Consultation feedback

Managing fairer access to hospital medical devices.

September 2019

PHARMAC
TE PĀTAKA WHAIORANGA

New Zealand Government

Contents

Executive summary

Consultation background

PHARMAC conducted a public consultation on its proposal on working in a new way with DHBs, suppliers and others to deliver fairer access to hospital medical devices.

This report provides a summary of responses to consultation. The feedback received ranged from high-level, to thoughts on operational detail. PHARMAC will consider all of this feedback as it determines the next steps.

Further feedback from the sector will be critical to develop and implement the new approach. The timeframe for implementation will be decided once feedback has been considered in more detail.

General consultation themes

Some overarching themes were raised across the consultation responses, including:

- Respondents frequently commented on the importance of PHARMAC remaining transparent in its approach. This included PHARMAC's management of the devices list and decision-making with expert advice.
- Submitters often commented that there are unique differences between medical devices and medicines that mean existing approaches concerning medicines may not be suitable. There was an agreement that expert opinion for devices would be different compared to medicines.
- Appropriate representation was another key overarching theme across submissions. Many submitters felt that groups who might be advising on or making decisions regarding medical devices would need to have the right expertise and experience and reflect a range of opinions including consumers and suppliers.

What was this consultation about?

The consultation on managing fairer access to medical devices outlined the new way DHBs, PHARMAC, suppliers and others are going to be working together.

Under the new approach, PHARMAC would be responsible for deciding which devices are funded for purchase by DHBs for use in the hospital or in the community.

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 list including deciding what gets added or removed.

For further information, and to read the full consultation document, go to www.pharmac.govt.nz/devices

Summary of consultation feedback

Section 1: 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.

There was more support for consumable devices to be in scope than to include capital devices (e.g. major built-in equipment) due to;

- their individual complexities
- associated products
- variation in DHB's situations and needs.

Several submissions commented that devices with multiple functionalities, highly specialised diagnostic equipment, and equipment which has already been made consistent across the country should be excluded from PHARMAC's device list.

Respondents suggested consideration should also be given to the inclusion of devices purchased by DHB-contracted services as this could increase DHB savings, but variation in individual clinical practice may make this difficult.

Section 2: 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.

There was overall support from the submissions for the principles to focus on equity, improving health outcomes and value-based assessment (not just the cost of the device). Several submissions also commented that even cost alone is not straightforward, there are other associated costs such as the cost to train staff, device upgrades and improvements and maintenance.

Other key points raised included:

- Any development of rules needs to be clear, consulted on, consistent and comprehensive.
- Monitoring requirements for compliance with the rules also needs to be considered and sufficiently simple.

Section 3: PHARMAC manages the list

PHARMAC would manage the national medical devices list, including deciding which items get added or removed. PHARMAC's 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.

There was concern with applying a cost-based approach to devices in the same way respondents consider it is currently applied to medicines. It was often argued that devices are unique and a similar approach to medicines could negatively impact on the medical devices market in New Zealand in the following ways:

- reduced competition
- exit of suppliers
- reduced range of products.

Submissions often commented that innovation and access to the latest technologies may be negatively impacted by proposed changes. They felt potential processing times and additional administrative work to make list changes could delay access to medical devices.

Section 4: 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.

Submissions largely centred on the role of DHBs and suppliers. A common theme across respondents was that DHBs should have a key role in requesting changes and contributing to decisions. It was argued that DHBs often have the most information about the devices they use and are in a good position to provide advice.

Suppliers highlighted that they wanted greater transparency regarding changes. They commented that they are most familiar with their devices so should be involved in the decision-making process.

Section 5: 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.

Submissions highlighted that where decisions are made regarding exceptional clinical circumstances, the appropriate people should be involved. Respondents highlighted the crucial role of those individuals who are familiar with the use of the specific devices.

Several submissions, in particular those from suppliers, argued there should also be consideration for exceptional circumstances relating to suppliers and manufacturers. These included; supply chain issues, manufacturing faults and customisable and highly specialised devices.

A key theme across the whole consultation process, but notably within this section, was the need for a simple and transparent decision-making process. Submissions mentioned this would be essential for:

- ensuring consistency across various stakeholders
- national consistency across DHBs
- clarity of the reporting process and roles in reporting
- stakeholders awareness of timeframes for processing and decision-making on exceptions applications.

Section 6: Decisions would be informed by robust expert advice

PHARMAC would need a wide range of expert advice to help it make decisions, and the type of advice sought would depend on the nature of the decision being considered. This would include clinical, technical and operational advice, as well as consumer advice where appropriate.

Three broad types of advice were proposed;

- Overarching advice (a mix of professionals with expertise in critical appraisal across the full set of therapeutic groups)
- Category-specific advice (on clinical, technical and operational aspects of products)
- Detailed use-base advice (gained from hands-on use of products in context)
- Exceptional circumstances advice (expert advice for exceptional clinical circumstances)

All submissions identified that establishing a new devices committee to provide advice, was the preferred option for obtaining overarching advice for decision-making.

All submissions identified that medical devices are category specific and supported using category specific groups for obtaining this type of advice. Furthermore, several respondents highlighted that the success of the category groups depends on the individuals and the expertise they provide, therefore PHARMAC should ensure the individuals in these groups have appropriate and demonstrated expertise.

Many submissions commented that the proposed approach to obtaining category specific advice could become time-consuming and impact on patient care. It was suggested that timeframes and processes be transparent to ensure stakeholders know how long decision-making could take.

Many submissions were concerned that the expertise of existing groups which provide PHARMAC with advice on its medicines activity would not be transferable to devices. However, some submissions did mention that existing groups should still be used so their expertise in decision-making and similar processes can be taken advantage of. Some submissions also highlighted that there is potential benefit in establishing smaller more targeted groups that can provide advice more efficiently.

Section 7: 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.

Submissions considered support would need to include proper change management approaches including plans, training and timeframes in order to assist DHBs implement changes. More broadly however, the full impact of the changes would need to be considered within DHBs; this includes the management of extra costs and user acceptance of approved devices.

Section 8: 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.

Most submissions commented that key stakeholders in this process need to be consulted early on when establishing contract and supply management processes. It was also highlighted that the processes and responsibilities need to be clear to all, especially in case of supply shortages.

Section 9: We'll all be involved in making this work

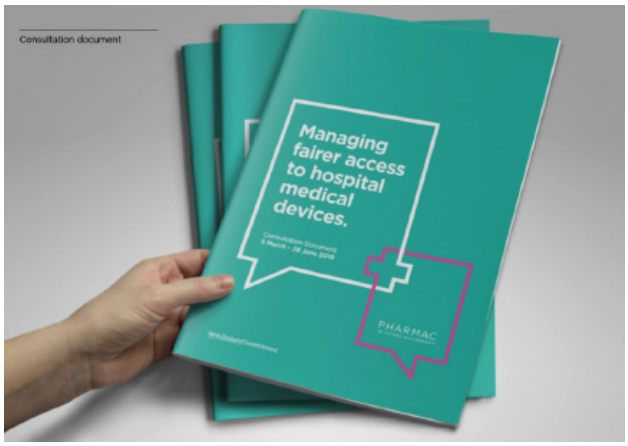
PHARMAC would work closely with stakeholders, including DHBs and suppliers, to keep refining the new approach and identify what support will be needed to put it in place.

Respondents mentioned that there needs to be a significant amount of time for successful implementation of this work, which may require extending the proposed 2020 timeframe. Some submissions also commented that this work should not be implemented until after any changes that may arise from the Therapeutic Products Bill. It was stressed that PHARMAC should take a partnership approach and be transparent with its processes and decision-making.
Many respondents expressed interest in being involved in many different aspects of this work. They suggested a range of methods PHARMAC could use to communicate about, and engage with stakeholders on, this work.

Consultation process

Consultation approach

The consultation on managing fairer access to hospital medical devices described what the next step in PHARMAC's approach could look like, provided more detail on some aspects of the proposed approach and sought feedback on some specific questions about this.



The consultation was open from early March to the end of June 2019.

PHARMAC held forums and attended meetings to promote the consultation. These engagements included:

- promotional forums at all 20 DHBs and with medical devices suppliers
- attending DHB leadership and management meetings including of the Chief Medical Officers, Directors of Nursing, Directors of Allied Health, Chief Financial Officers, Procurement Leads and Product Evaluators Health New Zealand
- presenting to a range of professional organisations.

Attendees were invited to make written responses, and asked to share information about the consultation through their networks. The discussions at these promotional engagements have not been reflected in this summary but, along with all the written submissions, will help inform PHARMAC's next steps.

PHARMAC will continue to work with the sector and seek further feedback to help shape the approach. When and how the new way of working would be implemented is still being considered.

Consultation document and questions

The consultation document provided information across nine sections:

1. The range of devices in scope
2. Deciding what devices to use
3. PHARMAC manages the list
4. Anyone could request changes and contribute to decisions
5. Using devices outside the list rules
6. Decisions would be informed by robust expert advice
7. Support to implement list changes
8. Shared responsibilities for contract and supply management
9. We'll all be involved in making this work

The consultation document included specific questions on four of these sections (sections 2, 5, 6, 9). For the remaining sections, no specific questions were asked as, through previous consultations, PHARMAC has received significant sector feedback. However submitter feedback was welcomed and was received on all parts of the consultation. A summary of the questions can be found in Appendix 2.

PHARMAC provided a range of options for submitters to respond, either online, email or via an editable feedback form.

Submissions

A total of 74 submissions were received. Table 1 provides a breakdown of the submissions by submitter type. Appendix 1 lists the submitters within each group.

The following report is structured around the nine sections in the consultation document. For each area the key themes are highlighted and supported with quotes where appropriate. Information from specific submitter groups has been highlighted in some sections.

Table 1: Breakdown of submissions received by submitter type

Submitter type	Total group
DHBs and their agents	25
Professional organisations	11
Health consumer organisation	3
Suppliers	30
Other health services providers	2
Government	1
Individual	2

Consultation responses

SECTION 1

The range of devices in scope

This section outlined 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.

While no specific questions were asked in this section, a number of submitters provided feedback which has been summarised.

Feedback on the range of devices in scope

The range of devices which are in scope was not clear to all respondents, and there was a call for more information about inclusions and exclusions. In particular, a supplier thought sub-category lists were not comprehensive and items in a large range were missed. More information was also requested about:

- how cost or volume were being used as inclusion criteria
- how the Therapeutic Products Bill affected this work
- how the length of useful life was being factored into the separation of categories
- what devices would be restricted.

Some DHB submitters felt that devices used by a DHB-contracted service should be in scope as ultimately the cost is borne by DHBs. The exclusion of devices used by DHB-contracted services was noted by suppliers, but not identified as a negative or a positive. A DHB respondent also felt that including devices used by allied health practitioners in the scope may be too difficult due to the significant variation in clinical practice.

A few respondents raised the issue that some devices may not be suitable for a list and felt such a broad definition of medical devices needed further work.

Many respondents focused on capital (e.g. major equipment) and consumables when discussing what should be in scope or not. DHB submitters felt that large capital items should not be included. They perceived the efforts to maintain a current list of options to be too resource intensive given how often those devices are purchased.

It was also not clear to respondents if products associated with large capital items, such as software, which is critical for use of the device, were in scope. It was also noted that given each DHB has such a different environment, specialist input at a local level would be needed.

A professional organisation felt that the proposed approach would work well for high use simple consumables with a single function so they should be in scope, but capital devices should not be. However, they recognised that this could be an issue for consumables that are only used with certain large capital devices. One supplier felt that only capital items should be in scope as consumables have short life cycles and are rapidly developed so would require continuous committee review.

There are specific types of devices that respondents felt should be excluded. A professional organisation felt that since implant devices had been made consistent through New Zealand Joint Registry Data, which is based on international registry data, that it would not be necessary for PHARMAC to manage this list.

Multiple respondents considered PHARMAC management could lead to suppliers leaving the market, taking their technical and education support, and could also lead to delays in availability of the device.

A professional organisation also suggested that any piece of highly specialised diagnostic equipment, or equipment with multiple functionalities should be out of scope. It noted that economies of scale would not be achieved, so there would be no financial gain and there would be an increased risk of poor health outcomes.

There was also a desire to include specific devices in scope. A health consumer organisation wanted vital equipment for people with certain diseases, especially if rare, to be included to ensure national consistency and reduce health and safety risks. A supplier also requested that sensory equipment should be in scope to help people in acute mental health situations.

Regarding the inclusion of rehabilitation devices, one DHB group was uncertain if this was appropriate. A health services provider felt that if community rehabilitation devices were included within scope, then these should be categorised into long-term and short-term equipment. This would be consistent with the provider's current pool management systems and would ensure continuity for providers and users.

A DHB submitter suggested that laboratory devices should be excluded because of the:

- complexity of the products
- public/private split
- benefits of dealing directly with the vendor.

The submitter considered a list of laboratory items for bulk purchases may be able to be developed through a collaboration of technical, clinical and scientific experts, if enough time was provided.

SECTION 2

Deciding what devices to use

This section described the principles for deciding what a devices list would mean for DHBs, and considerations for developing rules to support the principles.

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

See Appendix 2 for the consultation questions asked about this section.

Feedback on the proposed principles for managing the list

Overall, submissions were positive about the objectives of best health outcomes and improving national consistency, but more clarification was requested around principles and rules.

A range of other principles were proposed by the following groups:

- DHB groups:
  - Transparency
  - Supporting achievement of equity goals
  - Achieving value for money
  - Access to all tools required to provide healthcare
  - Evidence-based approach
- Suppliers
  - Transparency
  - Fit for purpose – now and in the future
  - Expandable, growable, serviceable
  - Allow for inclusion/community involvement
  - Ease of use for DHB staff
- Individuals:
  - End use should be determined by nurses and specialists
  - Length of time in use
  - How common the devices are

Equity

Regarding the principle of equity, DHB groups noted that DHBs manage their budgets differently and so this will make it more difficult to achieve equity and national consistency. More financially-challenged DHBs would find it difficult to purchase the same devices as more resourced DHBs. There are also some services that are provided by a small number of DHBs eg. Burns Services.

Health consumer organisation responses stated that they did not want cost to be the main driver, because this would potentially negatively affect access to needed devices and increase inequities, especially with variations in regional services. There was also a perception that PHARMAC's approach would serve the majority of people well, but not those who have rare conditions, or who perhaps need more specialised equipment.

Health outcomes

There was concern from many respondents around how the health outcomes would be achieved, and that this wouldn't be achieved if the current principles for medicines are used for devices. Some feedback suggested efficacy of devices does not require the same level of evidence, and the following considerations were highlighted:

- how health outcomes would be measured – quantitatively or qualitatively
- focus on long-term health outcomes, not short-term
- how different models of care will be considered
- how will health outcomes be achieved if access to innovation is limited.

Cost

Overall, respondents think that it would be good to not solely focus on cost, and some wanted to move towards a value-based approach that includes suppliers, procurement and health service providers in the decision-making process. A DHB individual highlighted that there is a difference between being financially responsible and being frugal. A supplier thought that PHARMAC should make the health economics data that it uses, publicly available.

National consistency

Regarding national consistency, there was concern from suppliers that a one size fits all approach would not work and flexibility would be needed as surgeons and other health professionals are trained in different devices. There was also a concern that a nationally consistent approach would not meet regional requirements, particularly where there are already competitive tendering processes that involve relevant clinical stakeholders, and which may not be improved by a national approach. A respondent asked how national consistency would be achieved, if DHBs can select some of the devices on the list and not use others. There was also concern that any reduction in variety to achieve this national consistency would be unfair on DHB staff and device users. It was suggested that a more nationally consistent approach could help reduce duplication of work across DHBs.

PHARMAC considerations for developing specific rules for the principles

Overall, there was support for the rules and principles, but the respondents wanted to know how they would be put into practice and also requested more clarification about what would be a rule, and what would be a principle. Suppliers consistently highlighted the need to use value-based assessments to achieve better health outcomes. It was suggested a wide range of stakeholders would need to be consulted in the development of the rules. Suppliers and DHBs reinforced that the rules would need to be flexible, could not take a one size fits all approach and would need to comply with national and international standards. DHBs highlighted the importance of flexibility in tertiary care to allow for timely patient discharges.

Suppliers expressed interest in working with PHARMAC to develop guidelines for principles and rules. They also said that any rules need to be in line with market and patient requirements, and that if rules restrict the use of a device for certain clinical indications, then this could be detrimental to patients and worsen health outcomes. They also wanted more information about how the rules would be implemented and monitored, and by whom.

A DHB individual queried who could request changes to the devices list. They also asked whether PHARMAC would be transparent about company applications – including which companies have applied for which products and when. This submitter wanted to make sure that all companies would a have a fair chance to submit proposals when the list is being changed.

A supplier wondered how decisions would be made on which devices if there is not consensus. They also submitted that advisers cannot have a vested interest in the devices they are considering.

Submitters considered changing the list, particularly delisting items, must require consultation and clear communication with DHBs and clinicians, especially when there are associated consumables. Decisions should incorporate clinicians' past use of devices, maintenance requirements, and longevity. DHBs would need support for change management, including training and this must be appropriate for the large number of clinical product lines.

DHB specific comments

DHB groups wanted to know how PHARMAC's rules would affect DHB procurement policies and what the purchasing process would be, especially with overseas applications that are not yet supported by trials in New Zealand.

DHB respondents also want to know how compliance with the rules would be informed by data; what infrastructure and investment would be required for monitoring compliance; the consequences of not following the list; and the compliance requirements when there is a product shortage.

Consultation with DHBs at the very beginning of any decision process was considered very important to them. This consultation needs to be extensive, and not just represent part of a workforce. Advisory boards could help make decisions and could include procurement specialists, supply chain experts, biomedical engineers, ICT staff, clinical staff and technical groups.

Feedback suggested there would need to be rules to ensure the list is relevant for specific clinical areas, especially when these are small. One individual from a DHB thought that devices that have been on the list for a long time, should have a higher funding priority.

Submitters suggested that rules around how shortages would be managed would need to be clear to all parties, and support must be available for DHBs in case of shortages. There should be requirements for minimum delivery time, and minimum stock levels, and the requirements for compatibility need to be considered. Respondents suggested that pre-approved suitable substitutes would be needed in case of supply shortages.

Supplier specific comments

Suppliers suggested the following rules for ensuring the whole life cost are considered for the device:

- Purpose
- Urgency
- Long-term or short-term
- Range and alternatives
- Supply back-up

Suppliers also perceive that placing restrictions on the list to cap expenditure would be a blunt instrument, and restrictions should allow for clinical discretion and take into account when indications are broad. Clinician choice should be supported to achieve best health outcomes.

For the disability sector, the rules need to align with the principles of Enabling Good Lives.

PHARMAC needs to recognise the impact of suppliers leaving the NZ market as a result of list changes. Suppliers think it is good that individual DHBs cannot limit the range of user-managed devices.

SECTION 3

PHARMAC manages the list

This section described how PHARMAC would make decisions to fund new devices; how changes to the range of listed products would be made; and how the list of devices would be maintained.

PHARMAC would manage the national medical devices list, including deciding which items get added or removed. PHARMAC's 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.

While no specific questions were asked in this section, a number of submitters provided feedback which has been summarised.

Feedback on the proposed approach to managing the approved device list

A large number of submissions expressed concern with a cost-based approach to medical devices. This approach was viewed by several respondents as being inappropriate and they preferred that devices are also selected based on other criteria such as value, clinician preference, history of usage, supplier technical support and amount of stock. Many submissions suggested that PHARMAC's management of medical devices has the potential to have undesired impacts including a reduced range of products, reduced competition, supplier exit and poorer health outcomes.

"Reducing costs may occur with greater investment in some devices (rather than less) and using clinicians engaged in active clinical change management linked with best practice evidence is important. It may be that greater investment in devices is needed to make overall savings."

– DHB group

Some respondents expressed concern with PHARMAC's approach to managing devices. There was a perception that devices would be managed in the same way medicines are currently managed. A few responses provided detail around the reasons why the approach to medicines would not work for devices. A common response was that the success of medicines and devices is measured differently. For instance, where a clear pharmacological effect might be shown in a randomised control trial; for devices, there are wider considerations such as adoption, user characteristics and organisational impacts.

Many respondents were concerned that potential restrictions around access to devices and process times could hinder access to the latest and most innovative technologies. There was also a concern that necessary safety and performance upgrades to devices that occur routinely may take longer under the proposed changes. There was a concern this could have an impact on both quality of care and health outcomes.

Some responses highlighted a potential impact of PHARMAC's management of the devices list is the exit of suppliers. They commented that New Zealand, in comparison to other markets, is small and it is fortunate to have the number of suppliers it does whom all contribute to the health system in some way. The potential consequences of supplier exit from New Zealand were identified as compromising fair access and reducing competition. It was also noted that it would be difficult to get suppliers to return.

> "Device suppliers tend to require local infrastructure (e.g. service personnel) so once a supplier exits it is a high hurdle to come back into the (very small) NZ market."
>
> **– DHB group**

Many respondents wanted certainty that enough public consultation would occur regarding the general management of the devices list. In particular, many respondents stressed that this consultation would be most important where there are additions or removals from the list. Potential groups identified for this consultation process were DHBs, professional boards, associations, health consumer organisations and national leadership groups.

Several respondents across a range of groups commented on the importance of ensuring devices on the list are supported by evidence. Some respondents identified

DHB specific comments

DHB groups commented on the timeframes of PHARMAC's potential processes and decision making. Submissions discussed that above everything PHARMAC needs to be transparent with its timeframes and ensure patients and clinicians are aware of expected times for applications for changes to the list to be reviewed. DHB groups also commented that PHARMAC must be conscious of internal DHB processes and timeframes in addition to their own when making decisions.

complexities around the testing and research of medical devices which make them different to medicines.

Some respondents articulated that consultation can support this process and most commented that submitters wanted transparency around how evidence on devices was used.

A question was raised about what would be done where listings are conditional, and require evaluation from DHBs, to prevent company representatives creating conflicts of interest through connecting with DHB representatives.

> "Consumers rightly should be sceptical of cost reduction based "value" programs and even more sceptical of promises that those savings will be reinvested in expanded care unless there is real transparency and reporting of the reinvestment."
>
> **– Supplier group**

Supplier specific comments

Suppliers expressed concern that the proposed management of the national devices list would be determined by the amount of funding available. There was a perception this would have a negative impact on patient outcomes.

Suppliers also stressed that they wanted more transparency in the way the list would be managed. Suppliers wanted to know how much funding PHARMAC had available, how PHARMAC would apply the funding plan, and what factors would be considered for a device to be added to the list.

Suppliers considered that there were risks to decision-making power being taken away from users and that access to innovation would be more limited.

SECTION 4

Anyone could request changes and contribute to decisions

This section described allowing anyone to request changes to the list and contribute to decision making.

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.

While no specific questions were asked in this section, a number of submitters provided feedback which has been summarised.

Feedback on the proposal on who could request changes and contribute to decisions

A key theme in this section was DHB involvement in requesting changes and contributing to decisions. Several responses outlined that DHBs often have the most information about the use of products within clinical environments and are in a good position to advise when a product is not effective.

One response highlighted that existing processes established in DHBs might support requesting changes and input on decisions. It was noted that existing processes have been successful at managing clinicians who might ask for products that are not necessities. Another response raised an opposing view and mentioned that all clinicians should be able to add inexpensive everyday items.

Suppliers overall highlighted they wanted greater transparency of changes to the list. They would appreciate being a part of the decision-making process as they are most familiar with their devices and can potentially provide useful information to support decision-making.

There was also concern that DHBs would not hear about innovative products if suppliers predominantly deal with PHARMAC.

SECTION 5

Using devices outside the list rules

This section described the exceptional circumstances, relating to the person or the device, which would support devices being used that are not on the list.

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.

See Appendix 2 for the consultation questions asked about this section.

Exceptional clinical circumstances relating to the person

Feedback on proposed exceptional clinical circumstances relating to the person

A common theme was that there should be exceptional circumstances relating to suppliers. Some suggested covering circumstances such as manufacturing faults, supply chain issues and customisable and highly specialised devices.

Many submissions highlighted that the process around decision-making would need to be transparent to key stakeholders such as suppliers. This would ensure that suppliers can have their own processes in place to avoid access issues as a result of supply chain delays and manufacturing faults.

Many responses commented that it is difficult to provide feedback unless there is more clarity on what is defined as urgent and non-urgent circumstances and asked for examples.

How decisions on exceptional clinical circumstances might be made

A common theme was ensuring that the appropriate people would be involved when decisions around exceptional clinical circumstances are made. Some respondents expressed discomfort with PHARMAC making clinical decisions noting it lacks sufficient clinical expertise and is removed from the reality of clinical decisions. A few responses mentioned that including clinical people in the decision making would be wise and may allay concerns that exceptional clinical circumstances may not be understood by PHARMAC.

A few submissions noted that the approach of not all DHBs having access to the same devices (as may occur through an exceptions process) was contrary to national consistency of access to medical devices.

Several submissions raised the importance of a simple and transparent decision-making process. Simplicity would help ensure correct reporting, and ensure it is clear who is reporting on what and when. Transparency would be with the intent that all key stakeholders including suppliers are aware of requests and would ensure all stakeholders, particularly DHBs, are following the same processes. In discussing transparency, many submissions also mentioned clarity on timeframes. They commented that timeframes around decision making must be clear to all stakeholders so that groups such as suppliers can ensure devices can be sourced in a reasonable amount of time.

A few responses highlighted their concern with the potential for a blanket or "one size fits all" model to be applied to all exceptional clinical circumstances. Several responses noted that each exceptional clinical circumstance can be different and may require special consideration.

DHB specific comments

Some DHB respondents highlighted that the processes outlined by PHARMAC both for urgent and non-urgent decisions could have a high administrative burden on providers. It was mentioned that those providers who might be dealing with the most extreme clinical circumstances could face a disproportionate amount of the administrative burden.

Some DHB respondents mentioned that they have their own existing internal processes for managing devices. They commented that the introduction of the proposed processes by PHARMAC may clash with these internal processes and would be unnecessary as they work. A few respondents suggested that PHARMAC consult further with DHBs to better understand how their process may supplement internal processes within DHBs.

Considerations for DHBs when establishing internal processes

Several submissions highlighted that greater clarity was needed on the internal processes supporting urgent decisions. Some submissions raised that some DHBs have long-established internal processes that work well for them and a new process may not work as well. A few submissions commented that smaller DHBs may be unfairly impacted as they do not have as many staff and as great an infrastructure as larger DHBs.

Some submissions raised that DHBs would need to also consider procurement and supply of devices under urgent clinical circumstances. They mentioned that, while devices may be approved for a person in an urgent circumstance, there is no guarantee that the device is either in stock in New Zealand or can be sourced quickly. A few submissions inferred that suppliers have little incentive to keep devices stocked in New Zealand if they are de-listed.

DHB specific comments

A key concern raised by DHBs was that the proposed approach outlined by PHARMAC would result in a high workload that would further pressure already strained staff and infrastructure. Some responses highlighted that, in addition to not having enough staff to manage the workload, they may not have the right expertise.

Supplier specific comments

Supplier groups frequently commented that clinician involvement in decision making was paramount. They highlighted that DHBs should be considering how best to involve clinicians as they have clinical knowledge, experience in medical devices and understand the patient's medical history.

Exceptional external circumstances relating to the device

Proposed exceptional external circumstances

Several submissions commented that the circumstances identified were appropriate and did not require any modification. Few responses commented specifically on the proposed external circumstances relating to the device.

How decisions on exceptional external circumstances might be made

Overall submissions largely raised the same points made in response to the question focussed on exceptional clinical circumstances relating to the person and how decisions might be made. Many responses again raised the importance of standardisation and simplicity in reporting to PHARMAC to help reduce administrative burden on DHBs. A few submissions also commented that resources such as templates and forms could support standardisation across DHBs and speed up the process. Similarly, many respondents highlighted the importance of appropriate groups being included in decision-making under urgent circumstances and that these groups are represented.

A few submissions commented that PHARMAC should be aware of devices that have been used in the past for exceptional circumstances. It was suggested that PHARMAC should support the continuity of care and support for these devices by retrospectively approving them.

Several submissions highlighted their support for DHBs to have control over decision making in exceptional circumstances. They agreed that DHBs should be able to make necessary urgent clinical decisions and then report to PHARMAC. It was commented that this enables urgent decision making to be closer to the team involved in the patient's care and avoids communication delays.

Supplier specific comments

The importance of transparency of decision making was common across all groups however supplier groups in particular commented that they wanted to be made aware of approval decisions through regular reporting.

Considerations for DHBs when establishing an internal process to make decisions on urgent external exceptions

Many submissions identified the need for greater clarity on how PHARMAC will either replace or complement established internal processes in DHBs. It was also noted that procurement and supply could potentially be difficult for devices that are not listed.

One submission commented that it is important all DHBs are aware of PHARMAC's goals and the framework they are operating within.

One submission highlighted the importance of monitoring and data collection. They commented that data should be collected when exceptions arise as they may indicate issues with existing devices.

One submission commented that DHBs should consider a range of factors when assessing devices for urgent exceptions. These factors include support from suppliers, patient outcomes and the experience of the supplier in the New Zealand market.

> "DHBs are encouraged to assess the manufacturers/ supplier's tenure and experience in the NZ and/or Australian market including the clinical performance of the device, the expected patient outcome and the level of support provided by the device manufacturer/ supplier throughout the continuum of care."
>
> **– Supplier group**

SECTION 6

Decisions would be informed by robust expert advice

This section explored the options for PHARMAC obtaining expert advice to inform decisions.

See Appendix 2 for the consultations questions asked about this section.

PHARMAC would need a wide range of expert advice to help it make decisions, and the type of advice sought would depend on the nature of the decision being considered. This would include clinical, technical and operational advice, as well as consumer advice where appropriate.

Three broad types of advice were proposed;

- **Overarching advice (a mix of professionals with expertise in critical appraisal across the full set of therapeutic groups)**
- **Category-specific advice (on clinical, technical and operational aspects of products)**
- **Detailed use-base advice (gained from hands-on use of products in context)**
- **Exceptional circumstances advice (expert advice for exceptional clinical circumstances).**

Overarching advice

Responses to PHARMAC's two identified options for obtaining overarching advice

Option 2 (having a separate medical device committee in parallel to the Pharmacology and Therapeutics Advisory Committee (PTAC)) was the strong preference across all submission groups.

Most submissions commented that medical devices differ to medicines and would require a tailored approach that they consider PTAC is not capable of providing. It was considered that establishing a new committee to provide advice would best serve medical devices as the group knowledge would be more appropriate and specific.

Several submissions highlighted that adding expertise to PTAC (Option 1) may not match the potential increased workload that would arise from the management of devices. There was also concern that adding to PTAC's workload risks compromising existing medicines processes.

A few submissions preferred option 1; they felt this was appropriate due to the reasonable overlap between medical devices and medicines. Moreover, some submissions commented that the experience of PTAC could prove useful in establishing and supporting a new process for devices.

> "The decision-making process needs to be transparent, with public participation supported throughout the decision-making process, not just towards the end."
>
> **– Health Consumer Organisation**

Several submissions commented that the advice process was largely clinician-focussed and lacked consumer input. They felt that more work was needed to ensure consumer interests are accurately represented in decision-making and that this decision-making is transparent to the public.

Several submissions commented about the importance of involving specific groups and individuals such as Product Evaluation Health NZ (PEHNZ), infection prevention

Supplier specific comments

Supplier groups frequently commented about their absence from the advice process. Most submissions highlighted that suppliers and device manufacturers are best equipped to provide information about their products. The submissions argued that suppliers should be included as expert advisors in the process.

and control, cleaning/sterilisation services and allied health professionals.

Several submissions suggested that a general medical devices committee be supported by subcommittees that could be established for managing complex device categories which require specialist expertise. A few submissions suggested including advisors other than clinicians, and clinical evidence. It was suggested that groups such as health administration, health population policy, consumer representation, health economics, manufacturer's industry representation and specialist clinical and nursing, also be included.

A few submissions commented that when seeking expertise PHARMAC should use groups that have been established and have expertise in medical devices.

A few submissions commented that advisors should be limited to clinicians and health professionals and should exclude suppliers and vendors.

> "This group (option 2) would have a clearer focus on devices and be specifically developed with the necessary expertise to support decisions – with the right membership in this group there will be trust and faith that PHARMAC will make well informed decisions."
>
> **– DHB group**

Considerations for implementing the most effective option

Most submissions commented that it was necessary to identify the most appropriate people and groups for advice. Several submissions highlighted that existing groups can be used to both aid in access to experts and avoid the duplication of groups.

Several submissions mentioned that there is greater clarity needed around how these groups might meet and through what medium (digital, face to face).

A few submissions suggested providing more detail about the scope of responsibility of the groups, the steps, and the timeframes around decision-making.

Category-specific advice from healthcare professionals with category expertise

Responses to proposal of using subcommittees to get advice from category-specific experts

Most responses commented that having subcommittees to obtain advice from category-specific experts was a good idea. The submissions noted that as devices can be highly specific, people experienced with particular categories should provide advice on these. Some submissions, while supportive of the idea, noted that the quality of category-specific advice would be dependent on the individuals who provide the advice. It was suggested that PHARMAC ensure the individuals in these groups have appropriate and demonstrated expertise in this field.

A few submissions highlighted that PHARMAC should be aware of supplier interest in these groups. They suggested that this interest should be monitored and managed to ensure the groups are able to provide unbiased and trustworthy advice.

A few submissions suggested that PHARMAC obtain advice on how to treat devices that cross over between categories. They highlighted that not all devices will be clearly in one category and their placement may impact on what kind of advice can be obtained.

Feedback on additional subcommittees that might be added and the scope of proposed subcommittees

Several submissions commented that additional subcommittees to those identified could be a good idea but highlighted that they may result in additional processes which could result in decision delays. It was often suggested that these groups are kept small and agile so that decision-making is not slow and access to devices is not impeded.

A few submissions highlighted that it is difficult to provide feedback on these subcommittees as they do not exist yet. They suggested waiting until the subcommittees have been established and have been running for some time to observe how they function and make any improvements.

Several submissions highlighted some categories of devices that may need special consideration, including:

- Separating anaesthesia & respiratory
- Equipment
- Laboratory
- Orthopaedic
- Enteral feeding
- Infection prevention

A submitter noted an opthalmology subcommittee was not included in the proposed list.

Responses to proposed approaches to provide subcommittees with more specialised advice

Many submitters commented that the establishment of sub-groups to provide subcommittees with more specialised advice, either regularly or occasionally, was a good idea. They noted that medical devices are broad and a large number of committees and subcommittees may be needed.

There were similar comments made in response to the previous questions, including about the:

- importance of the transparency of these groups
- cost and time impacts of establishing additional groups
- need to manage supplier interests and bias
- need for appropriate representation from a wide range of stakeholders including consumers and suppliers as well as clinicians and others involved in the selection of and support for medical devices.

A few submissions raised that because of the differences between some categories, some could require more time and expert input than others. They outlined this should influence how regularly and often groups meet and how much time is required of the respective experts.

A few submissions highlighted that it could be difficult to secure stable group membership. These submissions outlined that long-term consistency of advice depends on consistency of membership and PHARMAC needs to be conscious of how individuals are appointed, and of membership agreements. A few submissions commented that the criteria for decision making needs to be clear to all involved to ensure consistency between committees and subcommittees.

Category-specific advice from professionals with expertise in broader disciplines

Suggestions for additional groups to be included

Submitters suggested a range of groups should provide category specific advice:

- Health professionals including: Medical physicists, dieticians, primary care, occupational therapists, physiotherapists, mental health experts, sterile services, speech language therapists
- Other professionals including: finance professionals, sustainability managers, sterile services
- Consumers and funders.

Suggestions for getting category-specific advice from staff with expertise in broader disciplines

Seeking advice from individual sector groups was preferred by some submitters. They felt that more targeted groups would be in a better position to make accurate judgements about products as they have a better understanding of the products, and the desired outcomes. They may also assist in accessing existing groups for further advice if needed, without forming subcommittees.

If a collective of representatives of technical and scientific, service support, and operational groups is established to provide advice, the collective should be established through these individual groups and seek advice from them.

Potential alternative options for consideration

Submitters considered that the two proposed options (gaining advice from a collective or from individual groups) would be appropriate, with either option being able to be used depending on the device and the complexity. PHARMAC should consider that suppliers can also share their knowledge and information with these groups.

Obtaining use-based advice

Most submissions agreed that PHARMAC's proposed approach was appropriate and appreciated the tailoring of options depending on circumstances. However, many responded that the approach outlined lacked clarity and in particular they wanted more detail about what PHARMAC meant by use-based advice.

A few submissions commented the establishment of another group for this purpose may be unnecessary and could add delays to the process. It was suggested that PHARMAC use the proposed category-specific experts.

Similar to responses to earlier questions, a few submissions commented on the importance of including consumers in decision-making.

A few submissions expressed concern with PHARMAC making decisions regarding medical devices on its own. The submissions highlighted that PHARMAC should be considering the expertise of clinicians and health professionals generally and also for exceptional circumstances.

Supplier specific comments

Suppliers often commented that they have extensive knowledge of the application and use of medical devices and should be involved, by some mechanism, in providing use-based advice.

Most suppliers suggested that PHARMAC establish processes for accessing the knowledge that suppliers have and were eager to work with PHARMAC to provide advice.

Advice to support exceptional circumstances decisions

Responses to PHARMAC's proposal to getting expert advice to support exceptional circumstances decisions

Many submissions raised concerns that this process may be time consuming which may impact on clinicians being able to provide patients with the necessary care. It was suggested that timeframes are transparent to all stakeholders and that there should be an effort to reduce delays where possible.

Some submissions commented that PHARMAC may face difficulty in accessing appropriately qualified people to provide advice within tight timeframes. It was suggested that PHARMAC have a more flexible approach and include a range of people from many categories in decision-making. Some submissions suggested that involving existing experts who are involved in committees and subcommittees would make use of their existing understanding of the decision-making process.

A few submissions highlighted the potential for the integrity of these groups to be compromised by conflicts of interest. It was suggested that membership of these groups is transparent to the public and any conflict of interest is identified.

A few responses highlighted the importance of involving consumers but more specifically those with the exceptional circumstances.

> "We would recommend that this panel be made up of a cross-section of existing membership involved in the Committee/subcommittees. This will enable an existing understanding of process and the broader context within which these decisions will be made."
>
> **– Supplier group**

SECTION 7

Support to implement list changes

This section described what support would be available for implementing 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.

While no specific questions were asked in this section, a number of submitters provided feedback which has been summarised.

"The development of transition plans for introduction of new products is not mentioned. These are critical for DHBs to move from one product to the another. These should be agreed for each contract between the DHB sector and the supplier. PHARMAC needs to manage that process transparently."

– DHB group

Feedback on supporting the implementation of list changes

Submitter feedback focused on effective change management. DHBs need adequate training, information, transition plans, clear timeframes and additional resource for the changes to ensure normal activity is not impacted. DHBs advised avoiding periods of increased demand and times of reduced staff levels. Suppliers regularly offer training programmes, and also carry out product-specific launch seminars.

The use of one database of devices across all DHBs could make it easier to communicate changes and require less resource to keep updated. Suppliers also requested easy forms of communication and ways to submit lists of devices and technical requirements.

Submitters identified that when implementing changes, PHARMAC needs to ensure the full extent of the impact of the change is considered, even if the change is perceived as small. While this is most commonly for DHBs, small changes could be a big issue, especially around comfort with the device, for consumers. Submitters noted that there needs to be agreement about how extra costs will be managed, and what would happen if clinicians refuse to use the listed devices.

Supplier specific comments

Suppliers highlighted the importance of timeframes in terms of sourcing devices to New Zealand in time after a decision had been made.

SECTION 8

Shared responsibilities for contract and supply management

This section sought feedback on PHARMAC's proposed approach 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.

While no specific questions were asked in this section, a number of submitters provided feedback which has been summarised.

Feedback on contract and supply management

Key feedback themes focused on the sharing of information between organisations and what happens in case of device shortages. Respondents believed that PHARMAC's monitoring needs to include reporting back to DHBs, and that reporting should be streamlined to reduce duplication and increased efficiency, with the reasoning behind the different reporting requirements clear.

A key component, from all respondents, was that there must be sufficient consultation before any contracts are agreed to try to minimise issues arising later on. Expert panels should be used, and the timeframe for implementation should be clear.

In case of supply shortages, there needs to be clear processes, roles and responsibilities for all involved for how to manage these. Feedback loops should be created between DHBs, suppliers and PHARMAC in case of shortages. There also needs to be clarity around contact points for contract and device category management queries for easy escalation of issues.

DHB groups wanted similar processes for managing product shortages and recalls. They also want to know what the process would be if a company consistently has supply issues. In particular, at what point would PHARMAC list an alternative, and who would be managing suppliers at a strategic level.

DHBs provided feedback that they would not spend their own money on equipment to fill gaps in the list. They also considered PHARMAC has the resources and is able to manage shortages more efficiently. There was a suggestion that DHBs could manage supply issues with suppliers on a rotating basis as their resource allows.

The view was raised that there needs to be sufficient local device suppliers in the market to protect supply.

A health service provider which manages equipment supply, and states that it has a simple and agile process, felt that PHARMAC's involvement could add an unnecessary layer of management.

DHB specific comments

DHBs were worried about the resource implication for them when shortages happen. They want clear communication about processes, and information flow between DHBs, PHARMAC and suppliers.

Supplier specific comments

Suppliers commented they need to manage who is servicing the equipment. They need training and qualified technicians to ensure the right parts are used, the useful life of the device is not affected and there is no risk to the functionality of the device, and therefore the end user.

Suppliers also noted effective supply management requires an understanding of future demand, and this needs to be considered when changing the list. Timeframes for delivery need to be considered, especially if parts are not usually stocked in New Zealand. There was also a comment that stock should be held at hospitals, and not by suppliers.

SECTION 9

We'll all be involved in making this work

This section identified that everyone would need to be involved in this new approach, and timeframes.

PHARMAC would 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.

Respondents thought that clearly signalled timeframes are very important. They identified key considerations for timeframes included allowing enough time for PHARMAC to:

- generate the full list
- establish advisory groups
- undertake full consultation with stakeholders.

Respondents also wanted enough time for them to share information amongst multiple parties and ensure the information is clear and feedback mechanisms are in place.

Some respondents did not think that 2020 was a realistic date to implement the new approach. Suppliers in particular submitted that PHARMAC should consider not implementing any changes until the Therapeutic Products Bill is implemented.

DHB specific comments

DHBs emphasised the large volume of work required and the potential to consider a phased approach. They stressed the importance of allowing for sufficient time to clarify responsibilities, confirm structures, purchase stock and ensure that it does not put too much resource pressure on DHBs. They noted consideration needs to be given to the infrastructure and technology requirements, and the variation between DHBs. They wanted to understand what are the targets, objectives and incentives to meet PHARMAC's objectives.

Supplier specific comments

Suppliers noted that medical device companies are much smaller than pharmaceutical companies, and so cannot manage too many significant market changes at once (e.g. Therapeutic Products Bill and PHARMAC's changes). They want to ensure DHBs are given enough time to set up their new processes and train staff. They also noted the need to assess the risk of the change on patient outcomes.

How best to manage the change to the new approach

Submitters considered PHARMAC must consult widely and extensively. PHARMAC should take a partnership approach and could consider roles such as DHB account managers. Transparency around processes and funding, and clear and timely communication are very important to many respondents. Suppliers reiterated that PHARMAC should wait for the Therapeutic Products Bill to take effect.

Submitters commented that PHARMAC needs to address clinical risk and liability, and assign responsibility. PHARMAC also need to be careful not to implement changes when there is increased demand at hospitals. Other suggestions included forums for complaints, a review of international best practice, developing a clear evaluation methodology for assessing the value of medical devices, and educating companies.

Aspects of the new approach that submitters expressed interest in

Many respondents expressed an interest in being involved in all parts of developing the new approach. The key points noted were around the ability to identify committee members and ensure the right skill mix.

The beginning of the process is a key time to engage submitters. There was a range of interest from DHBs in participating in different aspects of the new approach from a range of groups, including medical and nursing staff, technical and operational DHB staff (including procurement, supply chain, biomedical and laboratory staff) and DHB leadership and management.

How best to involve stakeholders in specialist areas

Most respondents focused on the need for PHARMAC to effectively engage with stakeholders, not how best to involve them. Respondent groups identified the following key groups or methods for engagement:

DHBs

- Electronic communication
- Road shows
- Forums with Chief Medical Officers, procurement leads,
- Key liaison person within the DHB
- Connect with leadership groups

Professional organisations

- Engage with clinical societies and colleges

Suppliers

- Face to face meetings and feedback forums
- Small round tables with PHARMAC and clinicians with targeted discussions
- Publish minutes of subcommittee meetings

Appendix 1: List of consultation submitters

DHBs (and their agents)

Submissions came from a mix of national DHB groups (and agents of DHBs), individual DHB groups and staff.

Auckland DHB, Paediatric inpatient dietitians at Starship Child Health

Auckland DHB, Renal Medicine

Canterbury DHB, Nutrition and Dietetics

Canterbury DHB, All DHB

Canterbury DHB, Clinical Engineer

Canterbury DHB, Canterbury Health Laboratories

Capital & Coast DHB, All DHB

Capital & Coast DHB, Choosing Wisely committee

Capital & Coast DHB, NICU

Capital & Coast DHB, Nurse Educator

Counties Manukau DHB, Infection Services

Counties Manukau DHB, Implementation Specialist

DHB Chief Medical Officers

Hawkes Bay DHB

healthAlliance (FSPC) (with some feedback from Waitemata & Auckland DHB staff)

Hutt Valley DHB, Occupational Therapy

MidCentral DHB, All DHB

MidCentral DHB, Registered Nurse

New Zealand Heath Partnerships

Product Evaluation Health New Zealand (PEHNZ)

South Canterbury DHB, Radiology Services Manager

Waikato DHB, Allied Health Managers

Waikato DHB, Procurement and Supply Chain

Waitemata DHB, Procurement

Professional organisations

Australian and New Zealand College of Anaesthetists

Heart Rhythm New Zealand

New Zealand Orthopaedic Association

New Zealand Sterile Sciences Association

New Zealand Medical Association

New Zealand Nurses Organisation

New Zealand Society of Anaesthetists

Royal Australasian College of Surgeons

Royal Australian and New Zealand College of Radiologists

Royal Australian and New Zealand College of Ophthalmologists

Royal Australasian College of Physicians

Other health services providers

Enable New Zealand

Southern Cross Health Society & Southern Cross Hospitals

Health consumer organisations

Federation of New Zealand Ostomy Societies Incorporated

Breast Cancer Aotearoa Coalition

Cystic Fibrosis New Zealand

Suppliers

3M
Alcon Laboratories (Australia) Pty Ltd
Asia Pacific Medical Technology Association (APACMed)
Assistive Technology Suppliers New Zealand
Baxter
Becton Dickinson
BIOTRONIK Australia Pty Ltd
Carl Zeiss New Zealand Ltd (ZEISS Group)
Coloplast
Cubro
Downs Distributors Ltd
ECS Diatec
Edward Lifesciences
Essity Australia (BSN Medical)
Fisher & Paykel Healthcare
Fujifilm SonoSite Australasia Pty Ltd
GE Healthcare
Intermed
Jackson Allison
Johnson & Johnson Medical PTY Ltd
Lohmann & Rauscher
Medical Technology Association of New Zealand
Medtronic
Permobil New Zealand
Philips Electronics Australia Ltd
Protec Solutions Ltd
Sensory Corner
Stryker
Toomac Holdings Ltd
Universal Specialties Limited

Government

Ministry of Health, Data & Digital

Note: The two individual submitters are not listed.

Appendix 2: Summary of questions

The consultation document included specific questions on four sections (sections 2, 5, 6, 9). For the remaining sections, no specific questions were asked as through previous consultations, PHARMAC has received significant sector feedback. However submitter feedback was welcomed and was received on all parts of the consultation.

The range of devices in scope

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

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

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

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

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

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

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

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

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?

PHARMAC
TE PĀTAKA WHAIORANGA

New Zealand Government