Pharmaceutical or Medical Device needs to be carefully managed and significant time must be dedicated to factors including:

- For medicines, enabling patients to be able to safely transfer to alternative treatments.
- For medical devices, enabling training and clinical assessments that may be needed to transition products.

## **Keep us informed when transferring the supply of a medicine or medical device from one supplier to another.**

Get in touch with us. The rights and obligation of supply sit with the contracted party; however, we understand that changes at a global level, changes to licences for distribution, or other factors, mean that transferring an Agreement from one supplier to another may be required. Pharmac reserves its rights in this regard; however, we have a process in place to help manage this with you.

## **Pay rebates on time**

If your agreement includes rebate provisions, then please get familiar with these. If you have any questions, please contact your Contract Manager. Invoicing, data receipt and credit control is managed by Pharmac's Finance team in collaboration with Contract Managers. Medical device rebates are paid directly to the hospitals.

## **Report to us - Both regularly and as needed**

Our Agreements outline when you need to notify or report to us. Examples include:

- If stockholdings go below a certain level
- Sales data, including for rebates

Additionally, medical device Agreements have quarterly reporting requirements including sales data and KPI.

## How to work with us

### Procurement

Procurement processes are released by our procurement team on the New Zealand Government Electronic Tenders Service (GETS) via a Future Procurement Opportunity (FPO).

You can sign up to receive notifications for processes you are interested in. Pharmac's processes are searchable under "Pharmaceutical Management Agency".

### Contract Management

Every medicine and medical device supplier with an active agreement is assigned a Contract Manager. If you supply both medicines and devices you may have a Contract Manager for each category.

Contract Managers are generally contactable via phone or email, however in some instances written notification is required (such as when you're expecting a supply issue).

There is also opportunity for suppliers to meet with Contract Managers online or over a phone call at more regular intervals. This encourages open communication between Pharmac and suppliers and builds better working relationships. This can be organised by either the Pharmac Contract Manager or the supplier and can be a good opportunity to discuss items including ongoing supply issues or future goals and market projections.

### When to get in contact with us

Given that clinicians and patients are relying on access to these medicines and medical devices, if there is anything we need to advise the market about, it's important that we're notified as soon as possible and kept in the loop.

In instances where there is a potential or upcoming supply issue, suppliers are obligated to notify us as soon as possible. This is so we have enough time to help you to ensure there is as little disruption to patients as possible - often we can provide advice and assistance on how to manage the issue and maintain continuity of supply.

- Changes to product specifications (including packaging, pack sizes, specifications)
- Pricing change requests
- Discontinuations
- Potential Supply Issues

## Changes to medicines

Pharmac considers the clinical suitability of treatments prior to entering into supply agreements for pharmaceuticals. Before any changes are made to funded products, it is important that we are aware and supportive of these changes.

When making changes to medicines listed on the Pharmaceutical Schedule, a **Notification of Product Change (NOPC)** form should be completed. This includes both contracted and non-contracted products. For changes that have not been previously agreed with Pharmac, suppliers should discuss the change with their Pharmac Contract Manager before submitting this form.

## Changes to medical devices

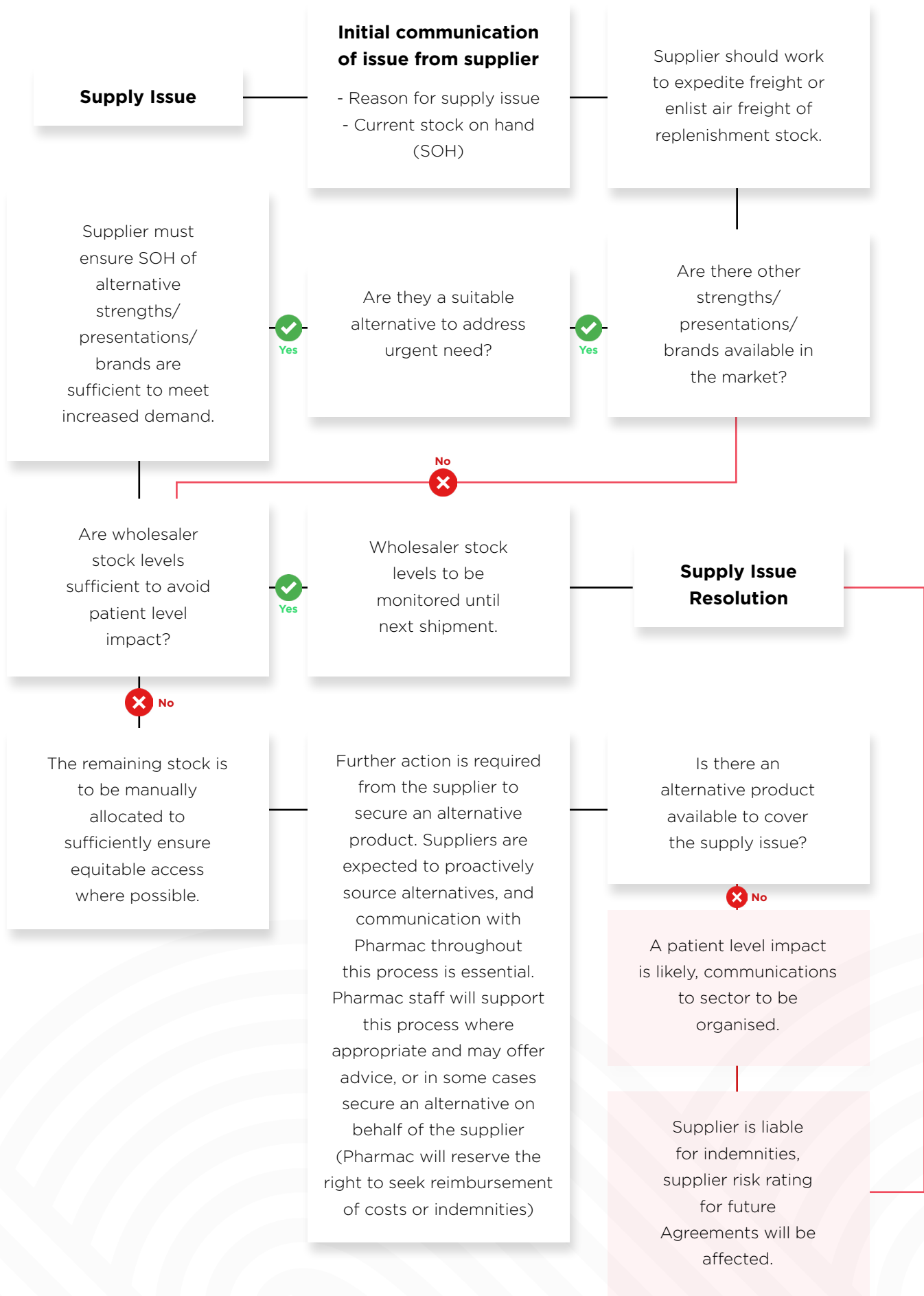
Pharmac has a separate process for managing device changes which includes listing of new brands, error correction, price changes and de-listing. If you are a medical device supplier and wish to progress a change to your product, please contact your Contract Manager who can provide advice and resources to facilitate this.

## What information is important when there is a supply issue

We know that not everything can be planned for, and supply issues can arise with little notice. When dealing with supply issues, it is important that we all act in a timely manner. It is important to give us as much notice as possible so that we can consider suitable alternative treatments and notify relevant people early on.

After you have noticed a potential supply issue, it is important to understand the likely impact on the market. This information will also assist us in deciding if we need to make any changes to the Schedule to limit the impact on New Zealanders.

The diagram on the following page is a summary of the information that is necessary for you to provide to us as soon as you become aware of a potential supply issue. Some of this information may need to be sought from other parties.



**Please note as well that this diagram is indicative only**

Further information will most likely be sought by Pharmac in the event of a supply issue specific to the product and nature of the issue.



## Key terms

**GTIN** refers to [GS1 Global Trade Item Number](#) and may be required for listing on the Pharmaceutical Schedule.

**GETS** is the [New Zealand Government Electronic Tenders Service \(GETS\)](#) website.

**Health New Zealand** is the organisation responsible for the operational functions of the Ministry of Health, with functions delivered at local, district, regional and national levels. It merges the functions of the 20 existing DHBs in New Zealand, its regional divisions and district offices ensuring continuity of services in the health system.

**Invitation to Tender (ITT)** is the [annual Tender process](#) Pharmac runs to invite suppliers to bid for certain Pharmaceutical supply Agreements in New Zealand.

**Medsafe** is the regulator responsible for assessing the safety and efficacy of medicines and operates independently of Pharmac.

**Notification of Product Change (NOPC)** is a form contains information that is required to finalise the listing of a community pharmaceutical or a hospital medicine in the Pharmaceutical Schedule.

**Potential Out-of-Stock Event** is outlined in individual supply agreements. Generally, it refers to when stock falls below the volume required to supply the funded market for a two-month period or when stock falls below two-thirds of your most recent three months' total sales of that Pharmaceutical.

The contractual definition provides a tangible figure for you to monitor, however in practice any instance where you feel there is a risk of a disruption to supply you will need to contact your Contract Manager.

**Pharmaceutical** refers to both medicines and medical devices.

**Pharmaceutical Schedule** is the list of all the medicines and therapeutic products that Pharmac has approved for funding. See the entry in [Introduction to Pharmac](#) for a full description.

**Pharmacode** is the unique six- or seven-digit identifier assigned to a pharmaceutical and assigned to you by the Pharmacy Guild. Medicine suppliers must apply to the Pharmacy Guild of New Zealand to receive a Pharmacode for each presentation of their pharmaceutical before it is listed.

**Te Tiriti o Waitangi** is a text made up of three articles, a preamble and the Ritenga Māori declaration ("Te Tiriti") that outlines the special relationship between the Crown and Māori. An explanation of Te Tiriti in the context of the wider health sector in New Zealand can be found on the [Ministry of Health website](#).

**WAND** refers [Web Assisted Notification of Devices \(WAND\) Database](#). For medical devices to be legally supplied in New Zealand they must be added to the WAND database.

## Contacts

If you need to get in touch about a contracted medicine or medical device, your Contract Manager is the best point of contact.

If you're not sure who your contract manager is, please email us.

**Medicines:** [contractmanagement-medicines@pharmac.govt.nz](mailto:contractmanagement-medicines@pharmac.govt.nz)

**Devices:** [contractmanagement-devices@pharmac.govt.nz](mailto:contractmanagement-devices@pharmac.govt.nz)

If you have any queries regarding other matters, the list below outlines the best point of contact.

### Non-contracted items or new potential items

- Medicines – Contact the relevant Therapeutic Group Manager
- Devices – Contact the relevant Contract Manager

### The annual multi-product tender

The Pharmac Tender team ([tender@pharmac.govt.nz](mailto:tender@pharmac.govt.nz))

### Specific Requests for Proposals or Requests for Tender

The Procurement team ([procurement@pharmac.govt.nz](mailto:procurement@pharmac.govt.nz))

## Useful references

[Online Pharmaceutical Schedule.](#)

[Medicines supply issue notices](#) – We use this webpage to provide up-to-date communications to patients.

[Our consultations and decision notifications.](#)

[Device advice newsletter.](#)

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