Managing fairer access to hospital medical devices.

Consultation Document
5 March – 28 June 2019

PHARMAC
TE PĀTAKA WHAIORANGA

New Zealand Government

Contents

Introduction

From the Chief Executive

To fully deliver the benefits the Government sought when it asked PHARMAC to apply our management approach to hospital medical devices, we need to mature our work in this area.

This will see us working with the sector to achieve more consistent access to medical devices, optimal health outcomes from sustainable spending, and transparency of funding decisions.

The most significant new activities to be undertaken by PHARMAC will include making decisions about introducing new technology that DHB hospitals can use and managing a process to deal with exceptional circumstances.

This consultation describes what the next step in PHARMAC's approach could look like. This will have implications for device users – both health professionals and consumers; those who decide on and support device use; and device suppliers.

We're seeking your feedback to ensure the new approach will be effective, practical and successful. Your input will also help us make sure we are appropriately recognising the different considerations devices raise compared to medicines.

This maturation of our approach will occur alongside the continuation of our current management activities to improve value for money from the list of already-funded devices.

We're seeking your feedback to ensure the new approach will be effective, practical and successful.

Our work to date has been underpinned by a wealth of information, feedback and support from our colleagues in the health sector.

Now we are looking ahead to the next step in our activity. We will take your feedback into account and continue to engage with you as we confirm and implement the new approach.

I look forward to receiving your feedback on this consultation by 5pm Friday 28 June 2019.

PHARMAC Chief Executive
Sarah Fitt

About PHARMAC

PHARMAC is the Government agency that decides what medicines are publicly funded in New Zealand.

More recently we have also been moving into the management of medical devices used in DHB hospitals. PHARMAC must secure for eligible people the best health outcomes that can reasonably be achieved from within the funding provided.

What's this consultation about?

Managing fairer access to DHB hospital medical devices

DHBs, PHARMAC, suppliers and others are going to be working together in a new way to deliver fairer access to publicly funded medical devices that are purchased by DHBs for use in hospital or in the community.

Under the new approach, PHARMAC would be responsible for deciding which devices are funded, based on a common set of broad considerations and taking into account expert advice.

DHBs would decide what devices are needed to deliver their local services, choosing the most appropriate devices from a national medical devices list.

PHARMAC would manage the national medical devices list, including:

- deciding what items get added or removed
- managing a process to consider access to items outside the list when exceptional circumstances require this.

What's a medical device?

The term covers diverse products and equipment that are generally used on, in or by a person for a diagnostic or therapeutic purpose. This includes consumable and durable products, implantables and complex equipment - everything from a cotton swab to an orthopaedic implant or home dialysis machine.

What are the benefits?

The new approach is about:

- supporting more consistent access to medical devices for consumers, regardless of where they live
- helping DHBs manage spending on medical devices in a sustainable way
- freeing up funding which may be used for new technology or other health initiatives
- ensuring there's a high level of transparency around funding decisions.

Why your feedback is important

This is your opportunity to help shape the proposed approach to managing fairer access to medical devices.

At this stage, we're looking for feedback on the broad outline of the new way we'll be working together, which has been developed by PHARMAC following careful consideration of significant feedback from DHBs, consumers, suppliers and others to previous consultations.

We want your ideas on key questions such as:

- how we would get the right expert advice to ensure we make good decisions
- the exceptional circumstances in which DHBs could use medical devices outside of the national medical devices list, and how decisions should be made about these.

Once we've established the broad outline of the new approach, we will work with the sector to develop the operational details – including identifying more specifically who will do what, and how, in the new arrangements.

We will consult again in the future on proposed operational details of the new approach.

We've highlighted the questions we're particularly interested in your responses to as part of this consultation. You're welcome to share your thoughts on any aspect of our proposals.

Who do we want to hear from?

We welcome feedback from anyone who's interested.

The proposal is likely to be of particular interest to:

- healthcare professionals and other staff who use DHB hospital medical devices
- DHB technical, executive, corporate and operational professionals involved in selecting, supporting or managing the use of medical devices
- companies who supply or service medical devices for DHBs
- consumers and family/whānau with an interest in how medical devices may affect treatment and services provided by DHBs.

How can you provide feedback?

This document includes specific questions we are seeking your feedback on, but we welcome and will consider all feedback we receive. The full list of questions is available on page 52.

We would appreciate your feedback by 5pm on Friday 28 June 2019.

You can provide your feedback in the following ways:

Email
Email your comments or download the editable feedback form and email to:
devices@pharmac.govt.nz

Online
Respond online by going to:
www.pharmac.govt.nz/devices

Post
Respond by post to:

PHARMAC
PO Box 10 254
Wellington 6143

Attn: Medical devices fairer access consultation

What will we do with the feedback?

We'll consider all the feedback we receive and will make a summary version available.

The feedback, along with input received during previous consultations, will help us continue to work with the sector to develop our proposed approach and how we will give effect to it.

Any feedback we receive will be subject to the Official Information Act 1982 (OIA). This means the identity of anyone providing a submission, and its contents, may need to be disclosed in response to an OIA request, whether the feedback is submitted:

- on your own account or on behalf of an organisation
- in a personal or professional capacity.

We're not able to treat any part of a submission as confidential unless you specifically request that we do, and then only to the extent permissible under the OIA and other relevant laws and requirements.

If you would like us to withhold any commercially sensitive, confidential proprietary or personal information, please clearly state this in your submission and identify the relevant sections that you would like withheld. We will consider your request, but can't guarantee we'll be able to accommodate it.

Why is this happening?

Applying the PHARMAC management model to DHB hospital medical devices

In 2012, the Government decided that the PHARMAC management model should be applied to DHB hospital medical devices.

This consultation is part of broader work PHARMAC is already doing to manage medical devices.

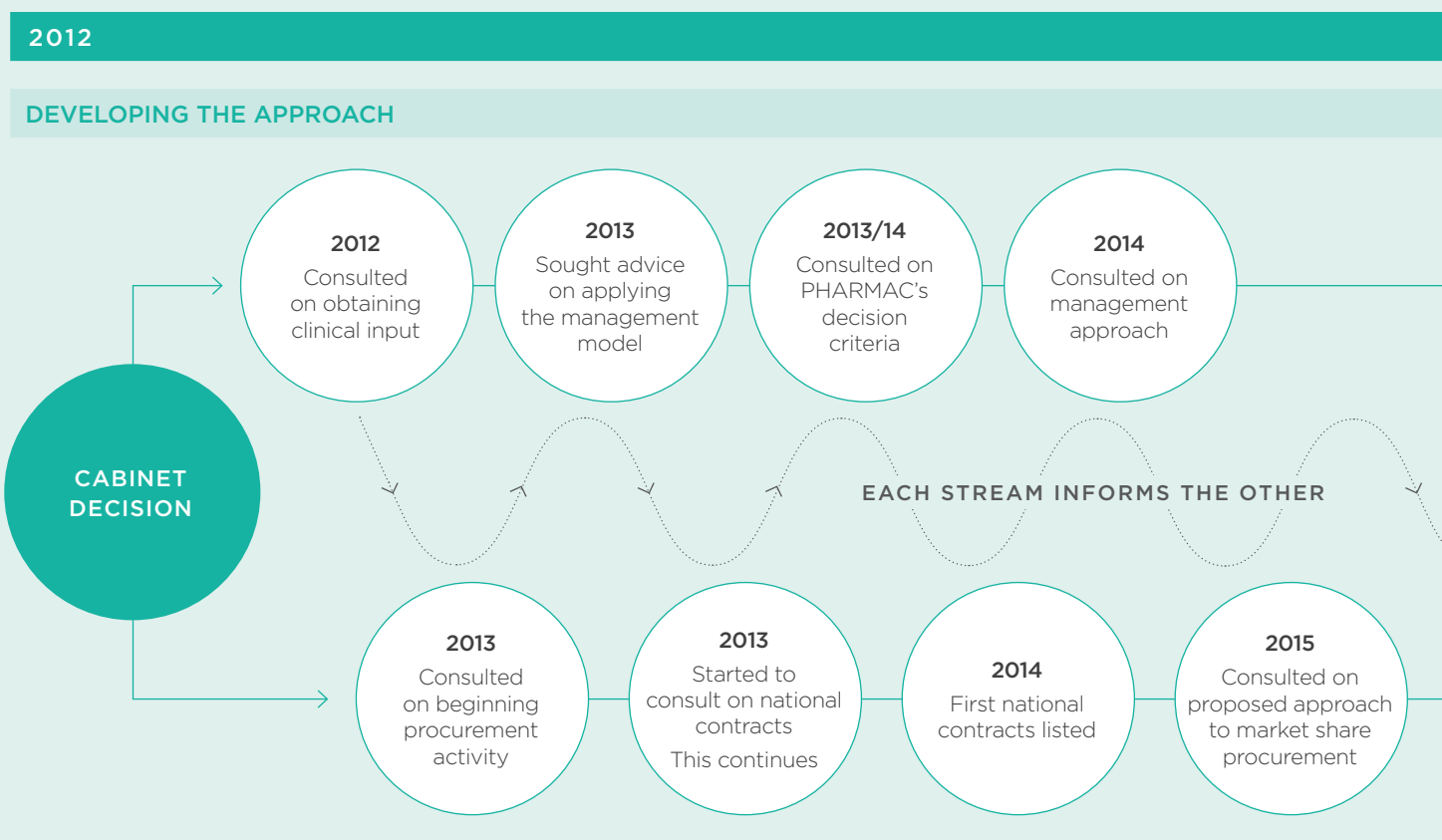
We understand that medical devices are different to medicines. For example, some devices have servicing and maintenance requirements, and may have operational impacts, that set them apart from medicines. So the approach we're taking to managing devices is, and will continue to be, specially tailored to account for these differences.

What's the PHARMAC management model?

Key features of the PHARMAC management model, which is about achieving the best possible health outcomes from fixed funding, include:

- making evidence-based decisions informed by expert advice

PHARMAC'S WORK IN HOSPITAL MEDICAL DEVICES



- applying commercial strategies to achieve competitive pricing
- comparing new products and prioritising their funding based on which options will deliver the best health outcomes.

A phased approach

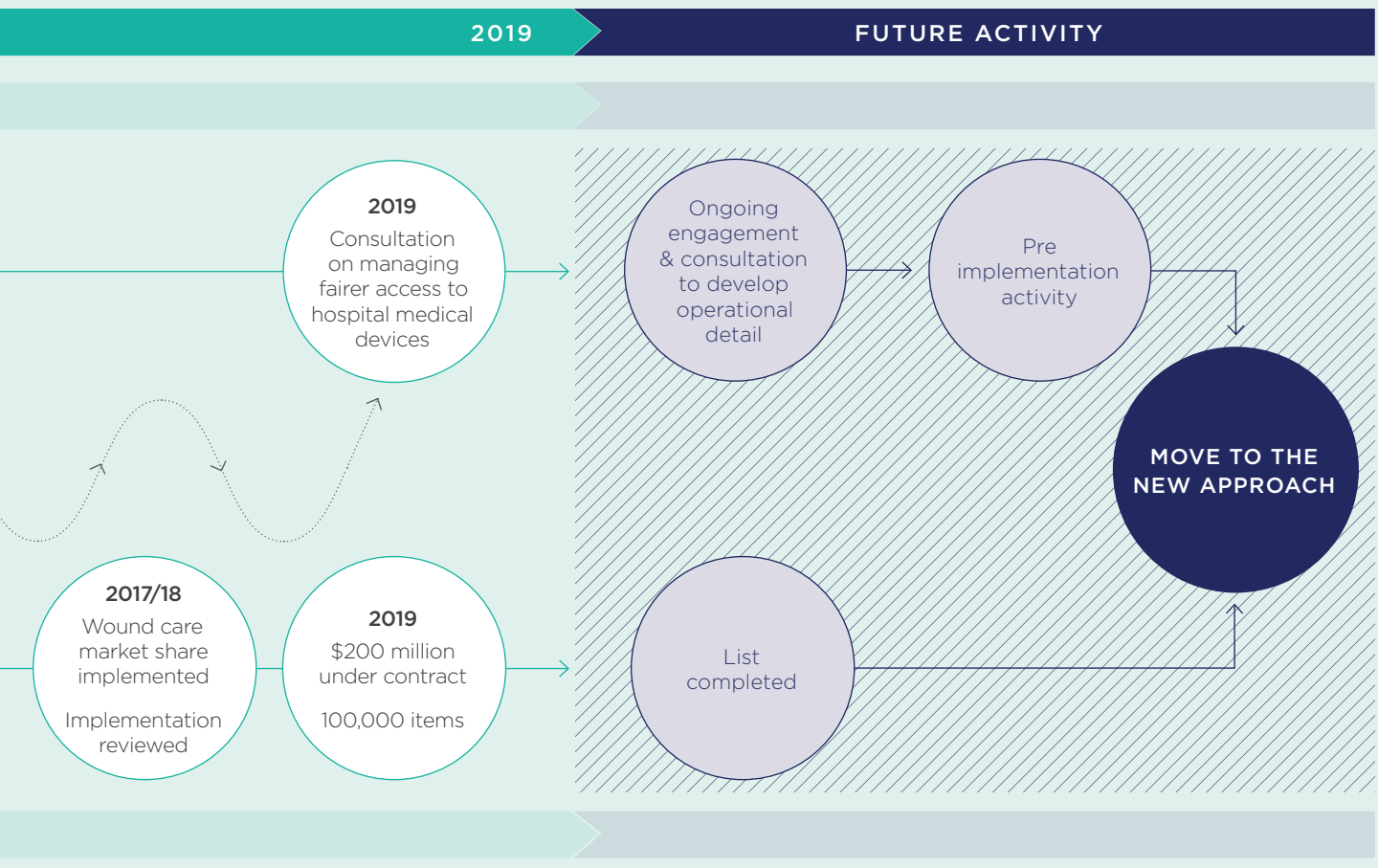
Because of the significant amount of work and change involved, we've been working with DHBs and others to progressively phase in PHARMAC's role in medical device management.

This is already benefiting consumers and DHBs, and helping to lay the foundation for the next phase that we're now consulting on.

Work done to date

The work we've done so far includes:

- gaining widespread feedback – through extensive consultation – to develop a proposed approach for medical devices management
- building the list of medical devices in use through negotiating national contracts which provide all DHBs with common terms, eg for pricing and supply.
- developing our understanding of the listed products
- negotiating the first market share agreements – guaranteeing suppliers a portion of the market in return for more competitive prices.



Continuing to work together

Ensuring the new approach works well

We recognise that the changes ahead represent a significant shift for DHBs, PHARMAC, suppliers and others. We also appreciate the work required to successfully implement the changes.

We're committed to working collaboratively to develop the new approach, to ensure it works well and can be implemented smoothly. In particular, we envisage working closely with parties who will have significant operational roles, to refine details of the new way of working together.

With any change of this magnitude, it's possible that potential improvements will be identified on an ongoing basis, and we're committed to making any modifications or refinements that may be necessary based on experience and feedback.

When would the changes being consulted on take effect?

Because of the significant scale of change and work involved, it's important we allow sufficient time to develop the approach ahead of its actual implementation.

We envisage that the earliest the changes could take effect would be 2020, however, this will depend on the feedback we get during this and any future consultations.

We're committed to working collaboratively to develop the new approach, to ensure it works well and can be implemented smoothly.

Proposal summary

What would fairer access to medical devices look like?

The range of devices in scope

The new approach would apply to diverse products and equipment purchased by DHBs for use in hospital or in the community.

Generally, these would be products and equipment used on, in or by a person for a diagnostic or therapeutic purpose. This includes consumable and durable products, implantables and complex equipment – everything from a cotton swab to an orthopaedic implant or home dialysis machine.

Find out more on page 13

Deciding what devices to use

DHBs would decide which devices they use locally, consistent with the rules of the national medical devices list managed by PHARMAC.

Find out more on page 15

Respond to our questions on page 18

PHARMAC manages the list

PHARMAC would manage the national medical devices list, including deciding which items get added or removed. Our approach would be based on a common set of considerations that are informed by expert advice and take into account the unique circumstances of each decision.

Find out more on page 19

Anyone could request changes and contribute to decisions

Anyone could request a change to the national medical devices list, such as seeking the addition of a new device. Consultation during the decision-making process would provide everyone an opportunity to have input into decisions.

Find out more on page 25

Using devices outside the list rules

There would be a process for considering access to devices outside the national list. The process would cover how decisions would be made in exceptional circumstances such as urgent or unusual situations.

Find out more on page 27

Respond to our questions on pages 29 and 30

Decisions would be informed by robust expert advice

High-quality advice would be sought from a range of sources to help us make well-informed decisions.

This would include clinical, technical and operational advice, as well as consumer advice where appropriate.

Find out more on page 31

Respond to our questions on pages 36, 39, 41 and 42

Support to implement list changes

Support would be available to DHBs to help implement changes to the national medical devices list, such as introducing a new device or changing the range of products available, where these may have a significant impact.

Find out more on page 43

Shared responsibilities for contract and supply management

DHBs, PHARMAC and suppliers would all have responsibilities for aspects of contract and supply management that are appropriate to their roles.

Find out more on page 45

We'll all be involved in making this work

We will work closely with stakeholders, including DHBs and suppliers, to keep refining the new approach and identify what support will be needed to put it in place.

Find out more on page 47

Respond to our questions on page 49

SECTION 01

The range of devices in scope

What's the definition of a device?

This consultation is about publicly funded medical devices that are used in or supplied to people by DHBs.

The consultation **does not** apply to medical devices that are:

- funded by general practice
- purchased directly by private entities (including NGOs) providing services under contract with DHBs
- used in private hospitals.

Generally speaking, the term 'medical device' includes anything used on, in or by a person for a diagnostic or therapeutic purpose, and which isn't a medicine.

Consumable and durable products, implantables, and complex equipment – including equipment managed as capital – all fall within the scope of the definition of medical devices.

Because this definition covers a huge range of products, there will always be questions about whether a particular product meets the definition or not, particularly as new technology comes onto the market. We would address these questions on a case by case basis.

Building the list and device categories

We're steadily building the list of devices currently used across DHB hospitals as we bring more products under national contracts.

Products under national contracts currently make up around 40 percent of the spend on medical devices.

Product categories identified so far - along with the types of devices within each category that we have national contracts for - are available on the PHARMAC website.

As we continue to negotiate new contracts and build our understanding of the devices currently in use, it's likely that we'll refine these categories further, including which types of device fall within particular categories.

You can view the current device categories at www.pharmac.govt.nz/categories or see Appendix 1 on page 56.

Consumable and durable products, implantables, and complex equipment – including equipment managed as capital – all fall within the scope of the definition of medical devices.

SECTION 02

Deciding what devices to use

How the national medical devices list would work

When we begin managing the national medical devices list, it would largely reflect the products being used in DHBs at that time.

The national medical devices list would effectively be a section of the Pharmaceutical Schedule.

This is the publicly available list of government-funded medicines and therapeutic products. Section H, Part III of the Schedule currently includes all medical devices that have been brought under national contracts to date.

You can view Section H, Part III at **www.pharmac.govt.nz/section-h**

Although devices aren't generally thought of as 'pharmaceuticals', they are included in the Pharmaceutical Schedule. The legal definition[1] of the term 'pharmaceutical' includes medical devices, and PHARMAC must give effect to its management role through the Pharmaceutical Schedule.

PHARMAC would make decisions about which products get added to and removed from the list.

We would make sure the national medical devices list is available in a form that enables it to be easily transferred into the particular catalogue system used by each DHB, including any national solution which may be implemented.

Although devices aren't generally thought of as 'pharmaceuticals', they are included in the Pharmaceutical Schedule.

1 New Zealand Public Health and Disability Act 2000

Proposed principles for the list rules

PHARMAC's legislative objective is to achieve the best possible health outcomes from within available funding, so the new approach would be based on a set of rules aimed at ensuring this objective is met.

At this stage, we're seeking feedback on the general principles or outline of what we'd want the rules to achieve. We will take this feedback into account as we develop detailed rules, which we will consult on in the future.

What it would mean for a device to be on, or off, the list

We propose that the national medical devices list would contain all the medical devices that DHBs can use. DHBs would not be able to use unlisted products, except in exceptional circumstances (see page 27).

Fairer access is as much about ensuring that listed products get used, as it is about not using unlisted products. DHBs would therefore be expected to use listed devices for all services they deliver, unless there's a compelling reason not to – for example, the hospital infrastructure doesn't support the use of a particular device, or they are already using a device that is equivalent to other listed items.

Product cost alone would not be a compelling reason to avoid using a particular device, if that device is the most clinically appropriate option. If device use varied based on financial considerations alone, this would undermine national consistency, which is a core feature of fairer access.

Each DHB would be responsible for deciding which devices it will use, consistent with the services that it provides. For example, a specialist paediatric ventilator would not need to be used by a DHB that doesn't offer neonatal or paediatric intensive care services.

It's not intended that changes to the list would require DHBs to change the services they provide and models of care they use. List changes may support or enable these changes where they are planned.

In many device categories, there would be a range of equivalent products to choose from. In these circumstances, DHBs would determine which items on the list would best meet clinical, technical and operational requirements. Cost could also be considered when choosing between products that offer similar health benefits

Restrictions

Over time, some products on the national medical devices list would likely have restrictions attached to them. PHARMAC uses restrictions to ensure that expensive products are only used for the consumers who are more likely to benefit from them.

For example, a restriction could mean a device is only able to be used:

- for a specific indication
- with or without other identified products

Any restriction would be developed based on expert advice; tailored to a specific funding decision; and consulted on before a decision was made to put it in place.

Capital medical devices

We acknowledge the complexities associated with including capital devices in the national medical devices list. This would especially be the case for major new capital equipment that's larger, more complex and which may involve a level of bespoke design, for example, an MRI scanner in a purpose-built facility.

Major new capital devices could be included in the national medical devices list in ways that preserve DHBs' flexibility to select appropriate options, including for specifications, configuration, service and support.

Different rules may also be required for major capital devices. This could include more flexibility in the requirements on DHBs to use listed major capital products, given DHB service configuration decisions, long-term capital requirements, and preferences for particular financing approaches (such as purchase or lease arrangements).

The appropriate rules would be determined for each product, and would be aligned with existing sector capital investment decision processes.

While medical devices that are considered major capital can have a very high cost per item, they will make up a small proportion of the scope of devices used by DHBs – by both product value and item numbers. The details of the options for managing capital equipment will be the subject of future consultation.

Giving effect to the rules

DHBs would be responsible for complying with the list rules and determining how this will be achieved at a local level.

This may require amending local policies and processes to ensure staff work in a way that's consistent with the new approach, and ensuring local activity reflects any changes to the list as these are made.

We would work with DHBs to identify any support we can provide to enable a smooth transition to the new approach to managing access to devices.

PHARMAC would also have a role in monitoring DHB compliance with the list and working with DHBs if there are any issues.

QUESTIONS – PROPOSED PRINCIPLES FOR THE LIST RULES

1. The new approach needs to support PHARMAC to achieve best health outcomes from the funding available, and improve national consistency of access to medical devices. Do the proposed principles for the rules achieve this, or would alternative principles be better?
2. Once the principles are confirmed, the next step involves developing specific rules which will give effect to the principles. What do we need to consider as we do this?

SECTION 03

PHARMAC manages the list

Our approach to decision-making

Managing the national medical devices list would involve us making decisions about:

- **new funding decisions** – adding products to the list or expanding the circumstances in which listed products could be used
- **improving value for money** – changing the range of listed products while maintaining health outcomes
- **list maintenance** – amending the list to reflect agreed changes such as new supplier arrangements, product updates and price changes.

New funding decisions

The aim of new funding decisions is to improve health while keeping costs within the funding available.

This would be achieved by:

- including new devices on the list, either with or without restrictions
- loosening or removing the restrictions on already-listed devices.

It is likely we would not be able to fund all new medical devices. There would always be more choices we could fund than we have budget for.

PHARMAC's role is to compare and prioritise new funding options. In other words, we compare all the products that could be funded, to determine which ones would achieve the best health outcomes within the budget available.

PHARMAC and DHBs would agree the budget within which PHARMAC could make new funding decisions, and DHBs would continue to hold this funding. If a potential new device wasn't funded on first consideration, this doesn't necessarily mean it wouldn't ever be funded. It would generally remain as an option that could be reconsidered if there were changes such as the availability of more funding, a price drop, or new evidence of a product's benefits.

Improving value for money

The national list would initially largely reflect the products currently used by DHBs.

Over time, we would identify opportunities to achieve greater value for money from the list, for example, by leveraging competition to achieve the same health outcomes at less cost. This could be done by offering exclusive benefits to a particular supplier or subset of suppliers of products which all deliver similar health outcomes, in exchange for more competitive terms.

This might result in a change to the range of similar products on the list, to favour a specific brand or products.

Expert advice would support us to determine the appropriate commercial strategies to leverage competition.

Rationalising areas where there are more product options available than is necessary to achieve the desired clinical outcomes would see some current products removed from the list.

When making these decisions, our aim would always be to achieve the best health outcomes possible from the available funding.

Clinical, technical, operational and, where appropriate, consumer advice will be critical to ensure PHARMAC fully understands the implications of any proposed changes.

Ultimately, seeking greater value for money is about reducing costs (making savings) which may then be used to fund new technology or other health initiatives.

List maintenance

List maintenance would involve ensuring that the national medical devices list remains current and reliable, given ongoing changes that could affect products and supplier arrangements.

The effect of list maintenance decisions could be that information relating to listed products would be changed, to reflect changes in the market.

Products could also be delisted, for example, if they were no longer available, not being used, or PHARMAC and a supplier had not reached agreement on a desired change.

We compare all the products that could be funded, to determine which ones would achieve the best health outcomes within the budget available.

How would decisions be made?

When making any decision, we would need to be confident it would advance our legislative objective of achieving the best health outcomes from within the funding available.

Because the different circumstances we'd be making decisions about would each present a different level of certainty of achieving this goal, our decision-making process would need to provide the necessary flexibility to accommodate this.

The less certain we are that a decision would achieve our legislative objective - for example, because the health outcomes are more uncertain or the costs are higher - the more in-depth the process we would use to reach the decision.

Our assessment of certainty would also affect the depth of expert advice we'd seek to inform our decisions. The greater the uncertainty, the more comprehensive the information that would be sought.

A flexible decision-making process would also help us manage the workload associated with making decisions. For example, it would enable us to concentrate our resources on decisions requiring a greater level of assessment, and apply a less intensive process where we have more certainty.

We expect new funding decisions with significant financial implications would require the greatest level of assessment.

PHARMAC may seek advice for some list maintenance decisions. However simple changes could be actioned following internal review.

Factors for Consideration

All decisions we make would be underpinned by the Factors for Consideration (the Factors). These were developed following comprehensive consultation with community and health sector stakeholders. The Factors were introduced as PHARMAC's decision-making framework in 2016.

The Factors were developed to be applied to both medicines and medical devices, so considerations relevant to medical devices are explicitly reflected in the decision-making framework.

The Factors mean that for any decision, we would consider:

- **Need** – what's the impact of the disease or condition which the device would address?
- **Benefits** – what health benefits would the device deliver?
- **Costs and savings** – what costs and savings across the health sector would result from a decision to fund the device?
- **Suitability** – what features of the medical device might impact on health outcomes?

We would consider each Factor on three levels – as it applies to:

- the **individual** requiring treatment or using the device
- their **family/whānau** and wider society
- the **broader health system**.

We recognise that not all Factors for Consideration would be equally relevant to every funding decision, so would use them as a guide and not apply them rigidly.

Further information on the Factors for Consideration can be found at:

www.pharmac.govt.nz/factors

Clinical, technical, operational, commercial and economic perspectives

When applying the Factors for Consideration, we would seek and assess information from clinical, technical, operational, commercial and economic perspectives.

Clinical

Understanding the role of the device in treatment, its clinical benefits, risks and suitability would be key to our decision-making.

PHARMAC has a strong reputation for making evidence-based decisions, and we would apply this approach to device funding decisions.

The level of evidence we'd seek would be proportionate to the level of certainty that the decision will advance our objective of best health outcomes within available funding.

This means, for example, that decisions to commit significant funding to new products would need to be underpinned by stronger evidence of better health outcomes, while less evidence would be sufficient for minor product changes.

We would consider information about any features of a device that may impact on its use, benefits, costs and savings, including safety features that reduce errors and injury to the user or consumer, and the ease of use of a device.

The relatively light pre-market regulation of medical devices in New Zealand would also affect the level of evidence we seek.

Until medical devices are fully regulated under the new Therapeutic Products regulatory regime, we would place a higher emphasis on seeking sufficient evidence to determine that a product's benefits outweigh its risks. The Ministry of Health's consultation on the draft Bill for this new regime started in December 2018 and will conclude on 18 April 2019.

Technical and operational

Understanding technical requirements and operational impacts would be important for our decision-making. More assessment would be carried out for decisions likely to have a greater technical/operational impact, and less assessment where the likely impacts are lower.

The particular technical requirements and operational impacts would vary significantly depending on the product. Based on feedback we've received, the range of aspects we may need to consider would include:

- whether a device has associated IT requirements, what level of servicing and maintenance it may require, facilities impacts, and any disposal costs
- whether there would be changes in distribution arrangements
- impact on staff time – for example, would the device enable more efficient use of staff time or conversely, would it require more time to use it?
- product training and support requirements – for example, is direct supplier support required?
- the costs of implementing a change – for example, would it require healthcare professional, other staff, or consumer training?
- other potential flow-on costs or benefits - for example, increased or reduced demand for treatment that could result from funding a new diagnostic tool
- sustainability – in accordance with government guidance.

We'd seek expert advice to ensure we're appropriately informed about the technical requirements and operational impacts associated with a particular device. Where appropriate, we would seek this advice from consumers.

We would engage with DHBs on these impacts where appropriate - including, for example, where DHBs might bear additional costs beyond that of the device itself, as a result of a funding decision.

Commercial and economic

An important part of what PHARMAC does is encouraging competition between suppliers.

This is because by getting better terms on which products are purchased – eg, for price, servicing and training - we can free up funding which may be used for new technology or other health initiatives.

That doesn't mean we would simply take the cheapest option, as that could compromise our aim of achieving the best health outcomes from the funding available.

We take care to consider costs and benefits across the health system, and for the lifetime of the device. Funding a device now may reduce costs elsewhere in the health sector, and in years to come.

When making any new funding decision, we would consider whether the evidence suggests it represents the best use of the funding available, or whether an alternative option would deliver greater value.

Our flexible decision-making process would support us to make decisions as efficiently as possible.

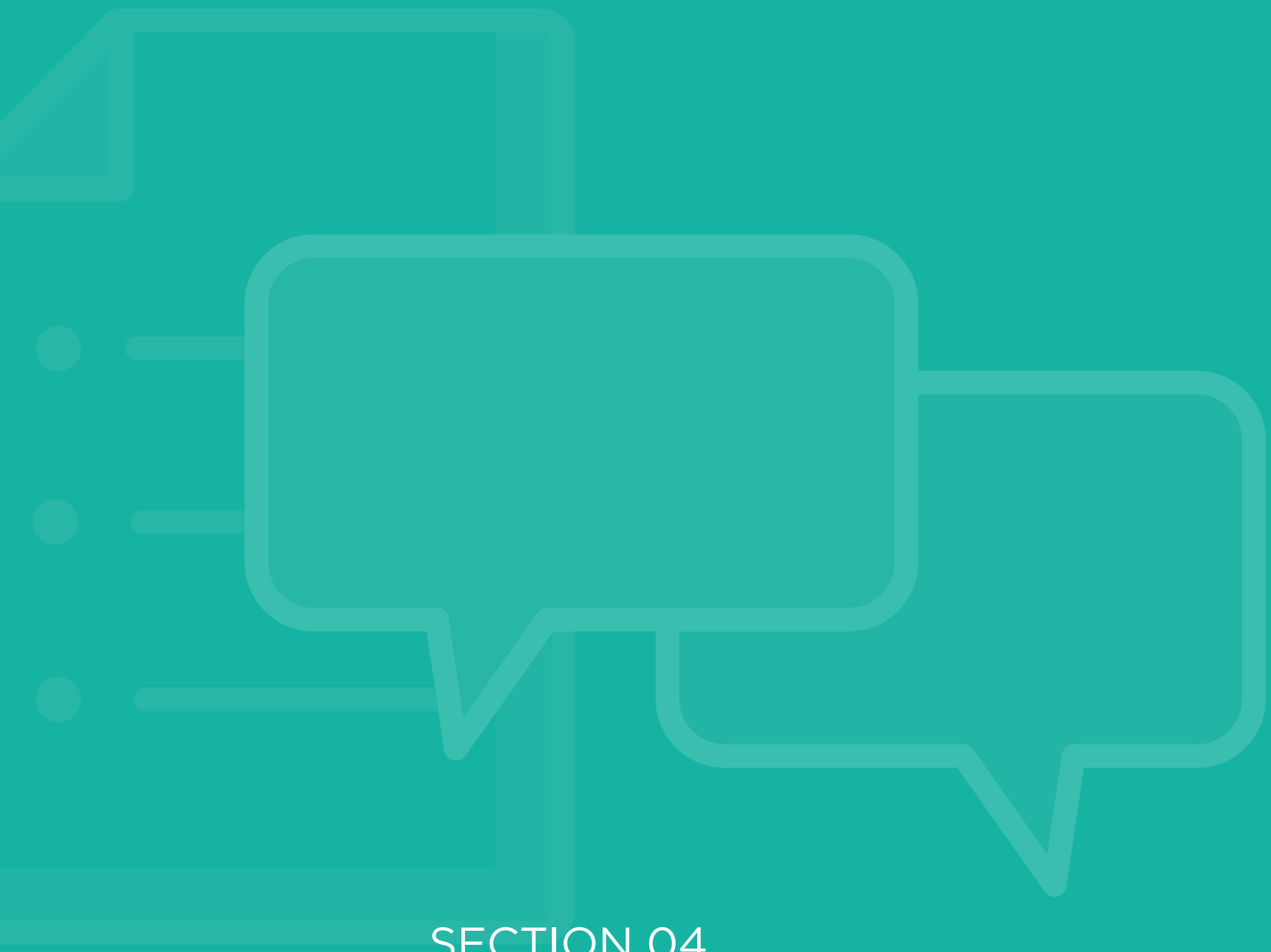
Making timely decisions

Our flexible decision-making process would support us to make decisions as efficiently as possible. This is because we could tailor our approach to the requirements of the particular funding decision being considered.

When it comes to funding new technology, if and when a new funding request is approved would depend on the other competing requests to fund new products, and the amount of funding available.

Because it's likely there would always be more new device options than the funding could meet, we would prioritise the options that achieve the greatest health outcomes from the funding available.

Each year, we would aim to ensure the entire fixed amount of funding that DHBs would agree is available for hospital medical devices, is used.



SECTION 04

Anyone could request changes and contribute to decisions

How would list change decisions be initiated?

Anyone could request that PHARMAC fund a new product or widen access to a funded product.

We envisage that most new funding requests would be made by suppliers, who would generally have more information about their products to support an application.

PHARMAC could also initiate considering a new technology for listing.

However, anyone could make a request – including DHB health professionals and technical, service support and operational professionals; colleges and societies; consumers; and consumer groups.

We'd provide guidance to those making funding requests, and would generally recommend a conversation with PHARMAC staff in advance of making an application.

This would allow for a discussion about the nature of the application, and the types of information we'd seek.

PHARMAC would generally initiate activity focused on improving value for money and identify the information it is seeking. This could be prompted by the availability of a new brand or product, or external advice.

List maintenance decisions would generally be initiated by suppliers, seeking to change details relating to one of their listed products.

Feedback on proposed changes to the list

We would be transparent about the new funding requests PHARMAC receives, and our progress in assessing these.

Interested groups would be able to proactively provide additional information, relevant to funding requests, for PHARMAC to consider.

We would also consult on all significant decisions. Consultation is an important way of getting input to support well-informed decisions.

Anyone could respond to consultation, which we would promote via advice to stakeholders and publication on the PHARMAC website. We could also meet with interested groups to discuss aspects of a decision.

Any information and feedback we receive would complement other expert advice we would seek to inform our decisions.

SECTION 05

Using devices outside the list rules

Exceptional circumstances and what they mean

An important aim of the national medical devices list would be that it contains sufficient products to comprehensively meet DHBs' reasonable requirements.

From time to time, however, it's likely there would be situations where DHBs want to use a device:

- not on the list, or
- outside the rules or restrictions that apply to the list.

We propose there will be an exceptions process to manage these situations.

This would recognise genuine exceptional circumstances that warrant funding a device outside of the list. It would not be intended to serve as an 'alternative' way to get a device funded, where the usual process to request an addition to the list would be most appropriate.

We don't envisage that a high volume of devices would need to be accessed via the exceptions process, as this wouldn't be an effective use of DHBs' or PHARMAC's resources.

We propose that exceptional circumstances for medical devices would fall into two main categories:

- exceptional clinical circumstances relating to the person
- exceptional external circumstances relating to the device.

When considering exceptions, we would apply the same decision-making framework used to consider changes to the list, including assessing requests using the Factors for Consideration.

Exceptional clinical circumstances relating to the person

This is where use of a device outside the list could be sought because of specific clinical circumstances relating to either a consumer or healthcare professional(s) using it.

Examples could include:

- a consumer or health professional may have an unusual clinical circumstance that wasn't considered as part of the listing decision, and which means the listed devices aren't suitable for them
- pre-existing or continuing use to ensure continuity of care in circumstances where an unlisted device has been used prior to PHARMAC managing the national medical devices list.

Making decisions on these circumstances

We propose that in non-urgent situations, PHARMAC would make these decisions. The level of information DHBs would need to provide and the decision-making process we'd apply would depend on the complexity of the circumstances, with a more streamlined process for less complex situations.

If necessary, we'd seek expert clinical or other advice to help inform our decision.

In urgent situations, we propose that DHBs would make the decision and report it to PHARMAC.

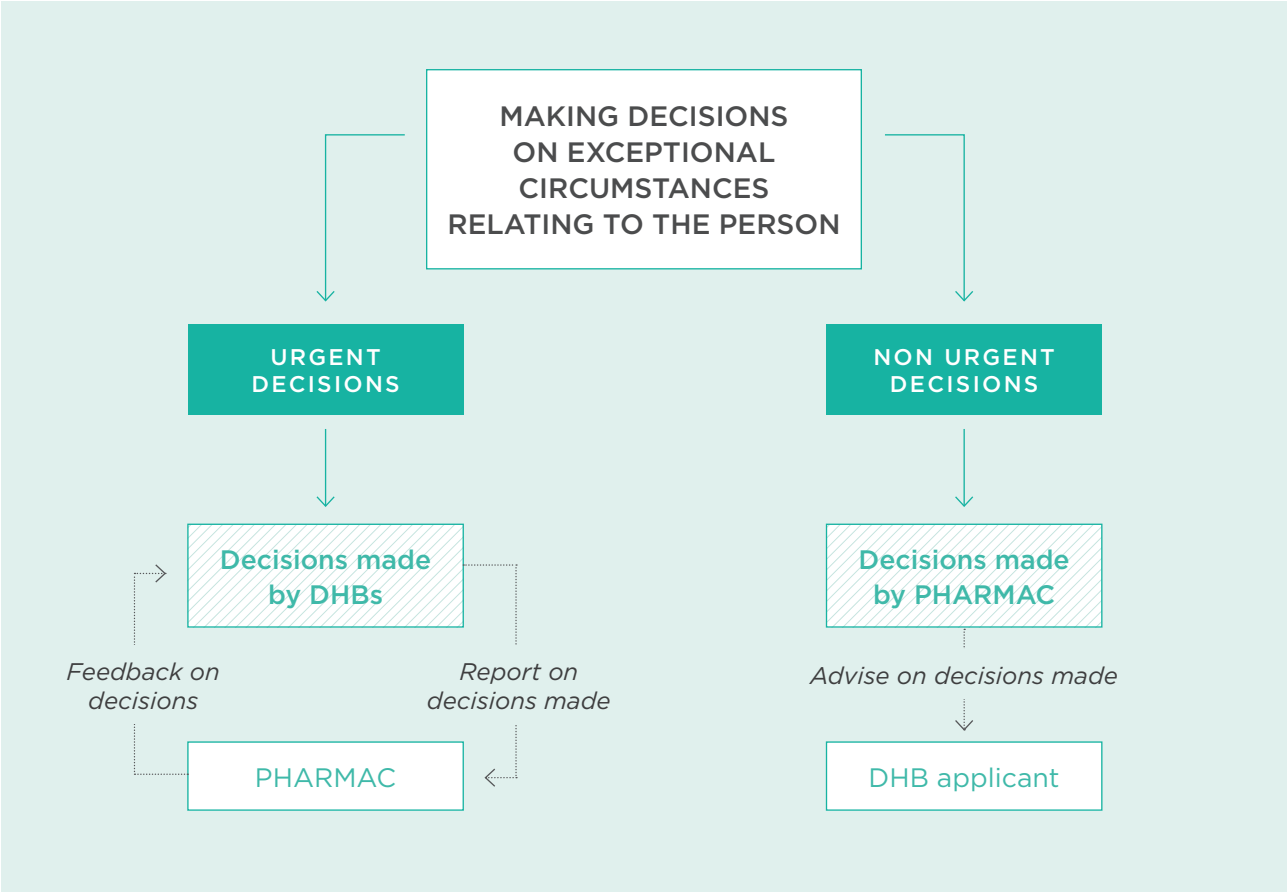
An example of an urgent situation would be where an unlisted device is considered to be clinically necessary during an acute procedure.

Each DHB would be responsible for developing the local process for making urgent decisions.

PHARMAC would review urgent decisions by DHBs, to check that these are:

- made in accordance with the exceptions framework, and
- outcomes are consistent across DHBs.

If we considered that decisions were not consistent with the framework, we would work with DHBs to provide feedback and guidance for future urgent applications.



QUESTIONS – EXCEPTIONAL CLINICAL CIRCUMSTANCES RELATING TO THE PERSON

3. PHARMAC has proposed some exceptional clinical circumstances in which devices outside the list would be considered for funding. Do you think these are appropriate? If not, why not? What suggestions do you have for alternatives?
4. PHARMAC has proposed how decisions on exceptional clinical circumstances would be made. Do you have any comments on this?
5. What would DHBs need to consider when establishing an internal process to make decisions on urgent clinical exceptions and report these to PHARMAC?

Exceptional external circumstances relating to the device

This is where use of a device outside the list would be sought because of external circumstances relating to the device.

Examples could include:

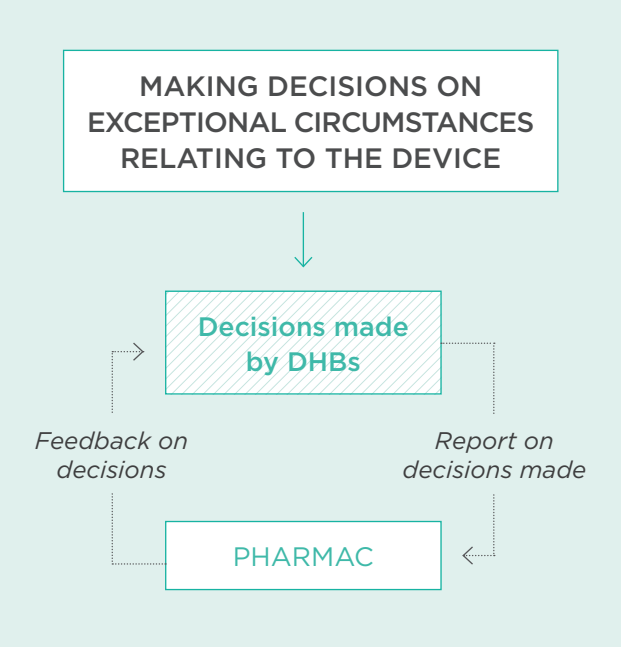
- the physical environment the device is used in – for example, an unlisted device may be required if the hospital infrastructure doesn't support using the listed devices
- funding of a device by a third-party, for example, via a registered clinical trial, other government funding or product development – we propose that unlisted devices provided by third-parties could continue to be used by DHBs, if this doesn't undermine the use of listed devices
- temporary use of a device to reduce or prevent broader system disruption.

Making decisions on these circumstances

We propose that DHBs would need to determine when the exceptional external circumstances provisions had been met.

PHARMAC would not need to be involved in the decision-making process. However, we would expect DHBs to inform us, through regular reporting, on all exceptional external circumstances decisions made.

As with urgent clinical circumstances relating to the person, if we considered that decisions were not consistent with the framework, we would work with DHBs to provide feedback and guidance for future applications.



QUESTIONS – EXCEPTIONAL EXTERNAL CIRCUMSTANCES RELATING TO THE DEVICE

6. PHARMAC has proposed some exceptional external circumstances in which devices outside the list would be considered for funding. Do you think these are appropriate? If not, why not? What suggestions do you have for alternatives?
7. PHARMAC has proposed how decisions on exceptional external circumstances could be made. Do you have any comments on this?
8. What would DHBs need to consider when establishing an internal process to make decisions on urgent external exceptions and report these to PHARMAC?

SECTION 06

Decisions would be informed by robust expert advice

A commitment to gaining quality advice

Getting sound expert advice would be critical to enable PHARMAC to make good decisions.

We would seek advice from a range of health care and other professionals, as well as consumers where appropriate, who are best equipped to provide the kinds of information needed for the decision being made.

All advice received would need to be objective, reflecting the knowledge and experience of the advisors, and not influenced by any assumption about what PHARMAC wants to hear. Any conflicts of interests that may influence the advice would need to be identified and managed appropriately.

We would be committed to a high level of transparency around the advice gathered, and where practical would proactively make this advice publicly available.

The right approaches to get the advice we need

We would need a wide range of expert advice to help us make decisions, and the type of advice sought would depend on the nature of the decision being considered.

This means we'd require a variety of approaches to enable us to get the advice needed, and the process followed when obtaining advice could differ for different decisions.

We recognise that many advisors will already have heavy demands on their time, so our methods for obtaining advice would need to be efficient and pragmatic.

Where regular, ongoing advice is needed from the same sources, establishing a formal structure such as a committee which meets regularly would likely offer the best means of obtaining this advice.

Different approaches would be required for other circumstances, such as when advice is needed on a less regular, case-by-case basis.

We would need a wide range of expert advice to help us make decisions, and the type of advice sought would depend on the nature of the decision being considered.

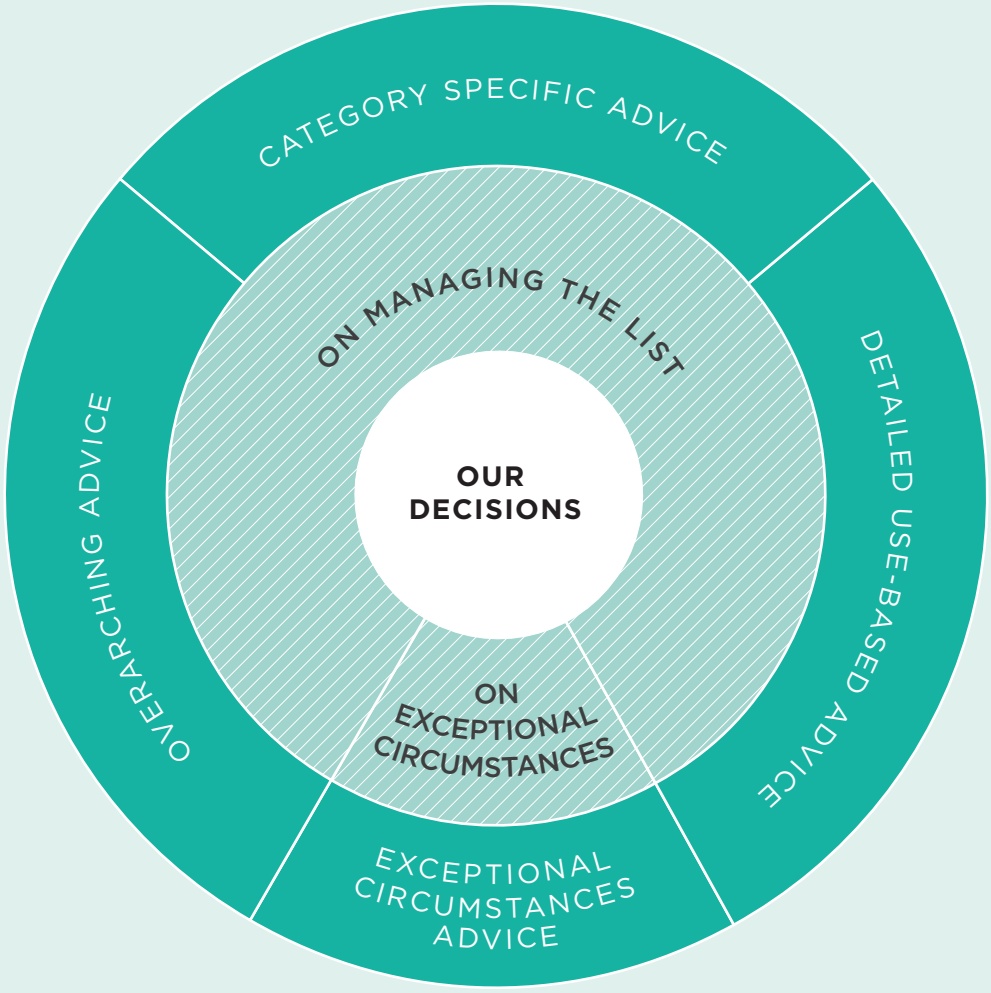
What types of advice do we need, and who from?

We've identified three broad 'types' of advice that we would need, to manage the list:

- **overarching advice**, informed by critical appraisal of evidence, to help us
  - compare and prioritise all the available options for funding new devices, or expanding access to currently funded products, and
  - comprehensively assess other expert advice received
- **category-specific advice** on clinical, technical and operational aspects of products
- **detailed use-based advice** gained from hands-on use of products in context.

We would also need expert advice to inform the exceptional circumstances decisions we would be making.

TYPES OF ADVICE



Overarching advice

We expect the main role of these advisors would be to help us compare and rank the different devices for which new funding is being sought.

This would involve critically appraising the evidence presented for each device, in particular advising on their clinical benefits and risks.

These advisors may advise PHARMAC to seek and consider category-specific advice and detailed use-based advice when making their recommendations. Their expertise could also be sought to help us assess evidence associated with other types of decisions.

The most likely source of this overarching advice would be a mix of healthcare professionals with expertise in critical appraisal, and the ability to assess proposals across the full set of therapeutic groups.

Category-specific advice

The responsibility of these advisors would be to help inform PHARMAC's decisions by sharing their knowledge and experience of using devices within a particular category, including the indications and circumstances they're used for. They would contribute to the assessment of new devices as well as activity aimed at achieving better value for money from currently listed devices.

We would require advice from healthcare professionals who have expertise within a particular category. This could include orthopaedic surgeons for joint implants, nurse specialists for ostomy bags, and physiotherapists for mobility devices.

We would also require advice from professionals who have expertise in broader disciplines relevant to a product being assessed, but who don't necessarily use the device day-to-day. These could include technical, scientific and service support professionals and operational professionals, as well as health professionals. (refer to page 40 for more detail.)

Detailed use-based advice

On occasions, a particular decision may require seeking advice based on using a product in its context.

This advice could support decisions about introducing potential new devices, as well as standardising the range of devices within a particular category.

If required, we'd likely seek this type of advice from relevant healthcare professionals, as well as technical, scientific and service support professionals and operational staff. We may also seek this advice from consumers where they are a key user of the product.

As user assessment of products can be costly and resource intensive, we would seek this only when confident we would achieve good value from the decisions it would inform.

How could we get this advice?

We've developed proposed approaches for how we could obtain the different types of expert advice we'll need.

In some cases, we've provided different options for obtaining a particular type of advice, along with the risks and benefits associated with each option.

As well as getting your feedback on what we've proposed, we're also interested in any ideas we may not have considered, or any risks and benefits we may not have identified.

There's no clear 'right' way of getting the different types of advice we'd need, so your feedback will be crucial to help us refine our proposed approaches or develop new ones.

Proposed approach to getting advice

Overarching advice

	OPTION 1 ENHANCED MEMBERSHIP OF PHARMACOLOGY AND THERAPEUTICS ADVISORY COMMITTEE (PTAC)	OPTION 2 NEW DEVICES COMMITTEE
DESCRIPTION	PTAC is the existing committee made up of senior healthcare professionals from a range of specialities, whose main responsibility is to make recommendations to PHARMAC on new medicine funding applications. They do this by considering clinical evidence, information provided by subcommittees, and by taking into account the Factors for Consideration. This option would involve adding to PTAC new members with greater knowledge and experience of medical devices.	This option would see a new committee created to focus solely on medical devices. The committee would be made up of a mix of healthcare professionals who have experience using medical devices, as well as strong critical appraisal skills. The membership would not need to be familiar with every type of device. The main requirements would be that members are able to critically assess information relating to a funding request and apply the Factors for Consideration. Member appointment would involve publicly advertising for candidates, and an interview. DHBs may want the opportunity to nominate potential candidates
BENEFITS	• PTAC is already established and experienced in providing advice to inform PHARMAC's decisions • there would be greater consistency in advice provided to inform both medicines and devices funding decisions • there would be lower recruitment and training costs to expand PTAC's scope.	• the committee would be able to provide robust advice, based on a deeper understanding of what medical device use involves • there would be a single focus on medical devices • there would be greater confidence this committee would be sufficiently resourced to meet the requirements of PHARMAC's devices activity.
RISKS	• enhancing PTAC membership would not necessarily provide the level of familiarity with medical devices that may be needed to provide quality advice • the extra devices work could exceed PTAC's capacity and it may not be possible to identify efficiencies that would compensate for the increased workload - affecting the timeliness of decisions.	• consideration of items that include medicine and devices elements may be more difficult • there may be less consistency of advice provided between medicines and medical devices • the costs of establishing a second committee, such as resources and training, could be greater.

QUESTIONS – OVERARCHING ADVICE

9. PHARMAC has described two options for getting overarching advice, and identified the benefits and risks of these. Are there any benefits or risks we haven't captured?
10. Is there an alternative option that should be considered? If so, please clearly describe it and its benefits and risks.
11. Which option do you think would be most effective in providing overarching advice and why?
12. What would need to be considered when implementing the option that you think would be most effective?

Category-specific advice

Category-specific advice from healthcare professionals with category expertise

Based on our early understanding of the categories of devices brought under national contracts to date, we envisage that separate subcommittees of the overarching committee could be responsible for providing this advice.

We appreciate, however, that other options may arise as part of our ongoing work in this area, and we welcome ideas about alternative ways of getting this advice.

Separate subcommittees could advise on a particular group or groups of devices. Their advice could be also be sought on devices that they have some experience of, but which fall outside their main area of focus.

In some instances, the scope of products would be so large it's likely that the standing members of a subcommittee would need to call on specialised advice on a regular basis. We propose this advice would be provided by setting up sub-groups to assist the relevant subcommittees.

These sub-groups could have a stable, ongoing membership. Alternatively, the sub-group could be put together by identifying relevant experts as needed.

PHARMAC may establish these subcommittees and sub-groups, or draw on existing sector groups for this advice.

Where there is significant overlap in the users of medicines and devices in a therapeutic area, there may be benefits in expanding the scope and membership of PHARMAC's existing medicines subcommittees so they advise on both types of products.

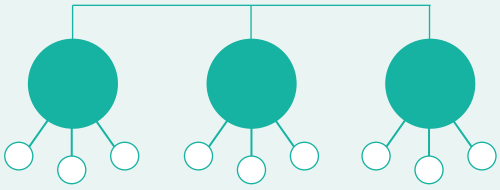
To appoint subcommittee members, we would seek nominations from Colleges and Societies and/or relevant national groups. DHBs may want the opportunity to nominate potential candidates.

A proposed subcommittee structure is provided on pages 37 and 38. This reflects PHARMAC's early thinking on the subcommittees that may be needed, and which subcommittees would regularly require additional advice, so would more likely have enduring sub-groups.

After considering the consultation feedback, we would engage with the relevant sector groups – including Colleges, Societies and DHBs – to confirm the approach for each subcommittee.

CATEGORY-SPECIFIC ADVICE FROM HEALTHCARE PROFESSIONALS WITH CATEGORY EXPERTISE

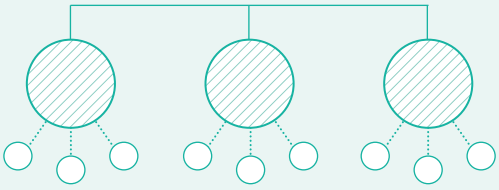
SUBCOMMITTEES **REGULARLY** REQUIRING ADDITIONAL ADVICE



PROPOSED SUBCOMMITTEES COULD INCLUDE:

- Critical Care and Patient Monitoring
- Rehabilitation Products
- Infection Prevention and Control
- Infusion and Transfusion
- Laboratory
- Medical Diagnostics
- Orthopaedic
- Surgical
- ...

SUBCOMMITTEES **OCCASIONALLY** REQUIRING ADDITIONAL ADVICE



PROPOSED SUBCOMMITTEES COULD INCLUDE:

- Anaesthesia and Respiratory
- Cardiology Devices
- Continence and Urology
- Dental
- Ear, Nose & Throat and Audiology
- Gastroenterology*
- Nephrology*
- Ostomy
- Radiology
- Reproductive and Sexual Health*
- Special Foods*
- Wound Care
- ...

**These Subcommittees currently provide advice to inform PHARMAC's medicines decisions. We propose that the Subcommittees could also advise on medical devices. Their membership may need to be enhanced for this purpose.*

KEY

Subcommittees regularly requiring additional advice

Subcommittees occasionally requiring additional advice

Sub/sector groups

Proposed approach to getting category-specific advice from healthcare professionals with category expertise – subcommittees

Proposed subcommittees which would regularly require additional advice could include

Critical Care and Patient Monitoring
Would advise on critical care, including neonatal, paediatric, and adult intensive care; and patient monitoring equipment.

Rehabilitation Products
Would advise on rehabilitation products and ward equipment.

Infection Prevention and Control
Would advise on devices reprocessing; personal protective equipment; hand hygiene, and sterile packaging.

Infusion and Transfusion Advisory
Would advise on conventional needles and syringes; infusion devices and equipment.

Laboratory
Would advise on laboratory equipment.

Medical Diagnostics
Would advise on medical diagnostic products.

Orthopaedic
Would advise on orthopaedic products.

Surgical
Would advise on sutures; surgical instruments; surgical implants; cardiothoracic surgical; surgical suction, chest and wound drainage; theatre furniture and equipment; drapes, gowns and packs; and other general surgical specialties.

Proposed subcommittees which may require additional advice from occasionally could include

Anaesthesia and Respiratory
Would advise on ventilation; respiratory and anaesthesiology.

Cardiology Devices
Would advise on interventional cardiology; cardiac electrophysiology and management; coronary care.

Continence and Urology
Would advise on continence and urology devices.

Dental Advisory
Would advise on devices for dental and oral health and surgery.

Ear, Nose & Throat and Audiology
Would advise on ear nose and throat devices; and audiology equipment.

Gastroenterology*
Would advise on gastroenterology scopes and devices related to enteral feeding.

Nephrology*
Would advise on renal replacement therapy, haemodialysis, and peritoneal dialysis.

Ostomy
Would advise on ostomy devices.

Radiology
Would advise on interventional radiology and diagnostic imaging.

Reproductive and Sexual Health*
Would advise on reproductive and sexual health devices.

Special Foods*
Would advise on special foods, feeding pumps, and associated devices.

Wound Care
Would advise on wound care and negative pressure wound therapy devices.

**These Subcommittees currently provide advice to inform PHARMAC's medicines decisions. We propose that the Subcommittees could also advise on medical devices. Their membership may need to be enhanced for this purpose*

After considering the consultation feedback, we would engage with the relevant sector groups – including Colleges, Societies and DHBs – to confirm the approach for each subcommittee.

QUESTIONS – CATEGORY-SPECIFIC ADVICE FROM HEALTHCARE PROFESSIONALS WITH CATEGORY EXPERTISE

13. What do you think of our proposal to use subcommittees to get advice from category-specific experts?
14. If we proceed with the subcommittee approach, are there any new subcommittees that should be added and/or should the scope of any of the proposed subcommittees be changed?
15. What do you think of our proposal to set up sub-groups to provide subcommittees with more specialised advice? Is there an alternative option that should be considered?
16. We've identified which subcommittees we think would have a broader scope of devices to advise on (so would regularly require more specialised advice from sub-groups) and which subcommittees would only occasionally need more specialised advice. Do you have any comments on this proposed allocation?

Category-specific advice from professionals with expertise in broader disciplines

	OPTION 1 SEEKING ADVICE FROM INDIVIDUAL GROUPS	OPTION 2 ESTABLISHING A COLLECTIVE TO PROVIDE ADVICE
DESCRIPTION	This option would see us seek advice from groups that represent the interests of the relevant disciplines. This could either occur through established groups, or if groups don't currently exist, PHARMAC could establish these. Options to seek advice from already-established groups could include: • gaining access to any regular meetings these groups are involved in (this could depend on their meeting frequency and the level of advice needed, which would likely vary over time) • other options such as email, depending on the nature of the advice being sought.	This option would see us establish a single group comprising representatives of the technical and scientific, service support, and operational groups identified above. Advice from supporting healthcare professionals would be sought separately based on the product in question, as is described in option 1.
BENEFIT	Using representative groups would mean advice could be sought from a range of professionals within a single discipline. As a result, the advice gained would likely reflect a breadth of views and experience, which can differ between DHBs.	This would bring professionals across different disciplines together to hear related views, which could lead to more robust, comprehensive advice.
RISK	The advice we gain from each group would be provided in isolation, whereas in a hospital context, the groups may work together to reach a comprehensive view.	To make this manageable, there would likely be a relatively small number of professionals from each group. This could mean we receive less comprehensive advice.

QUESTIONS – CATEGORY-SPECIFIC ADVICE FROM PROFESSIONALS WITH EXPERTISE IN BROADER DISCIPLINES

17. PHARMAC has listed the groups of professionals with expertise in broader disciplines that we propose seeking category-specific advice from. Are there any other groups that should be included?
18. We have proposed two options for getting category-specific advice from professionals with expertise in broader disciplines. Which option do you think would be most effective?
19. Is there an alternative option that should be considered? What are its risks and benefits?

Detailed use-based advice

It's difficult to identify specific situations that would require this type of advice, or how often it would be needed.

For this reason, we don't consider it possible or necessary for PHARMAC to establish in advance any particular structures for obtaining this advice.

We propose that it's sufficient for us to:

- understand the types of approach we could employ if needed, and what factors might impact on the approach we choose
- be able to tailor options depending on the circumstances.

We would likely seek advice from category-specific advisors on the best way to gather more detailed use-based advice for specific products as we needed it.

QUESTIONS – DETAILED USE-BASED ADVICE

20. PHARMAC has proposed an approach for gaining detailed use-based advice. What are your comments on this?
21. Is there an alternative option that should be considered?

Advice to support exceptional circumstances decisions

In some cases, we would need to seek expert advice to help us make decisions on exceptional clinical circumstances.

We propose that a dedicated exceptional clinical circumstances advisory panel would be established to provide this advice.

This advisory panel would:

- require strong critical appraisal skills
- be available to provide advice at short notice, because of the need to respond rapidly to some requests to access a non-listed device or use a funded device outside of the list rules.

The advisory panel could be made up of:

- a standing membership that's involved in all decisions, or
- a broad pool of members, from which relevant advisors would be identified depending on the specific decision.

If necessary, PHARMAC could also seek category-specific advice to support exceptions decisions.

QUESTIONS – ADVICE TO SUPPORT EXCEPTIONAL CIRCUMSTANCES DECISIONS

22. PHARMAC has proposed an approach for getting expert advice to support exceptional circumstances decisions. What are your comments on this?
23. Is there an alternative option that should be considered?

SECTION 07

Support to implement list changes

Implementing changes locally

Following a decision that results in changes to the national medical devices list, DHBs would be responsible for ensuring their local activity is consistent with these changes.

This means DHBs would be required to take a number of actions, such as:

- choosing which product options they would use locally (this would include making choices based on local product evaluation, if required) where there's a range of equivalent options on the national medical devices list
- updating their local catalogue
- making any necessary operational changes, such as swapping or introducing new products
- Supporting specific training and education required for the new device.

Supporting change management

Where required, PHARMAC would have a role supporting DHBs to carry out these actions. We would engage with DHBs as part of the decision-making process to identify what national support they consider would be needed.

The nature of the national support we would provide would vary depending on the nature of the change.

For example, if DHBs were using new technology as a result of a new listing, or a change to the listed range, we could work with DHBs and suppliers to ensure the following is provided:

- appropriate product information, training and education
- sample products and familiarisation activities
- other resources to support staff to use the new technology.

SECTION 08

Shared responsibilities for contract and supply management

Deciding arrangements for contract and supply management

Responsibilities for contract management and supply management would be shared between suppliers, PHARMAC and DHBs.

Suppliers would be responsible for meeting their contractual commitments, including engaging with DHBs and PHARMAC when there are any supply risks.

PHARMAC would ultimately be responsible for monitoring performance against the contract. This would include receiving quarterly reporting from suppliers and acting as an escalation point for performance issues or supply interruptions that are unable to be resolved at a local level or are persistent.

There are aspects of managing supply that best sit with DHBs, who would need to continue to engage directly with suppliers on these.

We propose that DHBs would be responsible for day-to-day operational aspects of contract and stock management, such as:

- ordering stock
- managing minor ordering and supply issues
- organising supplier-provided services, such as training or servicing, delivered at the local DHB level.

PHARMAC would ultimately be responsible for monitoring performance against the contract.

SECTION 09

We'll all be involved in making this work

Working together to make the change

Since the Government decision to apply the PHARMAC model to hospital medical devices, we've asked for your advice and gained a greater understanding of what our management of medical devices needs to involve.

This has enabled us to propose the broad approach set out in this document. However, there is still a lot of work to do to take things to the next step. We want to keep working closely with you as we do this.

What are the next steps?

After this consultation, we'll summarise the feedback we receive and make this available. We'll also share high-level decisions about our proposals.

Once we've determined the broad outline of the new approach, we'll work with you to develop the operational details.

We will need to work particularly closely with those parties who will have a significant operational role to refine these details.

An important part of this consultation is establishing who will need to be involved in this work, and how we will make this happen.

We will need to do this in a way that's practical, so we're keen for your views on the best way we can achieve this.

We will then consult on aspects of the proposed operational detail, so anyone can share feedback and continue to help shape the approach.

When would the new approach commence?

This will depend on the feedback we receive. We will also need to complete the list we're building of the medical devices that DHBs are currently using before the new approach could be implemented.

From our perspective, the earliest likely date that the new approach could take effect would be 2020. We're interested in your views on factors we will need to take into account, to help determine an appropriate timeline.

When changes of this magnitude are put into practice, it's likely that modifications will be required post-implementation. We will continue to seek feedback, and are committed to making any adjustments necessary on an ongoing basis.

We're interested in your views on factors we will need to take into account, to help determine an appropriate timeline.

QUESTIONS – WE'LL ALL BE INVOLVED IN MAKING THIS WORK

24. Following consultation, PHARMAC will want to identify a timeframe for implementing the new approach. What do we need to consider when deciding on this?
25. Moving to the new approach will involve significant change. How can we make the transition to this new way of working as smooth as possible?
26. PHARMAC wants to ensure that anyone interested can be involved in helping develop the operational detail of the new approach. What aspects of the approach do you want to be involved in shaping further?
27. How do you propose we can most effectively involve you, or the group or organisation you represent, in developing the detail of the aspects you're interested in?

We want your feedback

Summary of questions

The following pages include the specific questions we are seeking your feedback on, but we welcome and will consider all feedback we receive.

We would appreciate your feedback by 5pm on Friday 28 June 2019.

You can provide your feedback in the following ways:

Email
Email your comments or download the editable feedback form and email to:
devices@pharmac.govt.nz

Online
Respond online by going to:
www.pharmac.govt.nz/devices

Post
Respond by post to:

PHARMAC
PO Box 10 254
Wellington 6143

Attn: Medical devices fairer access consultation

The range of devices in scope (Pages 13 - 14)

Through previous consultations, PHARMAC has received significant sector feedback on the content in this section. We don't have any specific questions but will take any further feedback into account.

Deciding what devices to use (Pages 15 - 18)

Proposed principles for the list rules

1. The new approach needs to support PHARMAC to achieve best health outcomes from the funding available, and improve national consistency of access to medical devices. Do the proposed principles for the rules best achieve this, or would alternative principles be better?
2. Once the principles are confirmed, the next step involves developing specific rules which will give effect to the principles. What do we need to consider as we do this?

PHARMAC manages the list (Pages 19 - 24)

Through previous consultations, PHARMAC has received significant sector feedback on the content in this section. We don't have any specific questions but will take any further feedback into account.

Anyone could request changes and contribute to decisions (Pages 25 - 26)

Through previous consultations, PHARMAC has received significant sector feedback on the content in this section. We don't have any specific questions but will take any further feedback into account.

Using devices outside the list rules (Pages 27 - 30)

Exceptional clinical circumstances relating to the person

3. PHARMAC has proposed some exceptional clinical circumstances in which devices outside the list would be considered for funding. Do you think these are appropriate? If not, why not? What suggestions do you have for alternatives?
4. PHARMAC has proposed how decisions on exceptional clinical circumstances would be made. Do you have any comments on this?
5. What would DHBs need to consider when establishing an internal process to make decisions on urgent clinical exceptions and report these to PHARMAC?

Exceptional external circumstances relating to the device

6. PHARMAC has proposed some exceptional external circumstances in which devices outside the list would be considered for funding. Do you think these are appropriate? If not, why not? What suggestions do you have for alternatives?

7. PHARMAC has proposed how decisions on exceptional external circumstances could be made. Do you have any comments on the proposal?
8. What would DHBs need to consider when establishing an internal process to make decisions on urgent external exceptions and report these to PHARMAC?

Decisions would be informed by robust expert advice (Pages 31 - 42)

Overarching advice

9. PHARMAC has described two options for getting overarching advice, and identified the benefits and risks of these. Are there any benefits or risks we haven't captured?
10. Is there an alternative option that should be considered? If so, please clearly describe it and its benefits and risks.
11. Which option do you think would be most effective in providing overarching advice and why?
12. What would need to be considered when implementing the option that you think would be most effective?

Category-specific advice from healthcare professionals with category expertise

13. What do you think of our proposal to use subcommittees to get advice from category-specific experts?
14. If we proceed with the subcommittee approach, are there any new subcommittees that should be added and/or should the scope of any of the proposed subcommittees be changed?
15. What do you think of our proposal to set up sub-groups to provide subcommittees with more specialised advice? Is there an alternative option that should be considered?
16. We've identified which subcommittees we think would have a broader scope of devices to advise on (so would regularly require more specialised advice from sub-groups) and which subcommittees would be considering a narrower scope of products so would occasionally need more specialised advice. Do you have any comments on this proposed allocation?

Category-specific advice from professionals with expertise in broader disciplines

17. PHARMAC has listed the groups of professionals with expertise in broader disciplines that we propose seeking category-specific advice from. Are there any other groups that should be included?
18. We have proposed two options for getting category-specific advice from professionals with expertise in broader disciplines. Which option do you think would be most effective?
19. Is there an alternative option that should be considered? What are its risks and benefits?

Detailed use-based advice

20. PHARMAC has proposed an approach for gaining detailed use-based advice. What are your comments on this?
21. Is there an alternative option that should be considered?

Advice to support exceptional circumstances decisions

22. PHARMAC has proposed an approach for getting expert advice to support exceptional circumstances decisions. What are your comments on this?
23. Is there an alternative option that should be considered?

Support to implement list changes (Pages 43 - 44)

Through previous consultations, PHARMAC has received significant sector feedback on the content in this section. We don't have any specific questions but will take any further feedback into account.

Shared responsibilities for contract and supply management (Pages 45 - 46)

Through previous consultations, PHARMAC has received significant sector feedback on the content in this section. We don't have any specific questions but will take any further feedback into account.

We'll all be involved in making this work (Pages 47 - 49)

24. Following consultation, PHARMAC will want to identify a timeframe for implementing the new approach. What do we need to consider when deciding on this?
25. Moving to the new approach will involve significant change. How can we make the transition to this new way of working as smooth as possible?
26. PHARMAC wants to ensure that anyone interested can be involved in helping develop the operational detail of the new approach. What aspects of the approach do you want to be involved in shaping further?
27. How do you propose we can most effectively involve you, or the group or organisation you represent, in developing the detail of the aspects you're interested in?

Appendix 01: Current device categories

We're working through the categories of hospital medical devices. Here's our progress and timeline.

PHARMAC CONTRACTS*	CATEGORIES WE'RE WORKING ON IN 2018/2019	OTHER CATEGORIES COMING UP (2019/2020)
Anaesthesia small equipment	Audiology	Diagnostic imaging
Disposable laparoscopic devices	Cardiothoracic surgery	Gastroenterology equipment
Endomechanical and electrosurgical	Dental equipment	Invasive ventilation equipment
Haemodialysis	Drapes, gowns and procedure packs	Personal protective equipment
Hand hygiene	Enteral nutrition	Rhythm devices and electrophysiology
Interventional cardiology	Infusion devices	Surgical instruments
Interventional radiology	Laboratory products	Theatre equipment
Needles and syringes	Non-invasive ventilation equipment	Ward equipment
Negative pressure wound therapy	Obstetric and gynaecology	
Orthopaedic implants	Ophthalmology	
Patient warming and cooling products	Patient monitoring (excluding ECG and critical care)	
Respiratory care	Rehabilitation equipment	
Single use instruments	Surgical implants	
Sterilisation packaging products	Surgical suction and wound drainage	
Surgical gloves		
Surgical sutures		
Thermometers		
VTE prevention		
Urology, ostomy and continence		
Wound care products		

**DHBs must use PHARMAC contracts when they buy products listed within these categories.*

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