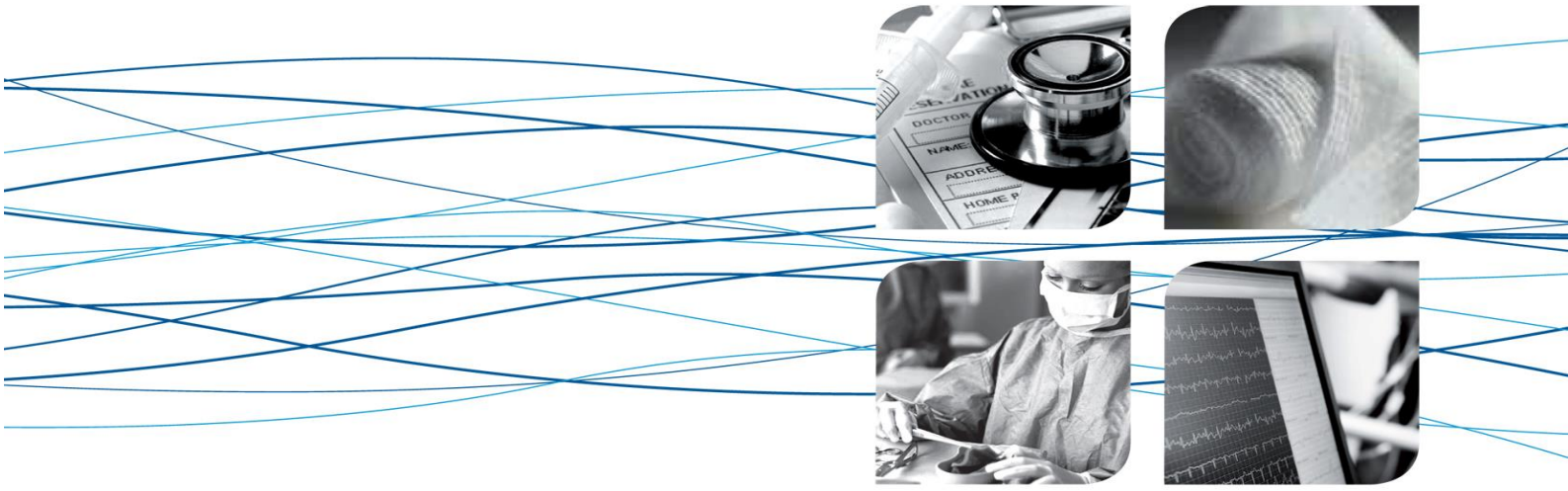

Medical Technology Association of New Zealand Submission

For

PHARMAC's "Managing fairer access to hospital medical devices"

June 2019

medical technology
ASSOCIATION OF NEW ZEALAND

Introduction

The Medical Technology Association of New Zealand (MTANZ) wishes to submit comments, on PHARMAC's proposed expanded activities which will include making decisions upon introducing new medical technology into the District Health Boards (DHBS). MTANZ is the only industry body representing medical technology manufacturers, importers and distributors of medical devices. MTANZ is a strong supporter and representative of New Zealand researchers and manufacturers in the development of medical devices for export.

The New Zealand medical device sector is estimated to account for $1 billion of Vote Health expenditure.It is estimated that 99% of medical technology is imported and thus subject to global supply chain dynamics. New Zealand also has a growing manufactured medical technology export market generating approximately $1.3 billion in revenue. The local manufacturing and export companies depend on support from local DHBs to evaluate and develop devices before looking to an international market.

NZ patents for medical technologies are the most numerous across all patent categories reflecting the underlying strength and research and development investment of the industry.

MTANZ research shows that New Zealand has a vibrant medical technology sector which contributes substantially to the national economy, employing thousands of New Zealanders directly and indirectly.[1] Further, despite the challenges of distance and scale, the medical technology sector in NZ has been shown to have capability to deliver 'first in class' devices to the market.[2]

New Zealand's health system delivers the most robust self-reported health outcomes in the OECD. Our agile, skilled and innovative medical technology sector is a key contributor to the strength of our health system.[3]

Currently, New Zealand enjoys an open and competitive medical technology market which supports these robust outcomes. There is a real risk to patient outcomes and the competitiveness and innovation of the industry to introduce measures that unintentionally establish a closed and controlled market, creating possible market access trade barriers.

Significant Issues

1 **Delay Implementation**

PHARMAC is proposing to introduce a new process for assessment of medical technology in 2020, yet much of what will underpin this new process is still to be determined, including the proposals for Health Technology Assessment (HTA). Currently, the Ministry of Health is also consulting on the introduction of therapeutic regulations for medical devices entering the New Zealand market with the establishment of the Therapeutic Products Bill.

Unlike the pharmaceutical industry, the global medical technology industry is composed predominantly of Small to Medium Enterprises (SMEs). Further there is no equivalent to the Pharmaceutical Generic Industry within the Medical Device sector. This dynamic is reflected in the New Zealand medical technology industry. SMEs have

[1] Medical Technology Association of NZ (MTANZ) NZ Health Technology Review 2016

[2] NZ Health Technology Review 2016

[3] The Economist Intelligence Unit Case Study: NZ Ministry of Health leveraging digital health to improve care 2018

limited resources locally to manage the cumulative effect of two significant market changes at the same time. The separate, but parallel, implementation of central procurement and enacting of the Therapeutic Products legislation could lead to the reduced availability of necessary medical device products, proving to be commercially uneconomic to enter the NZ market. There are numerous practical considerations for both the sector and government in the resourcing required to ensure the effective operation of the new regulator.

MTANZ wishes to work closely with government to ensure the new regulator is effective for all parties who will interact with it

Recommendation:

PHARMAC's intended expansion of its authority to include assessment and reimbursement of new medical technology should be delayed until after the new therapeutic products legislation is fully and successfully operational.

This will ensure PHARMAC has confidence in the safety and performance of a device if it is already registered for the New Zealand market. PHARMAC does not have the expertise or capacity to assess the safety and performance of a medical device. It follows that there are risks for both the government and industry, particularly regarding resourcing, confusion and duplication, in implementing these changes in parallel.

Establishing the regulator should be the priority, especially as there has been no independent risk assessment on the PHARMAC proposals and so much of the proposed model has operational detail yet to be determined.

2 Time to market

It is a matter of record that PHARMAC processes in procurement of pharmaceuticals have resulted in public disquiet on the lack of funding of innovative and even established drugs. These systemic delays in access for patients, without explanation, do not give the medical technology industry confidence that PHARMAC's proposal for medical devices' assessment and reimbursement will be fit-for-purpose to manage complex medical devices with the essential in-market support and education.

Medical devices often undergo rapid, iterative improvements in safety and improved care. Delays in assessment and approval for funding with PHARMAC's intention to control all entry of devices into New Zealand public hospital system will likely slow and halt the entry of many innovative life-saving medical devices.

The industry are concerned that the complexity of medical devices and their differences to medicines are still not being identified and factored into the PHARMAC approach in this consultation document.

Recommendation:

An independent assessment of the patient risks from the reforms and how these can be mitigated must be conducted to ensure confidence in PHARMAC' s capability and capacity for the continued supply of innovative medical technology to New Zealand in a timely manner. 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.

The medical technology industry must have assurance of procedural fairness in any procurement process proposed by PHARMAC.

3 Budget management

PHARMAC has stated their aim is $1 billion in medical technology savings by 2025. MTANZ argues that this arbitrary approach is wrong*; the focus should be improved patient outcomes*.

A global study by LEK Consulting in 2011 found that procurement processes, like that proposed by PHARMAC, not only struggle to reduce overall healthcare spending but also lead to issues affecting patient access, market competition and process fairness. Experience globally from our members also indicates that such changes will likely stifle innovation and investment.[4]

LEK recommends that "*to achieve a balance between the cost and quality of care, governments must partner with caregivers and industry to develop flexible procurement paradigms that consider the total cost of care, although also ensuring sufficient clinical input and creating rewards for innovation.*[5]

PHARMAC is proposing to introduce assessment of a medical device in isolation from the total product life cycle and the essential integration of the medical device within the delivery of a model of care. Medical devices are generally one part of a more complex treatment plan. Focussing on price at one point in a patient's care ignores the potential of ensuring value across the entire continuum of care.

The medical technology believes the government cannot deliver its objectives through the proposed PHARMAC reforms without undermining patient outcomes and eroding value for patients and funders of the health system.

The role of medical technology in delivering robust patient outcomes should be a key component to address the underlying challenges to the sustainability of the health system. To enable this, we need a more coordinated, connected network where technology empowers providers to deliver better care to patients throughout their health journey and where outcomes that matter to patients are prioritised relative to the cost. *Value-based procurement is a driver of value-based healthcare.*

<u>Recommendation:</u>

We strongly recommend that PHARMAC consider **value-based procurement principles**. Value-based procurement is a multidisciplinary approach for collaboration between healthcare providers, procurers and medical technology suppliers to achieve better outcomes and cost-efficient healthcare, resulting in economically most advantageous offers.

Any changes to the process for procurement of hospital medical devices is an ideal opportunity to embed the principles of value in procurement decisions, but as currently constructed they will only serve to have the opposite effect. Therefore, the medical technology industry cannot support a proposed cost-based procurement for medical devices as proposed by PHARMAC but supports a value-based approach to procurement of medical devices for New Zealand.

[4] Graves. K, Journal of Medical Marketing, vol 11,2,2011 101

RESPONSE TO PHARMAC QUESTIONS

SECTION 02 (pages 15-18)

Deciding what devices to use. How the national medical devices list would work

QUESTIONS – PROPOSED PRINCIPLES FOR THE LIST RULES

1. The new approach needs to support PHARMAC to achieve best health outcomes from the funding available, and improve national consistency of access to medical devices. Do the proposed principles for the rules achieve this, or would alternative principles be better?

2. Once the principles are confirmed, the next step involves developing specific rules which will give effect to the principles. What do we need to consider as we do this?

MTANZ answers	
Q1	We support the need to achieve the best health outcomes for patients and national consistency of access to medical devices but question the inclusion of "from funding available" when this remains an unknown quantity and will causes considerable uncertainty. We cannot support a process that is focused on cost-based procurement only. This approach has the potential to result in cost-shifting from the PHARMAC's budget to increased hospital cost for delivering specific treatments and delay access to life-saving innovative medical technology. We strongly recommend that PHARMAC consider **value-based procurement principles**. Value-based procurement is a multidisciplinary approach for collaboration between healthcare providers, procurers and medical technology suppliers to achieve better outcomes and cost-efficient healthcare, resulting in economically most advantageous offers. The patient is at the centre of care and value is measured in terms of long-term patient outcomes rather than short-term patient outcomes *Devices are generally one part of a more complex treatment plan. Focussing on price at one point in a patient's care ignores the potential of ensuring value across the entire care continuum.* However, we await evidence and detailed plans from PHARMAC that show the fair access to innovative technology that currently exist will be maintained and improved under PHARMAC's remit. Accountability of PHARMAC's procurement decisions must be measured by improved patient outcomes. We strongly agree that "product cost alone would not be a compelling reason to avoid using a particular device" (pg 19) and "if device use varied based on financial considerations alone, this would undermine national consistency… a core feature of fairer access" (pg 19).. Transparency of how principles are enacted is currently missing from PHARMAC's processes. We would argue tranparency of enacting current principles should be the priority for the industry to have confidence that PHARMAC is capable of managing

	the assessment of, in many cases, the complex interplay between medical technology and clinician capability.
Q2	We respect the need for a process to be implemented in order to give effect to the principles that will guide these decisions. A prescribed list of rules that restrict use of a device for specific indications may be detrimental to patients and not translate to the best health outcomes. Likewise, a surgeon may, to ensure optimum patient outcomes, prefer, a particular device that requires in-depth training to ensure safety of use. We therefore recommend flexibility in these rules and deviation away from a one-size-fits-all approach. We respectfully contend that restricting market access to devices may force suppliers to exit the small NZ market, reducing competition and potentially compromising fairer access both on behalf of the patient and supplier. In particular,the provision of training, servicing and support directly to DHBs. For example 20 NZ independent medical device suppliers (20% of MTANZ membership) estimate 47,000 hours of training and support are delivered annually to DHBs resulting in well in excess of 250,000 hours of training annually received by DHBs and other healthcare employees. Focus on unit price risks elimating this level of training or shifting the burden, cost and increased patient risk to DHBs. In order to ensure the proposed principles are implemented effectively, we recommend the involvement of all key stakeholders in defining the “best outcomes” for devices, depending on their different uses within specific clinical settings. PHARMAC’s new approach must demonstrate value which considers the continuum of care and not restricted to the device in isolation from the improved delivery of treatment. Prior to implementation, it is recommended that a review into international best practice be undertaken, looking into methods of assessing the value of medical technologies and a clear outline of the recommended evaluation methodology to be utilised in this context be made available to stakeholders to provide feedback. Industry would welcome the opportunity to work with PHARMAC in this important initiative. Industry would also welcome the opportunity to work with PHARMAC to develop a set of guidelines that will support the guiding principles (and transparency thereof) more effectively. In order to do so, we respectfully request more detail on the current planning in this space including examples of restricted devices, how the rules will be implemented and monitored, and by whom. Implementing principles requires PHARMAC to have plan (adequately informed by clinicans, colleges and medical associations) and resources to ensure appropriate support is delivered to ensure clinical need is achieved with improved patient outcomes.

Additional Comments

The medical technology industry is committed to ensuring that New Zealand’s healthcare system remains successful and sustainable into the future.

In considering PHARMAC's approach to decision-making (pg 20), it is essential to highlight that assessment of medical devices entails fundamentally different criteria and approach to that of pharmaceuticals. The medical device supply chain is complex, interdependent on diverse stakeholders and subject to multiple external forces. The decision making process will need to

take account of, and allow for, iterative product development and approval, which occurs more frequently for devices than pharmaceuticals.

The consultation document states that, as part of improving value for money, PHARMAC would consider “offering exclusive benefits to a particular supplier or subset of suppliers of products which all deliver similar health outcomes in exchange for more competitive terms” (pg 21). What is being proposed by PHARMAC could have the potential to force the exit from the small NZ market of otherwise productive device suppliers.

Further, as of now, the data systems used by DHBs are not fit for the purposes that PHARMAC propose in regard to ensuring compliance with PHARMAC device procurement commitments. The likelihood of these systems ever being made fit for purpose is low and well outside the timeframes PHARMAC proposes for implementation.

We support the Government's objective of improving value for money however, in moving towards a cost-based procurement model, we raise the risk of losing access to essential training and technical support, the benefits of competition, stifling innovation, limiting the products and therapies available to patients, and reducing the number of full service medical device suppliers in New Zealand.

PHARMAC must investigate and consider value-based procurement as a driver of value-based healthcare. The role of medical technology in delivering strong patient outcomes should be a key component to address underlying challenges to the sustainability of the health system. To enable this, we need a more co-ordinated, connected network where technology empowers providers to deliver better care to patients throughout their health journey and where outcomes matter to patients are prioritised relative to the cost. While short-term price benefits may be realised, these may be offset by longer term effects of these policies and ultimate benefits may not be realised by patients.

PHARMAC has stated their purpose is to generate $1 billion in medical technology savings by 2025. This is the wrong focus; *which should be improved patient outcomes*.

The government cannot deliver its “Wellbeing” objectives through the proposed PHARMAC reforms based on unrealistic, inflated cost savings without undermining patient outcomes and eroding value for patients and funders of the health system.

SECTION 05 (pages 27-30)

Using devices outside the list rules

QUESTIONS – EXCEPTIONAL CLINICAL CIRCUMSTANCES RELATING TO THE PERSON

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

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

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

MTANZ answers	
Q3	Due to the small market size and compliance requirements of listing on the

	Pharmaceutical Schedule, devices required in exceptional circumstances, especially patient specific, are unlikely to be held in stock and therefore will require fast track actions (registration and funding) to ensure timely clinical use. Once the new therapeutic regulations are established and the cost to suppliers known, it is anticipated many such medical devices will become uneconomic to hold in stock to supply the NZ market. The consultation document states that an example of an exceptional clinical circumstance is where a “consumer or health professional has an unusual clinical circumstance that wasn’t considered as part of the listing decision” (p 28). In many cases it may be difficult for the consumer to advocate on their own behalf and the support of a clinician or patient representative group will be required. As a result, this function should be mandated as part of the decision-making process. There needs to be considerable consultation and transparency as to what would be considered “exceptional clinical circumstances”.
Q4	The consultation document states, "When considering exceptional circumstances, we would apply the same decision-making framework used to consider changes to the list, including assessment of requests using Factors for Consideration". In some circumstances, the exceptional circumstances warranting the request for funding may fall outside the criteria included in the Factors for Consideration. It is recommended that a one-size-fits-all approach not be mandated in assessing these cases, and the expert view of the clinician, in addition to the viewpoint of the patient and/or their advocate be explicated as a consideration criteria in cases that fall under exceptional circumstances. In the case of non-urgent decisions, it is recommended that PHARMAC include in the decision-making process the expert opinion of DHBs, individual clinicians and manufacturers, who can provide evidence-based input based on experience and previous use cases.
Q5	Clinician input should be the foremost factor in decision-making on urgent clinical exceptions. Clinicians are equipped both to assess their own expertise and capabilities in working with different medical technologies as well as what will be best suited to their patient's circumstances, given their professional knowledge and insight to the patient’s medical history and prognosis. To improve efficiency and clinical autonomy, it is recommended that the clinicians directly involved in the patient’s care are solely responsible for making decisions on exceptional circumstances. 88 per cent of clinicians believe they need to make the appropriate choice of medical technology for their own patients.[5] Simplicity of process is required for both urgent and non-urgent submissions for DHBs.

QUESTIONS – EXCEPTIONAL CLINICAL CIRCUMSTANCES RELATING TO

THE Device

[5] UMR Research – September 2010 Clinician Survey.

6. 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?

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

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

MTANZ answers		
Q6	Device exceptional (funding) decisions need to be developed to a greater degree of sophistication than pharmaceutical decisions. As currently observed, PHARMAC can take many years to decide to fund/list a pharmaceutical. The time to decide to fund a medical device in exceptional clinical circumstances inevitably will have some need for urgency to the process. Therefore, we support that in urgent situations that DHBs will have the autonomy to make the decision, based on clinical need and report to PHARMAC after the fact.	
Q7	The consultation document states that "PHARMAC would not need to be involved in the decision-making process. However, 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. .	
Q8	How a DHB manages their internal process will differ from DHB to DHB and reporting to PHARMAC would be in consultation with the Clinicians.	

SECTION 06 (pages 31-42)

Decisions would be informed by robust expert advice

QUESTIONS – OVERARCHING ADVICE

9. PHARMAC has described two options for getting overarching advice, and identified the benefits and risks of these. Are there any benefits or risks we haven't captured?

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

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

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

MTANZ answers	
Q9	The consultation document does not reference 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 and guiding surgeons in theatre 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".
Q10	Currently, PHARMAC's assessment to fund a pharmaceutical is undertaken by the PTAC committee then recommended for funding. The time between the decision to fund a pharmaceutical (e.g. The Epipen) and being added to the pharmaceutical list for patient use can stretch to many years. It is unclear why timeframes extend although is generally assumed that there is a dependency on funding becoming available within the "capped" budget. 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. PHARMAC should continue to seek savings with national contracts being established but should not be driven by the need to meet an arbitrary $1 billion savings by 2025 as promoted by PHARMAC. This approach is likely to have a profound effect on the small NZ medical technology sector of SMEs. It will likely result in a significant reduction of suppliers in NZ and subsequent support for technology in the market. This approach by PHARMAC will also reduce the range of medical devices available for treatment in NZ. The domestic medical device market is only estimated to total approximately $1 billion and NZ enjoys considerable investment into the provision of healthcare by international medical technology manufacturing companies based in NZ. It is to be noted that NZ imports approximately 99% of medical devices required for treatment

	and diagnosis in the delivery of healthcare. PHARMAC's target of $1 billion in savings will likely deter and erode international investment in NZ. We are reliant on such investment to ensure world-class treatments will continue to be available for NZ patients. 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. In 2011/12 the DHB spend on medical device consumables was estimated to be $909 million increasing to $989 million in 2015/16[6] – an increase of $80 million or 8.8% over five years. During that period, elective surgery cases increased substantially many under contract to the private sector and thus outside PHARMAC's remit. Data, although incomplete due to inadequate data systems, shows *increases in device spending is volume not price driven.* Medical devices are a small percentage of total health spend at 4% - 6% consistently[7] – yet the impact they can have on patient outcomes are significant. Getting the best technology for the patient at the right point of intervention can deliver both short- and long-term savings to the healthcare system.
Q11	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. It will be essential to create a new committee to focus solely on medical devices as proposed in **Option 2**. **Medical Technology Advisory Committee (MTAC)** However, the industry is concerned that the new committee will be limited in access to evidence-based evaluation data for a medical device in order "to provide robust advice, based on a deeper understanding of what a medical device use involves". as described in the benefits of a new committee. We would argue that given the complexity of specialised medical devices, the membership of the Committee needs to reflect that clinicians are often very subspecialised, and this expertise will be required for assessment. Also, membership of the Committee will require significant care to ensure that the clinicians involved are current with clinical practice.
Q12	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 a clinical setting and knowledge of the necessary technical training

[6] MTANZ Official Information Act (OIA) request of 20 DHBs spend data 201/12 – 1015/16

[7] LEK Consulting 2011

	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. We would like to suggest that PHARMAC consider the work that has been undertaken by Professor Michael Drummond, York University, UK to establish a process for evaluating medical devices within a clinical environment to enable improved assessment of that device within the delivery of a model of care. Coverage with Evidence Development (CED) is gaining global recognition and this, or other means, is a method of an "early access scheme" to gain knowledge and understanding in the clinical environment and the value to NZ of the device being nationally funded (or not). This would be an opportunity for PHARMAC to collaborate with the clinician, manufacturer/ supplier and hospital to develop comparative effectiveness within a NZ hospital setting. Medical technology often provides impact beyond a single disease state (e.g. A Bariatric weight loss surgical procedure often cures patients who also have diabetes and relieves their symptoms of arthritis). It is often better to measure the health-impact of medical technology used upon the patient rather than the unit cost of a specific procedure or device alone, the difficulty here is that medical devices cannot be assessed in the same way as pharmaceuticals. Firstly, there is a lack of robust randomized control trial (RCT) evidence as blinding of patients is not feasible. The use of many medical devices involves an interaction between the device, a clinical procedure, and the clinician (or operator**),** where important improvements in a technical performance of a new technique may occur over time – 'learning curve' effect. There is some evidence showing that the performance of users improves over time, so it is important to assess the value of a device after an average performance level has been reached.[8]

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

13. What do you think of our proposal to use subcommittees to get advice from category-specific experts?

14. If we proceed with the subcommittee approach, are there any new subcommittees that should be added and/or should the scope of any of the proposed subcommittees be changed?

15. What do you think of our proposal to set up sub-groups to provide subcommittees with more specialised advice? Is there an alternative option that should be considered?

[8] Guillou PJ, Quirke P, Thorpe H, Short-term endpoints of conventional vs laproscopic-assisted surgery in patients with colorectal cancer: Lancet 2005

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 subgroups) and which subcommittees would only occasionally need more specialised advice. Do you have any comments on this proposed allocation?

MTANZ answers	
Q13	Expert advice on specific categories of medical devices will be required but this process should be simplified as much as is possible. It is recommended that subcommittees be limited to a small number of participants to facilitate more agile and effective discussion and decision-making. It is recommended that subcommittees are selected carefully so that their expertise is sufficient in consulting on the category area, thus precluding the need for sub-groups of subcommittees, which will likely add a layer of complexity. It is also recommended that each subcommittee have a dedicated overarching Committee sponsor, with some expertise in that category area, who is responsible for representing the views of the subcommittee to the overarching Committee. This will simplify the impact of multiple subcommittees by ensuring only one person is maintaining and relaying their feedback and decision making, hopefully resulting in a more efficient process. 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. We would expect to see timeframes instigated for decisions to ensure that a lengthy assessmentt and subsequent decsion to fund doesn't strectch to years resulting in medical devices being funded that have either been supersceded or obsolete.
Q14	As per above, 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. As suggested in Q12, PHARMAC will need to establish early-access schemes to speed the process up and develop the required evidence from the clinical setting within a hospital rather than delays through layers of committees.
Q15	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.
Q16	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. Category expertise will also require an understanding of the often-unique features of a device This aspect should be taken into consideration when requiring experts to commit time from their busy clinical schedules.

QUESTIONS – CATEGORY-SPECIFIC ADVICE FROM PROFESSIONALS

WITH EXPERTISE IN BROADER DISCIPLINES

17. PHARMAC has listed the groups of professionals with expertise in broader disciplines that we propose seeking category-specific advice from. Are there any other groups that should be included?

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

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

MTANZ answers	
Q17	While it is commendable to look to broader disciplines of professionals for category-specific advice, there is concern at the time it will take to assemble such groups and how often they would meet? If this advice is required, we would like to suggest that the representatives of broader disciplines are included in the subcommittees.
Q18	The industry would prefer to see one subcommittee per identified category that includes both healthcare professionals (page 36/37) and professionals from other disciplines (pg 42/43) plus patient representatives. It seems inefficient to have two separate forums for category-specific advice? Therefore, we don't support either Option 1 or 2
Q19	As per above, we recommend only one subcommittee per category-specific discipline to avoid excessive time delays and resourcing issues. The category-specific subcommittees must have the flexibility to address the complexity of clinical subspecialties.

QUESTIONS – DETAILED USE-BASED ADVICE

20. PHARMAC has proposed an approach for getting expert advice to support exceptional circumstances decisions. What are your comments on this?

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

MTANZ answers	
Q20	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.

Q21	Most companies that supply medical devices in New Zealand employ experienced, highly trained experts to deliver specialised training and ongoing education to healthcare professionals and hospitals to ensure the best possible outcomes for patients. The current etablished practice within DHBs of evaluating treatment paths for patient outcomes and DHB efficiencies should be maintained and evolved and utilised when international data is insufficent or the device is disruptive to current care procedures. Refer to Q12 and the recommendation of implementing a CED process for reviewing evaluation data. It is stated in the consultation paper (pg 46) it is likely that PHARMAC and DHBs will need to work with suppliers to support change management, particuarly in circumstances where training and education is required for a new device and in addition to broader familiarisation activities.

QUESTIONS – ADVICE TO SUPPORT EXCEPTIONAL CIRCUMSTANCES DECISIONS

22. PHARMAC has proposed an approach for getting expert advice to support exceptional circumstances decisions. What are your comments on this?

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

MTANZ answers	
Q22	We understand that urgent exceptional circumstances relating to the person, will be made by the DHB clinician within the department's clinical team but non-urgent decisions will be made by PHARMAC (page 28) While exceptional circumstances decisions relating to the device will be made by the DHBs. Therefore, the proposed approach for expert advice relating to exceptional circumstances will be confined to non-urgent decisions or approval following the DHB's decions to use a particular device in 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. 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.
Q23	As per above, we recommend that PHARMAC access expert advice currently available on the category-specific subcommittees.

SECTION 09 (pages 47-49)

We'll all be involved in making this work

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

24. Following consultation, PHARMAC will want to identify a timeframe for implementing the new approach. What do we need to consider when deciding on this?

25. Moving to the new approach will involve significant change. How can we make the transition to this new way of working as smooth as possible?

26. PHARMAC wants to ensure that anyone interested can be involved in helping develop the operational detail of the new approach. What aspects of the approach do you want to be involved in shaping further?

27. How do you propose we can most effectively involve you, or the group or organisation you represent, in developing the detail of the aspects you're interested in?

MTANZ answers	
Q24	These are significant changes with many stakeholders involved in the transition and thus will require time to adequately implement processes that reduce the risk of unintended negative consequences. It is likely that it will take well in excess of 24 months to implement, therefore it is recommended that the timeline be extended beyond 2020 to ensure due consideration and planning has taken place to minimise disruptions to patient access and the broader healthcare sector as a result of these changes. It would be imprudent for PHARMAC to introduce assessment and reimbursement of new medical technology until after the new therapeutic products legislation is operational. Establishing the regulator 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. Unlike the pharmaceutical industry, the global medical technology industry is composed predominantly of SMEs. Further there is no equivalent to the Pharmaceutical Generic Industry within the Medical Device sector. This dynamic is reflected in the New Zealand medical technology industry. SMEs have limited resources locally to manage the cumulative effect of two significant market changes at the same time. The separate, but parallel, implementation of central procurement and enacting of the Therapeutic Products Legislation could lead to the reduced availability of necessary medical device products in the New Zealand market. There are numerous practical considerations for both the sector and government in the resourcing required to ensure the effective operation of the new regulator. PHARMAC's reforms should be postponed until the new regulatory scheme is fully and 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.
Q26	As a major stakeholder in this process we would see the industry playing a central role in all further aspects of the consultation and requests 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.
Q27	Industry welcomes the opportunity to engage in a follow up discussion with clinicians, PHARMAC and Government representatives to discuss items relating to the consultation document. The industry wishes to engage in constructive dialogue to mitigate the risks associated with these proposed changes and ensure that New Zealand’s health care system remains “world-class” and sustainable into the future. Any PHARMAC process established for the assessment and funding of medical technology entering the NZ market must undergo a review within three 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.