Canterbury
District Health Board
Te Poari Hauora ō Waitaha

Submission on Managing Fairer Access to Hospital Medical Devices

To:	PHARMAC
Submitter:	Canterbury District Health Board Attn: Evon Currie Community and Public Health C/- Canterbury District Health Board PO Box 1475 Christchurch 8140
Proposal:	DHBs, PHARMAC, suppliers and others are going to be working together in a new way to deliver fairer access to publicly funded medical devices that are purchased by DHBs for use in hospital or in the community.

SUBMISSION ON MANAGING FAIRER ACCESS TO HOSPITAL MEDICAL DEVICES

Details of submitter

1. Canterbury District Health Board (CDHB).

Details of submission

2. The Ministry of Health requires the submitter to reduce potential health risks by such means as submissions to ensure the public health significance of potential adverse effects are adequately considered during policy development.

General Comments

3. The CDHB welcomes the opportunity to comment on Managing Fairer Access To Hospital Medical Devices. The underpinning principles and potential benefits for DHBs are sound.

4. The proposed definition of medical device differs from that contained in the Therapuetic Products Bill consultation. While that definition is still likely to change as the Bill proceeds it would be preferable to align the definitions. Alternatively align the definitions but then make explicit if the PHARMAC coverage differs.

5. It should be noted that large DHBs may get less favourable pricing under this proposal than they do currently. The CDHB wonders how PHARMAC will benchmark the pricing of medical devices to manage this and how they will determine what a 'good price' is. The funding model for DHBs will mean the impact of any price increases will be felt at a local level. Therefore the question is inevitably raised as to whether this proposal, and the attractiveness of having "common terms" will better manage public funds or whether the primary benefit will be for the financial security of suppliers.

6. The CDHB has some concern that not including General Practice and private services will increase inequities in access to medical devices rather than achieving the goal of this proposal which is fairer access. It should also be noted that some services are majority privately owned across NZ. For example, laboratories (70% private compared to 30% public), therefore including these types of services within the scope of the proposal will result in limited cost savings and threaten the ability

for public laboratories, such as Canterbury Health Laboratories (which is a division of the CDHB) to survive in a commercially competitive environment.

7. The CDHB also has concerns as to how the "rules" will be enforced and how the approach to off-list devices will be managed. In particular, transparency around savings and their reinvestment may provide incentive for compliance with the 'rules' provided it can be demonstrated that any savings made are reinvested back into healthcare.

8. The CDHB has chosen to comment on some specific, but not all consultation questions as detailed below.

Specific comments

Question	**Recommendation and Rationale**
Question 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 better?	The complexity associated with capital devices is acknowledged in the consultation document. The discussion following this acknowledgement provides an introduction into the many issues. Asset purchases at the major capital level tend to be strategic purchases for DHBs with many technical and operational interfaces. They exist within each DHB in a different ecosystem of associated technology, software platforms, staff capabilites, vendor support capabilities and DAPs. Each major capital purchase is unique and requires specialist input at local level. PHARMAC involvement in these purchases is unlikely to deliver returns to the NZ health system. On the contrary, PHARMAC involvement may add a layer of complexity, and inhibit responsive local decision making. For PHARMAC to maintain current listings of these high value devices and all the options available (typically software packages, options and licences) would be extremely resource intensive for only infrequent usage.

	There are also others which should be excluded from the device list, such as specialised diagnostic devices for which a 'one size fits all' approach is likely to fail. **The CDHB recommends that PHARMAC coverage should exclude major capital purchases.** While the exact threshold can be further debated an indicative value of around $200,000 would likely differentiate those infrequent strategic purchases from the more routine.
Question 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 current proposal, which includes listing all currently purchased devices, has limited impact and limited savings potential. The future signalled rationalisation of available devices has considerably higher impact. It potentially damages supplier relationships with the NZ health sector, including potential to have key suppliers exit the market. 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. Rationalisation also introduces local change management including staff retraining and usability impacts with associated degraded patient safety. Technical interfacing issues can be very high and the local costs of change may well exceed headline savings. Additionally there is no detail within the proposal as to the aniticpated timeframe for DHBs to implement list changes. Such changes may require significant internal resource, which may not be available within DHBs and need to be considered as a change management process. PHARMAC needs to consider how implementation of list changes will be resourced across DHBs. Similarly, the transition period needs to carefully consider the life span of devices. For example, it is not clear as to what

	would happen for devices with a 10+ year lifespan when the product is removed from the initial list. This may impact the associated consumables for the device, therefore would such items automatically fall under exceptional circumstances and how would changes to operational support and supply of consumbles/parts be managed when there is potential for the supplier to withdraw from the NZ market because of this change? Similarly the management of infrequent CAPEX purchases (which can be every 8-10 years) need to be considered, given market changes and shift to automation over time which may make rental/lease options more practical. Consideration is needed as to whether devices which are currently used are in fact supported by best evidence rather than adding all those in use to the list. List rules need to incorporate functionality and performance according to agreed quality standards. Currently there are no regular quality assurance checks for all devices, so a device list does have potential to either mitigiate or increase the risk of sub-optimal quality devices being used. **The CDHB recommends considerable further consultation with DHBs about this phase before it commences given the number of process issues identified.**
Question 9. PHARMAC has described two options for getting overarching advice, and identified the benefits and risks of these. Are there any benefits of risks we haven't captured?	Option 1 has a significant risk that the devices work would be perceived as "just an add on" to the current work of PTAC. For the devices project to be successful PHARMAC need to ensure it is well resourced and seen to be well resourced. As is noted in the consultation document the device sector is extremely complex and diverse so it is important that the overarching advice is given the priority it deserves. **The CDHB does not support Option 1, as it appears to fail this criteria.**

Question 11. Which option do you think would be most effective in providing overarching advice and why?	As noted above the CDHB supports Option 2 over and above Option 1 which carries significant risk. The Devices committee needs the skills and time to dedicate to the devices sector. Additionally the committee needs to be clinically led rather than supplier/vendor led and recognise the need to avoid monopolies within a small market to ensure suppliers remain engaged. There also remains a question as to what role local procurement teams would continue to hold given their primary function is to negotiate on device prices for their DHB.
Question 12. What would need to be considered when implementing the option that you think would be most effective?	Although detailed assessments will be made by subcommittees the overarching committee must have the knowledge to critique those assessments. This requires technical and scientific knowledge that reaches well beyond most clinical training. Additionally, there is concern as to where the clincial capacity to provide such expert advice will be coming from and how these experts will be supported. Such a role is likely to require a significant time commitment from the 'expert', and the process to ensure clincians with the right experience, knowledge and contact both upstream and downsteam are chosen should be transparent. The management of conflict of interest also needs to be considered. For example, some experts in NZ will need to be drawn from relatively small pools of specialists, which will unavoidably bring conflict of interest under the current DHB funding structure. **The CDHB recommends that the overarching committee needs to include membership from technical and scientific sectors.**

	The CDHB recommends that advice provided by experts are somehow made visible by PHARMAC to mitigate issues around conflict of interest.
Question 13. What do you think of our proposal to use subcommittees to get advice from category-specific experts?	**The CDHB supports the use of subcommittees for advice from category-specific experts as a necessary and sound concept.** There is some risk of "siloing" that the overarching committee would need to be cognisant of and manage. Maintaining a current list will be a resource intensive task. Medical devices develop significantly faster than pharmaceuticals and are updated regularly. Many medical devices are software intensive now and new software and options are released regularly. For major items that are purchased infrequently the resources required to maintain a current list will outweigh the benefit to the health system. This supports the earlier recommendation to exclude major capital items from PHARMAC coverage.
Question 14. If we proceed with the subcommittee approach, are there any new subcommitteesthat should be added and/or should the scope of any of the proposed subcommittees be changed?	Oncology doesn't appear to fit anywhere currently. Radiation Oncology is extremely device dependent and has the highest value (and arguable highest risk) medical devices in the health system. Noting earlier comments about a preference to exclude major capital purchases from PHARMAC coverage, these treatment devices require specialist advice if they are covered. Medical oncology would overlap existing subcommittes (eg infusion devices). **The CDHB recommends that a new subcommittee is created for Oncology.**
Question 17. PHARMAC has listed the groups of professionals with	Medical Physicists are specialists in use of radiation within medical devices and in imaging of various kinds including PACS (Picture Archiving and Communication Systems).

expertise in broader disciplines that we propose seeing category-specific advice from. Are there any other groups that should be included?	**The CDHB recommends that Medical Physicists should be listed within Technical and Scientific Services.**
Question 20. PHARMAC has proposed an approach for gaining detailed use-based advice. What are your comments on this?	An area not addressed in the consultation is the need for an ongoing feedback mechanism from DHBs to PHARMAC. DHBs purchasing devices from the list need a mechanism to provide feedback that informs other purchasing DHBs and future PHARMAC listing. For example problems with device quality or supplier performance should be shared across the sector to maximise the benefit of the PHARMAC approach. This feedback may inform future list changes but preferably isn't restricted to that purpose. Currently DHB Clinical Engineering and Procurement departments provide this function to varying degrees but if a national purchasing list is to be established then this function should be visible nationally. **The CDHB recommends that an ongoing feedback mechanism from DHBs to PHARMAC is included within the process.**

Conclusion

9. Thank you for the opportunity to submit on Managing Fairer Access to Hospital Medical Devices.

Person making the submission

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Date: 27/06/2019

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