Managing fairer access to hospital medical devices.

Feedback form
Due 5pm, Friday 28 June 2019

PHARMAC
TE PĀTAKA WHAIORANGA

New Zealand Government

Thank you for taking time to give us feedback

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.

This form includes the questions we're particularly interested in your responses to as part of this consultation. It also provides space to share your thoughts on any aspect of our proposals. We suggest you complete this form in conjunction with reading the consultation document **www.pharmac.govt.nz/devices**

The feedback boxes will expand to capture all the comments you wish to make.

Once completed please email this form to **devices@pharmac.govt.nz**

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

Any feedback we receive will be subject to the Official Information Act 1982. You can find out what this means on page 5 of the consultation document.

ABOUT YOU

Name

Dr Ingrid van Rijn

Role

Executive Officer

Organisation (if applicable)

Assistive Technology Suppliers New Zealand

THE RANGE OF DEVICES IN SCOPE

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

If you have no feedback please move onto the next page.

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?

The general principles need to be:

- fit for purpose

- expandable/growable/serviceable

- allow for inclusion/community involvement

These principles seem to take autonomy in decision making around which devices are used away from the users. The length of the list in each category will determine how much flexibilty the users have in each category. Inclusion of a large number of options will facilitate a better uptake of/comformity to the approach.

There is a considerable risk that fairer access to hospital medical devices will actually be compromised with a focus on cost reduction and ATSNZ suggest that Pharmac should take a value-based approach that depends on collaboration between healthcare providers, procurers and medical technology suppliers. The value-based approach will likely lead to achieving better outcomes and cost-efficient healthcare, resulting in the economically most advantageous offers. A cost based approach will likely lead to a reduction of the quality of our health care system.

The principles developed by Pharmac do not reflect an understanding of the complexities of the interplay between clinican capabilty and medical technology. These principles are currently not generating confidence in Pharmac to deliver mutually beneficial outcomes.

National consistency in access to medical devices would not necessarily lead to better health outcomes. The wide range of products and the hugely varying levels of complexity brings significant challenges to this focus. Procurement in powered wheelchairs for example over recent years has been hampered by lengthy trials because of the complexity in matching a product to a users needs. The situation is affected by stock levels of different products needed in the process. There is a cost to holding stock which needs to be balanced by businesses and this needs to be taken into account by Pharmac when developing an approach that requires national consistency of access to medical devices.

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?

The rules need to take into account the fundamentals of the Enabling Good Lives strategy, where choice and control are important in facilitating better lives for disabled people. A seemless transition from the hospital environment to the community environment needs to be considered when developing specific rules.

The Enabling Good Lives strategy aligns to the New Zealand Disability Strategy 2016-2026. The outcomes defined in this strategy are also relevant in Pharmac decision making and the rules developed need to align to this overarching strategy. The bold goal that Pharmac can save a $1BLN by 2025 suggests a single-minded focus on cost reduction, without concern for the Disability Strategy goals. Cost efficient heathcare does not necessarily result in a major cost saving, as higher expenditure may be requried to achieve better health outcomes, which should be the ultimate focus.

Principles and rules must support the continued supply of innovative medical technology to New Zealand in a timely manner. Restrictions on choice will likely have a negative effect on outcomes in the long term. There is a significant risk of losing access to essential training and technical support, the benefits of competiton, stifling innovation, limiting the products and therapies available to patients, and reducing the number of full service medical device suppliers in New Zealand.

Restrictive rules will not serve better health outcomes, so there needs to be a hgh level of flexibility in the rules Pharmac will be developing. Consultation with stakeholders in this process is paramount to achieving the desired outcomes of better health and fairer access. We would hope to be involved in further stages of development.

PHARMAC MANAGES THE LIST

Through previous consultations, PHARMAC has received significant sector feedback on the proposed approach to managing the list. We don't have any specific questions but will take any further feedback into account.

If you have no feedback please move onto the next page.

Acknowledgement that many products in the medical devices categories are not high volume or high cost needs to be recognised, so that products can be purchased by DHBs outside of the list.

ANYONE COULD REQUEST CHANGES AND CONTRIBUTE TO DECISIONS

Through previous consultations, PHARMAC has received significant sector feedback on the proposal on who could request changes and contribute to decisions in this section. We don't have any specific questions but will take any further feedback into account.

If you have no feedback please move onto the next page.

Transparency is key to building acceptance of the proposal. Where successful funding requests lead to exclusion of other suppliers, transparency in the process from the beginning is important.

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?

There needs to be more consultation and clarification around what exceptional clinical circumstances may be. Transparency around when this occurs would benefit further understanding and management of funding options.

4. PHARMAC has proposed how decisions on exceptional clinical circumstances would be made. Do you have any comments on this?

How much variation is there in a listed product. There are many medical devices that have considerable complexity added. If the variation in listed products is significant, the likelihood of requests as exceptional circumstances will be high.

It is recommended that a one-size-fits-all approach not be applied in assessing these cases. The expert view of the clinician, in addition to the views of the patient and/or their advocate need to be the most important factors in the consideration criteria.

5. What would DHBs need to consider when establishing an internal process to make decisions on urgent clinical exceptions and report these to PHARMAC?

Choice and control should sit with patient and clinician and not be severly resticted by Pharmac. A simple and flexible process is what is required.

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?

Pharmac currently appears to have a limited ability to foresee exceptional cirmcumstances and therefore needs to relinquish some level of control in these situations. In urgent situations DHBs should have the autonomy to make the decision, based on clinical need and report to PHARMAC after the fact. Pharmac over time will improve their ability to foresee exceptional circumstances and will be in a better position to manage to their remit.

7. PHARMAC has proposed how decisions on exceptional external circumstances could be made. Do you have any comments on this?

We would expect DHBs to inform the manufacturer/ supplier, through regular reporting, on all exceptional circumstances decisions made".

It would be appropriate to establish a feedback mechanism to ensure PHARMAC can reconsider funding for "exceptional" device use that over time proves useful.

This is a more suitable model as it vests responsibility for clinical care decisions in the DHB, as is appropriate. Therefore, we support that in urgent situations that DHBs would make the decision and report to PHARMAC.

8. What would DHBs need to consider when establishing an internal process to make decisions on urgent external exceptions and report these to PHARMAC?

How a DHB manages their internal process will differ from DHB to DHB and reporting to PHARMAC would be in consultation with the Clinicians.

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?

The consultation document does not define a role for industry in the current advice framework.

Manufacturers are experts in the regulatory, clinical, safety and quality aspects of their products. Highly trained, technical specialists provided by companies play an integral role in training clinicians to bring about the best patient outcomes. Furthermore, manufacturers play an integral role in advising how medical technologies can be used in this context to appropriately integrate with other equipment and surgical factors.

There is a risk that under the PHARMAC proposal, decisions to fund a medical device are made in isolation of essential input from the manufacturer and supplier of the device being assessed.

Therefore, we would highly recommend the inclusion of industry technical advice when seeking all three aspects of advice but crucial in complex "category-specific advice"

10. Is there an alternative option that should be considered? If so, please clearly describe it and its benefits and risks.

Could have a subcommittee of PTAC that effectively looks at aspects outside of the clinical evidence, such as inclusion and community benefit.

The industry is concerned that the new committee will be limited in access to evidence-based evaluation data for a medical device.

11. Which option do you think would be most effective in providing overarching advice and why?

Option 2.

Diverse range of products and clinical need of patients. It's not just about an improved medical outcome but also lifestyle outcomes.

12. What would need to be considered when implementing the option that you think would be most effective?

There is a need for Professional Advisors, not aligned to the current infrastructure. It would be inappropriate to use Enable/Accessable Professional Advisors currently in their employment.

Time to market is crucial for medical devices as iterative improvements in safety and/or performance are often introduced within 18-24 months. PHARMAC must consider an option that reduces the time to fund a device to avoid the supply of what would be considered “old technology” that has been superseded with improved and more effective technology. In many cases, there is limited scope for manufacturers to continue supporting “old technology” with spare parts or servicing in a small market, such as NZ.

The industry is very concerned that PHARMAC’s current process is too slow to ensure NZ has access to innovative medical technology that can improve patient outcomes and ensure clinical choice for what is best for the patient.

The industry rejects management of medical devices expenditure in the form of a “capped budget”. Devices are not subject to generic replacement which drives global drug prices down by up to 95% thus allowing more units to be procured for less expenditure over time. Devices tend to have relatively stable prices and deliver iterative enhanced value over time. A “capped budget” risks ‘locking’ in current devices with little latitude to introduce new technology or provide the training and technical support to ensure patient outcomes and safety.

The industry is not convinced that PHARMAC can provide assurances with their decision-making process as currently utilised for pharmaceuticals. Health technology assessments for devices are much more complex and are generally much less certain than for pharmaceuticals which derive their evidence from randomised controlled trials where the pharmacological effect is clearly demonstrated.

Complex category-specific medical technology will need to be assessed by clinical experts in that field of speciality with an intimate knowledge of the performance in their hands in clinical settings plus knowledge of the necessary technical training and support for the medical device. Benefits of investment in that technology cannot be assessed by desktop analysis in isolation of day-to-day clinical practice.

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?

Rehabilitation Equipment is complex, therefore needs a subcommittee.

We require further clarification of PHARMAC resourcing and process with regard to sub committees to ensure that the process doesn't unreasonably extend the time frames for decisions. Noting that device lifecycles and innovations are shorter than pharmaceuticals and devices are subject to obscelesence rather than generic replacement.

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?

This may become clearer over time, if deficiencies in the subcommittees are identified.

The need to simplify the advice process and the suggestion to set up another layer of advice via sub-groups to sub-committees will result in lengthy delays for access to essential medical devices.

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?

Sub-groups within subcommittees may add layers of cost, time and complexity. There will, of course, be circumstances in which subcommittees require additional advice. However, it will be difficult to pre-empt all circumstances in advance, so additional expert consultation should be drawn upon more informally on a case-by-case basis.

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 only occasionally need more specialised advice. Do you have any comments on this proposed allocation?

Some category-specific committees would require more expert input than others depending on the complexity and could be determined by the risk-based classification of the device. This aspect should be taken into consideration when requiring experts to commit time from their busy clinical schedules.

Category-specific advice from staff 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?

Occupational Therapists

Physiotherapists

Speech Language Therapists

Visiting Neurodevelopmental Therapists

18. We have proposed two options for getting category-specific advice from staff with expertise in broader disciplines. Which option do you think would be most effective?

Option 1.

That would ensure we don't have duplication of skills. It is a tough market to find enough people with the skills required.

19. Is there an alternative option that should be considered? What are its risks and benefits?

The industry would prefer to see one subcommittee per identified category that includes both healthcare professionals and professionals from other disciplines plus patient representatives. It seems inefficient to have two separate forums for category-specific advice.

Detailed use-based advice

20. PHARMAC has proposed an approach for gaining detailed use-based advice. What are your comments on this?

Clinical/user based research from suppliers is another source to include.

PHARMAC should consider formalising a mechanism to draw upon the extensive, specialised knowedge of application and use held by trained experts working for medical device companies that supply to New Zealand.

PHARMAC should also consider inviting proactive submissions from these stakeholders when significant improvements in a product's technical performance are observed over time and likewise when technological updates are implemented.

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?

It would be good to understand where Pharmac anticipates that these exceptional circumstances are likely to occur. The smaller the lists in each area, the more likely the exceptional circumstances will occur. Currently trial periods for equipment are relatively long, caused in part by the complexity of the products involved and the difficulty in assessing the appropriate solutions for persons in need of the equipment. With reduced ability to choose between products there is likely to be an increase in exceptional circumstances.

Where expert advice is required to support decsions in exceptional circumstanaces 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. Engaging an entirely new and separate panel, who may or may not have the required knowledge of the clinical circumstances and does not have an intimate knowledge of the broader functioning of the group, will likely add an unnecessary layer of complexity.

23. Is there an alternative option that should be considered?

Multiple suppliers in each category, reflecting the need to provide a wide range of choices, particularly where products are considerably complex.

SUPPORT TO IMPLEMENT LIST CHANGES

Through previous consultations, PHARMAC has received significant sector feedback on the proposed approaches to supporting the implementation of list changes. We don't have any specific questions but will take any further feedback into account.

If you have no feedback please move onto the next page.

A problem could be that DHB's continue to support products that are not on a list.

SHARED RESPONSIBILITIES FOR CONTRACT AND SUPPLY MANAGEMENT

Through previous consultations, PHARMAC has received significant sector feedback on the proposed approach to contract and supply management. We don't have any specific questions but will take any further feedback into account.

If you have no feedback please move onto the next page.

There must also be a strategy to support NZ made products that have been designed to meet the NZ requirements as in NZ standards and council requirements, especially in complex situations.

We need to follow the NZ standards and the building codes closely when it comes to the safety of clients that require equipment that will also keep them safe while they recover, but also consider other people like children or family that live in this situation.

Prefered suppliers should be a call made on a case by case basis by those who know the needs of the clients and can judge the quality and the service supplied by the supplier and pick equipment that is good quality and meets all the NZ safety standards.

Suppliers of devices need assurance that devices are serviced by trained and qualified technicians – either by contracted services independent of the original supplier or the device suppliers themselves. In some situations the complexity of the device requires an expertise and skill level only available from the device supplier, as they have ready access to OEM information and parts supply. There is a risk that devices, if serviced by contracted services, will have repairs and maintenance performed that are not compliant with OEM or industry standards. This can present a risk to the end user and or affect the working life and functionality of the device itself.

With this frame work in place it would be expected that service and maintenance budget should be allocated to DHBs to manage, independent to DHBs, to prevent untimely delays e.g. for breakdown repairs.

Time frames for delivery of these services would need some consideration and be set down on the contracts as required. It is to be acknowledged that uncommon parts for imported devices may not be stocked in NZ and that time frames need to observe and set some controls around this reality.

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?

Suppliers have existing networks/inventory/contracts that would take time to exit or commence.

Establishing the Regulator for Therapeutic Products should be the Crown's priority, especially as there has been no independent risk assessment on the PHARMAC proposals and so much of the proposed model is operational with detail yet to be determined.

PHARMAC's reforms should be postponed until the new regulatory scheme for Therapeutc prroducts is fully operational AND an independent assessment of the risks of the reforms to patients and how these can be mitigated has been conducted.

This independent assessment should include consideration of the impact of these reforms on patient outcomes, clinician education, retention and training, patient and clinician choice and sector competitiveness. It should also consider the implications on the overall health budget as a result of the proposed model.

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?

Keep communciation levels high and access open.

As a major stakeholder in this process we would see the industry playing a central role in all further aspects of the consultation and request to be actively consulted on, and involved in, key decisions hereafter.

All consultation processes must not be considered a "tick box" exercise by PHARMAC but seriously considered for input and ongoing collaboration to ensure what model of medical device procurement, assessment and funding is established doesn't significantly impact on the ability for the NZ companies to supply and support medical devices in NZ.

We cannot introduce barriers to market access and stifle the very innovation that NZ needs to improve patient outcomes and deliver healthcare efficiencies, if we expect to continue to enjoy a "first-world" healthcare system.

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?

The supply of equipment/services to aging and disabled members of the community is our area of focus. As an industry we would hope to be involved in all parts of the process, to help develop the understanding of the complexities faced in the proposed approach..

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?

ATSNZ represents the industry members/suppliers of equipment/services, so best understands what is needed for the provision of Assitive Technology, especially as it gets more complex. Being a party in relevant discussions focused on operational aspects of the Pharmac approach would provide the opportunity to delve into the needs of the users and the associated requirements in relation to equipment.

Any PHARMAC process established for the assessment and funding of medical technology entering the NZ market must undergo a review within 3 years to ensure that the medical devices funded by PHARMAC continue to deliver and improve patient outcomes and the supplier companies continue to reside in NZ to support in-market medical devices.

ADDITIONAL FEEDBACK

Please provide below any feedback on topics for which we have not asked specific questions.

There needs to be more clarity and/or transparency in the structure around contract management and procurement decisions, particulalry which organisations are operating in which areas and how this will evolve over time.

It is inadvisable to have organisations that have responsibitlies in both procurement and contract management sourcing their own product to supply to Pharmac contracts. Not only does this represent a conflict of interest in managing their own contracts, but potentially impacts negatively on the sector, leading to a diminishing competitive market and ultimatey may result in a monopoly in certain areas.

Competitive pricing is good for increasing access to products and services within a fixed funding scenario, but the drive to achieve large anticipated savings may result in the unintended consequence of reducing the competition to the level of negative returns. This is a larger risk in a small market.