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Re: PHARMAC consultation managing fairer access to hospital medical devices

The New Zealand Society of Anaesthetists (NZSA) welcomes the opportunity to comment on PHARMAC's consultation which seeks to develop an effective and practical approach, with strong clinical input, to develop its system for managing fairer access to hospital medical devices.

We appreciated PHARMC's Fiona Rutherford, Principal Advisor for Medical Devices presenting at our joint meeting with ANZCA NZNC on 28 June, particularly the question and answer session. The presentation provided greater clarity on the consultation and enabled us to strengthen our submission feedback.

About the NZSA
The NZSA is a professional medical education society, which represents over 650 medical anaesthetists in New Zealand. Our members include specialist anaesthetists in public and private practice, and trainee anaesthetists. We facilitate and promote education and research into anaesthesia and advocate on behalf of our members and the safety of their patients. As an advocacy organisation, we develop submissions on government policy and legislation, work collaboratively with key stakeholders, and foster networks of anaesthetists nationwide. The NZSA, established in 1948, also has strong global connections, and is a Member Society of the World Federation of Societies of Anaesthesiologists (WFSA).

Overview
The NZSA is pleased that PHARMAC has recognised that medical devices require a different management model to pharmaceuticals. We are supportive of PHARMAC's aims in relation to medical devices, including improving national consistency of access, helping DHBs to manage spending on devices in a financially sustainable way, freeing up funding to be redirected to new technology and other initiatives, and strengthening transparency around funding decisions.

In its consultation document, PHARMAC asks how to best obtain appropriate expert, evidence-based advice to ensure good decision making for medical devices that are focused on delivering the best health outcomes – the NZSA believes it is imperative that clinician input be sought very early in the process of this decision making, whether in deciding the medical devices list or determining exceptional circumstances for devices outside of the list. Therefore, it is imperative PHARMAC continues to consult specialist societies and associations as it states it will do in its consultation document, and to ensure clinicians are the key drivers behind sound decisions.

PHARMAC's decision making process must be flexible and agile, due to the fast-moving landscape of medical devices. This may include new evidence which emerges about a product's benefits, or new technology introduced to the market. It was encouraging to hear from PHARMAC's Fiona Rutherford, Principal Advisor Medical Devices in her presentation at our joint meeting with ANZCA NZNC on 28 June that PHARMAC will be proactive and seek advice on horizon scanning, and that it will look three to five years ahead to plan which devices are added to New Zealand's national list.

Our submission below begins with comments on clinician input, specifically in relation to subcommittees. We then provide comments in response to sections of the consultation document, as well as answers to some of the questions. Our comments are based on the PHARMAC consultation paper, as well as the Fiona Rutherford's presentation to our joint meeting, including the question and answer session.

Clinician input and sub-committees

We are supportive of PHARMAC's proposal to have an anaesthesia and respiratory subcommittee. However, as anaesthesia reaches across multiple areas of healthcare delivery, it cannot be solely confined to one committee as vital areas pertaining to anaesthesia may be missed. A recent example that illustrates this point is the formation of a group to look at endoscopy medical devices, led by crown subsidiary NZ Health Partnerships Limited which works on behalf of the DHBs. These medical devices include flexible bronchoscopes, often used by anaesthetists, and videolaryngoscopes, almost solely used by anaesthetists. We have only recently been approached about this group, in an ad hoc manner and through an individual anaesthetist rather than through our organisation, as a professional body for anaesthetists. While we commend HPL and the DHBs for being proactive in setting up the group, it is unfortunately an example of poor communication which can undermine confidence in PHARMAC's medical devices process. This situation leads to concern that there may be other groups or committees being formed that we are not aware of but need to know about and have input in. We expressed this view to PHARMAC's Fiona Rutherford when she presented at our joint meeting. We acknowledge that keeping apprised of these developments is a challenge for our professional bodies as well as PHARMAC. This scenario also highlights the difficulty of grouping devices.

We have provided a response to the consultation document question regarding subcommittees later in the document but would also like to highlight further criteria for subcommittees:

- As PHARMAC proposes, the composition of expert subcommittees requires seeking nominations from Societies and Colleges to secure suitable candidates. Advice from anaesthetists on these committees must be representative of the views of professional bodies i.e. NZSA, NZNC and the NZ Anaesthetic Technicians' Society, not solely the personal views of anaesthetists, or views relating to their DHB.

- Advice from anaesthetists on PHARMAC medical devices committees needs to cover the broad areas of healthcare that anaesthetists are involved in.

- Subcommittees must be enduring.

- Adequate resourcing of subcommittees is essential.

Subgroups of subcommittees are required to cover the broad areas of healthcare anaesthetists are involved in. The following list is by no means exhaustive but covers some categories that anaesthetists may need to have input in:

Anaesthesia (e.g. airways, anaesthesia machines, infusion pumps)

- Intensive Care (monitoring, ventilators, central lines)
- Emergency medicine (US machines, arterial lines)
- Retrieval medicine
- Patient warming and cooling
- Drapes gowns and procedure packs
- Respiratory equipment and consumables (arterial blood gas syringes etc.)
- Infusion equipment
- Non-invasive ventilation equipment.

Page 3 Benefits of the new approach
One of the benefits listed is to free up funding which can be redirected into new technology or other health initiatives. It will be important to know whether the savings will be ringfenced for this, or be allocated to the DHB pot, or will the funds be used to pay for the administration of the process? How will financial savings be demonstrated to show that the end goals are achieved?

Page 7 National list of medical devices
In developing and managing the national devices list, how will PHARMAC ensure that the national list is accurate given the difficulty of obtaining accurate lists from the various DHBs, all with various coding mechanisms? This will be a massive undertaking. However, we believe that having a complete national list of devices being used in DHBs will be a tremendous step forward and we are very supportive of this work by PHARMAC.

We are interested to know what problems were encountered with wound care and coronary stents that have gone to national contracts. How will these problems be avoided with a larger roll out? With coronary stents. PHARMAC have insisted on 60% of stents being the ‘standard’ recommended one and 40% of usage for the more expensive stents; in practice, has that been easy to achieve? How have end users found the restriction? What happens with product development, how will PHARMAC keep up with the rapid changes that occur in medical devices?

Page 8 Timeline
The consultation document states: “We envisage that the earliest the changes could take effect would be 2020.” This is certainly an ambitious timeline given the slow progress in developing a national list. Clinicians are very busy and the expert panels and other means of gathering expert advice will need time to meet and consider feedback.

Page 14 Building the list and device categories
It is interesting that most anaesthesia small equipment is already under national contract. The availability of a national list, including costs, will be beneficial for DHB comparison and to improve transparency around costs and funding.

Page 17 Proposed principles for the list rules and Q1 Do the proposed principles for the rules achieve best health outcomes?

We found this section somewhat perplexing as while some of what was outlined could be defined as principles, other aspects appear to be rules. However, our feedback to the principles is as follows:

National medical device list would contain all the medical devices a DHB can use
This would be very positive on the proviso it is a complete list.

DHBs will be expected to use listed devices for all services they deliver unless there are exceptional circumstances, e.g. hospital infrastructure does not support the listed device
This will be known about, so PHARMAC should list the devices the hospital infrastructure can support and as below, surely this device will be on the list as the national list will start with all devices currently in use.

DHBs will be expected to use listed devices for all services they deliver unless they are already using a device that is equivalent to one on the list
If the list is generated at the start by listing all devices in current use, then why would this device not be on the list?

National consistency to promote fairer access
We support PHARMAC saying that cost alone will not be the driver for deciding which devices are part of the national list. The evidence base for many devices however will not be as robust as for pharmaceuticals. How will a decision be made on the threshold of evidence needed?

Restrictions
Regarding restrictions attached to some medical devices and an expert panel to decide on these restrictions – who will make up this panel and how long will such processes take?

Capital medical devices
Obtaining agreement on such items, e.g. anaesthetic machines, will be challenging even with an expert panel. Agreement may be easier if there are fewer machine types on offer, however there will be site specific requirements for such items e.g. footprint size that must be part of the decision-making process. As the document states, major new capital devices could be listed in ways that preserve DHBs' flexibility to select appropriate options, which take into consideration the specifications, configuration, service and support of these devices.

Page 20 Approach to decision-making

1. New funding decisions – How long will it take to make new funding decisions? A nimble infrastructure is needed to enable timely decisions. We need to ensure that New Zealand does not lag behind other countries we often compare ourselves with.
2. Improving value for money – Containing our health spend is a positive objective but we must ensure that the administration time does not delay decisions.
3. List maintenance and list amendments – ultimately, who will make decisions for the medical devices which are on the list, and will there be a prerequisite they have clinical experience?

4. As we outline in more detail below, the decision-making approach must consider the environmental sustainability of products throughout their life cycle.

Page 22 List maintenance
The document states: "PHARMAC may seek advice for some list maintenance decisions. However simple changes could be actioned following internal review." What PHARMAC deems as simple list maintenance changes may have significant end user ramifications. e.g. impacting the surgeon's ability to do their case safely. We would therefore suggest a low threshold for obtaining external or expert opinion in such cases.

P.22 Managing the list and factors for consideration

Integral addition of environmental sustainability criteria
PHARMAC's consultation document says that decisions on which medical devices are part of the list will be based on the Factors for Consideration: Need, health benefits, costs, savings, and suitability. It is also essential that PHARMAC add environmental sustainability (ES) to these factors. This would mean considering and exploring the environmental impacts of a product's whole-of-life cycle, such as: procurement, manufacture, production, packaging, use, recycling and reuse of medical devices and their means of disposal, the latter of which can be very expensive. To gather this information, PHARMAC would need to engage with suppliers and the DHBs. Essentially, ES provisions can lead to cost increases and PHARMAC would need to consider cost implications in its decision-making. However, once the costs of disposal are rightly apportioned, any increase in procurement cost may be off set.

The Health Minister's letter of expectations to DHBs and PHARMAC states that they are expected to contribute to the Government's priority outcome of environmental sustainability and to undertake work that leads to specific actions, including reducing carbon emissions, to address the impacts of climate change on health. PHARMAC repeatedly says in its document that it will work in partnership with DHBs and therefore PHARMAC and DHBs must consider their ES responsibilities when making decisions on procurement.

Page 23 Decision-making and information sought – clinical, technical, operational etc.
We support a fairer system, but imagine that the number of business cases that will need to be developed to secure funding for new devices will be considerable. It is important to consider all aspects of the device to guide decision-making, from technical support through to maintenance costs. The document states that the decision-making process will need to flexible and efficient; is that the case with medicines at present? If not, what are the changes that would need to be implemented?

Page 26 Decisions on list changes
Having access to a list of decisions relating to the national list, including information on declined applications, would be useful.

Page 28 Exceptional circumstances
The NZSA supports DHBs being able to make decisions to purchase items that are not on the list in exceptional clinical circumstances relating to the patient. We also support allowing DHBs to make decisions in urgent situations, although the process for this will need to be timely and flexible. We assume this decision making would encompass issues such as those we recently experienced with

the Enflow fluid warmers.[1]

The document states that one condition for exceptional use is when a user has used the device before – surely this would mean that the device is on the national list as part of the initial consultation?

With pharmaceuticals the process for exceptional circumstances has been quite unwieldy and slow so we need to work towards a process that is more efficient. PHARMAC has suggested a DHB process and a parallel PHARMAC process; it would not seem unreasonable that if DHBs are to fund such devices that they also be involved in the decision-making process. We suspect current DHB processes are not very mature in the majority of DHBs. We would encourage PHARMAC to help foster development of a robust DHB process and to ensure that this is consistent. This would be a quantum leap forward.

Responses to feedback questions

Q.1 Do the proposed principles for the rules best achieve this, or would alternative principles be better?
Please refer to our response on p.2 where we discuss the section on principles.

Q. 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?
This will be very challenging. We support the principles and general rules but are interested to know how these will be put into practice.

Q.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?
We have expressed some concerns regarding devices previously used earlier in this submission as it we would have thought these would be on the original list. Otherwise what is proposed seems reasonable.

Q.4 PHARMAC has proposed how decisions on exceptional clinical circumstances would be made. Do you have any comments on this?
The process seems reasonable, however both PHARMAC and the DHBs must have processes in place which are flexible, timely and robust.

Q.5 What would DHBs need to consider when establishing an internal process to make decisions on urgent clinical exceptions and report these to PHARMAC?
There would need to be a nominated group which will act in these circumstances so that decisions are made in a timely fashion.

Q7 PHARMAC has proposed how decisions on exceptional external circumstances could be made. Do you have any comments on the proposal?
Answer as for Q4 above.

[1] https://www.bmj.com/content/364/bmj.l1126

Q.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?
We believe the two options cover the pros and cons adequately.

Q.11 Which option do you think would be most effective in providing overarching advice and why? Q.12 What would need to be considered when implementing the option that you think would be most effective?
Gaining quality advice is crucial, however we need to recognise the time that this will take. It is also important that the consultation make sense, rather than sending out long lists of product numbers.

In response to options provided by PHARMAC, the expansion of the existing Pharmacology and Therapeutic Advisory Committee (PTAC) risks having members on PTAC who are not particularly interested in, or knowledgeable about medical devices. We think a separate committee is essential to maintain focus and to be able to respond in a timely fashion. The corollary benefit of forming a device specific group is that in advertising and recruiting specifically to that role the participants are much more likely to be uniquely interested in medical devices. Although a costlier option, this is a more fit-for-purpose model and is likely to achieve better outcomes.

We support the separate sub-committee approach as outlined on p.38, however an Anaesthesia and Respiratory Sub-Committee proposed on p.37 would also need to include intensive care. It is important that representation on this committee cover the key areas and that there is clinical input across areas such as ICU, monitoring, anaesthesia and respiratory, infusion and transfusion. We could also have an airway rep on one of the sub-committees.

As outlined at the beginning of our submission, anaesthetists need to have representation and input into numerous subcommittees and subgroups beyond the subcommittee referred to above. This would reflect the broad nature of the specialty's involvement across multiple areas of healthcare delivery. Therefore, the proposed anaesthesia subcommittee while supported, will not suffice as the only committee anaesthetists belong to.

Q.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? Q.19 Is there an alternative option that should be considered?
A mix of the two may be necessary. Some aspects will need group specific feedback, but other areas will benefit from a broader perspective. Maybe a collective with subgroups?

Q24 Following consultation, PHARMAC will want to identify a timeframe for implementing the new approach. What do we need to consider when deciding on this?
How long will it take to generate the national list and form the required committees to evaluate and to feed back? These need to be in place before rollout can occur.

Q25 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?
We need robust information dissemination and transparency around the process. Giving real life examples of processes that have already been implemented and how they are working. Trying to allay some of the fears regarding device restriction, risk of supply with sole supplier agreements, and the worry that this mechanism will stifle competition in the New Zealand market and reduce options of

available devices. Evidence that the process will not cause significant delays for new device approvals. Transparency over PHARMAC funding to oversee the administration of the programme.

Q27 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 are interested in?
PHARMAC must continue to engage the Society and College throughout this long-term consultation.

Other comments

New Technology
It is our impression that new technologies are introduced in a haphazard manner and mainly relate to the enthusiasm and loudness of those requesting it. Promoting robust and consistent systems at DHB level in parallel with PHARMAC would be useful. Hopefully this would predominantly be a national process but the demographic/geography of each DHB may require some regional variability.

Closing comments
We understand from our engagement with PHARMAC that once a broad outline of the new approach for medical devices is developed, consultation will be ongoing to work towards developing operational details. The NZSA would like to continue to be kept informed of developments throughout the process to provide input and to keep our members updated, as well as seeking their views to inform our feedback.

The NZSA is happy to discuss our comments and to answer any questions in relation to this consultation. I can be contacted at president@anaesthesia.nz

Yours sincerely

Kathryn Hagen
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