New Zealand Medical Association
Te Hauora mō ngā Iwi Katoa

20 June 2019

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By email: devices@pharmac.govt.nz

Managing fairer access to hospital medical devices

Dear Sarah

The New Zealand Medical Association (NZMA) wishes to provide feedback on the above consultation. As you know, the NZMA is New Zealand's largest medical organisation, with more than 5,000 members from all areas of medicine. The NZMA aims to provide leadership of the medical profession, and to promote professional unity and values, and the health of all New Zealanders. Our response has been informed by feedback from our Board and Advisory Councils.

General comments

1. The NZMA has taken a keen interest in this complex area ever since PHARMAC was asked in 2012 by the then Government to apply its management approach to DHB hospital medical devices. Our previous submissions on this area include the following: PHARMAC and hospital medical devices – obtaining clinical input;[1] Feedback on PHARMAC's initial medical device activity;[2] Applying the PHARMAC model to hospital devices management.[3] Since these consultations, we understand that PHARMAC has been developing a proposed approach for managing medical devices, building the list of medical devices in use through negotiating national contracts, and negotiating the first market share agreements.

[1] NZMA. PHARMAC and hospital medical devices: obtaining clinical input. 25 March 2013. Available from http://www.nzma.org.nz/__data/assets/pdf_file/0016/1492/sub-PHARMAC-and-hospital-medical-devices.pdf
[2] NZMA. Feedback on PHARMAC's initial medical device activity. 11 June 2013. Available from http://www.nzma.org.nz/__data/assets/pdf_file/0015/1464/Sub-PHARMAC-Initial-Medical-Device-Activity.pdf
[3] NZMA. Applying the PHARMAC model to hospital medical devices management. 12 December 2013. Available from http://www.nzma.org.nz/__data/assets/pdf_file/0006/17736/sub-medical-devices.pdf

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2. Under the approach that is being proposed, we note that PHARMAC would be responsible for deciding which devices are funded, based on a common set of broad considerations and taking into account expert advice. DHBs would decide what devices are needed to deliver their local services, choosing the most appropriate devices from a national medical devices list. PHARMAC would manage the national medical devices list, including deciding what items get added or removed, and managing a process to consider access to items outside the list when exceptional circumstances require this. We note that the primary benefits being touted to this new approach include supporting more consistent access to medical devices for people regardless of where they live, helping DHBs manage spending on medical devices in a sustainable way, freeing up funding for other health initiatives, and ensuring a high level of transparency around funding decisions. While these are laudable objectives, the NZMA has several major concerns and questions relating to the proposed approach. These relate to the range of devices in scope, the availability (or lack thereof) of evidence to guide decisions, challenges with securing expert advice, and the implications of the approach for the wider health system. We elaborate on these concerns in the following paragraphs.

Specific comments

Range of devices in scope

3. The definition of medical device is very broad, covering equipment that is used on, in or by a person for a diagnostic or therapeutic purpose. This ranges from simple consumable products to implantables to sophisticated diagnostic instruments. While the proposed model would likely work well for widely used consumable products that are purchased in bulk and have a relatively simple, singular function (eg, wound dressings, IV cannulae, BP monitoring devices, thermometers, central lines, urinary catheters, gloves, masks, gowns, etc), we envisage serious problems when it comes to highly specialised and complex multipurpose equipment such as molecular diagnostic instruments for microbiological testing. In an appendix to this submission, we include a case study that flags some of the issues PHARMAC is likely to encounter with such equipment.

4. We believe that PHARMAC needs to critically re-evaluate the range of devices that will fall under its scope. It is our view that devices that are highly specialised diagnostic or therapeutic instruments with complex and multipurpose functionality, and for which only one or two may be required nationally, should be excluded from scope. Such instruments would not have the benefits of economies of scale, so the financial gains from taking a national purchasing approach are likely to be negligible anyway, while the risks of achieving a perverse or unhelpful outcome are considerable.

Evidence and expert advice

5. One of our biggest concerns relates to the quality of the evidence that will be used by PHARMAC to guide its decisions on what medical devices are funded. While evidence for regulatory purposes (such as that relating to product safety, quality and manufacturing standards) can be obtained and will be evaluated under the Therapeutic Products Bill once it becomes legislation, evidence for the purposes of procurement based on health outcomes will be much more difficult to ascertain. For medicines, evidence is derived from randomised controlled trials where the pharmacological effect is clearly demonstrated and informs the QALY assessment, which in turn informs the pharmaco-economic assessment. For devices, this is generally not the case. Health Technology Assessments (HTAs) are much more complex and the results are generally much less certain than with medicines. There is some literature on the challenges of

applying health economics to devices for procurement decisions.[4] Key challenges include practical difficulties in conducting randomised controlled clinical trials, allowing for a 'learning curve' and user characteristics, accounting for wider organisational impacts of introducing new devices, and allowing for variations in product characteristics and prices over time.

6. We are pleased that PHARMAC acknowledges the importance of getting sound expert advice to enable the agency to make good decisions. We note that PHARMAC has identified three broad types of expert advice that it would need: i) overarching advice informed by critical appraisal of evidence; ii) category-specific advice on clinical, technical and operational aspects of products; iii) detailed use-based advice gained from hands-on use of products in context. With respect to overarching advice, we note that PHARMAC is proposing two options – enhanced membership of the Pharmacology and Therapeutics Advisory Committee (PTAC) or an entirely new Devices Committee.

7. Despite what PHARMAC is proposing, for many devices, we believe that it will be impossible to convene a group of experts, particularly as a standing committee, that can take into account of all of the issues noted in paragraph 5 and arrive at an assessment that is fully underpinned by evidence. We are not convinced that PHARMAC will be able to provide assurances that the decision-making process for devices will be as robust as the process for medicines. While a consistent approach may be applied, that approach may not consistently arrive at the right decision in terms of best clinical outcome. Consultation with 'users' will be vital to obtain comprehensive information for the purposes of evaluation, but we seek further details on how the consultation processes will reach the clinicians that need to be asked. With respect to 'detailed use-based advice', we seek clarification on where this advice will come from for products that are new to the New Zealand market. For instance, will there be a case for international expertise to be brought in? Is there any scope for products to be trialled in New Zealand first before decisions are made?

8. The above limitations notwithstanding, we reiterate the importance of consulting the appropriate specialist societies and associations, and ensuring they are an active part of the process of recommending suitable devices. When deciding on equipment, these societies and associations will be best placed to advise on various matters including the ability to partner with other centres and the compatibility of equipment with centres conducting international clinical trials. Conflicts of interest are obviously important to document.

Risks

9. The consultation document is silent about procurement strategies for devices, but if these are to be the same as for medicines, then we are likely to end up with a much smaller number of devices in each therapeutic group, and in some cases, sole supply arrangements. While PHARMAC has recognised the greater degree of uncertainty when dealing with devices compared with medicines, these uncertainties extend beyond the clinical assessment decision making process and will magnify the inherent risks of having a small product list and a small number of suppliers. For example, if a particular device is removed from the list and the supplier exits the New Zealand market, we ask what would happen if the suitability of the preferred product proves to be questionable?

[4] Sorenson C, et al. Applying health economics for policy decision making: do devices differ from drugs? Europace. 2011 May;13 Suppl 2:ii54-8. Available from https://academic.oup.com/europace/article/13/suppl_2/ii54/412320

Exceptions process

10. We welcome the proposed exceptions process. This needs to be flexible, timely and responsive. It is good that DHBs will have the ability to make decisions to purchase "off-list" items in exceptional clinical circumstances relating to the person. We note that each DHB will be responsible for developing the local process for making decisions in urgent situations. How this will work in practice remains to be seen. We are concerned that due to deficits and other pressures, there could be a large variation in criteria between DHBs and, therefore, greater variation between different regions – an outcome at odds with the aims of this initiative.

System wide implications

11. The shift that is being proposed to the procurement of DHB devices will have system wide implications. Many medical devices are used across the health system including in public hospitals, private hospitals, A & M clinics, general practice and rest homes. While PHARMAC is not directly responsible for what happens outside its remit with the DHBs, it is essential that the knock-on effects of this proposed approach are carefully considered, with particular thought given to mitigating the impacts / risks to the rest of the system. We have questions on how industry will respond. For example, will industry try to recoup reduced profits by charging a higher price to non-DHB purchasers? Will we see inequity with those with insurance or ACC cover having access to superior (or more individually specified) products? Will the limits on the range of products that are funded ultimately reduce the range of products that are available across the system? Will the proposed approach create barriers to having some hospital services provided in the community (eg, through Primary Options for Acute Care [POAC] arrangements?). It is also important to take into account all related costs to the health system, not just the cost of the piece of equipment per se. For instance, something that costs less to purchase but leads to a longer admission may not be the best choice for the health system overall.

Timeliness of process

12. An additional concern relates to the slowness of the PHARMAC processes. As PHARMAC moves into the device space, it is essential to minimise any additional delays that will be introduced to avoid adversely impacting on good patient care. This may mean PHARMAC needs to considerably expand its resourcing and / or limit the scope of work it undertakes.

Other aspects to consider

13. We note PHARMAC's proposed involvement in procuring devices that are major new DHB capital investment purchases and we seek further information on how this would work. While the budget for medicines is agreed between DHBs collectively, we understand that there is less uniformity between DHBs for capital expenditure. We also seek clarification on what would happen if a donor wishes to fund the purchase of medical equipment – specifically, will PHARMAC limit such purchases to what is on the list?

14. We have some concerns that the document focuses solely on the savings benefits of the proposed approach and completely ignores the value of investment in health. For example, the section about improving value for money on page 21 states that "ultimately, seeking greater value for money is about reducing costs (making savings) which may then be used to fund new technology or other initiatives." While improving value for money is certainly a laudable aim, we

suggest that it is important to recognise spending on health as an investment.[5] We understand that PHARMAC has long celebrated its savings record, estimating it has saved $6.89 billion since 2008. Politically, it is likely that the move into devices will raise expectations of similar savings for devices. We seek further information on the baseline spend for devices, the targeted spend for PHARMAC, and timeframes for when these are expected to be achieved.

15. Finally, we note that the Minister's letter of expectation for PHARMAC 2019/2020 includes specific reference to improving environmental sustainability by reducing carbon emissions.[6] As such, we believe that it is important that any decision making about devices takes into account the carbon costs associated with the manufacture, packaging, transport, use and disposal of such products.

We hope our feedback is helpful. Given the number of questions that need answers and that are of concern to the wider sector, we expect that there will be opportunities for further consultation as PHARMAC progresses work in this important and complex area.

Yours sincerely

Dr Kate Baddock
NZMA Chair

Appendix. Case study illustrating difficulties applying PHARMAC approach to complex specialised equipment

The following scenario was described by a member of our Specialist Advisory Council and relates to their recent experience of an RFP process to purchase high and medium volume molecular diagnostic testing platforms for microbiological testing.

The issues that need to be navigated during this process are highly technical. For example, each of the testing platforms need to run a variety of different PCR assays (28 for the medium volume instrument), some of which are commercially provided by the producer of the instrument, others which are provided by other commercial suppliers, and yet others which are assessed developed and validated 'in house'.

For each instrument, the compatibility of each individual assay had to be individually evaluated based on workflow, cost, turnaround times and assay performance. These factors are in turn influenced by the following: the volume and frequency of test requests for each assay; the throughput capacity of the platform; the case mix of the population served; the frequency with which positive and negative controls / calibrators need to be run; the need for batching / ability to mix and match different assays on a single run; the robustness of positive and negative controls used on the platform; the ability to multiplex and detect multiple PCR targets in a single assay; the capability to produce quantitative as well as qualitative results; the ability for non-specialised

[5] NZMA. Health as an investment. Position Statement. September 2017. Available from http://www.nzma.org.nz/__data/assets/pdf_file/0003/77277/Health-as-an-investment_FINAL.pdf
[6] Available from https://www.pharmac.govt.nz/assets/2019-20-Letter-of-Expectations.pdf

technical staff to use the equipment after hours; and the ease with which the instrument can accommodate both in- house assays and assays supplied by other commercial suppliers.

Many of the assays we plan to use on this platform are highly specialised and geared toward conditions that are rare but have a high clinical impact if undiagnosed. As such they may only be performed once or twice a year and may not be provided anywhere else in the country. They are certainly not provided by private community laboratories.

During this process, even with all the relevant local technical specialists, scientists and clinical microbiologists around the table, we found it highly challenging to work through these issues in relation to the diverse products proposed by 20 odd vendors. Many of the claims by vendors couldn't be taken on face value and we discovered numerous fish-hooks and technicalities at every point in the process. We found, for example quite late in the process, that seemingly small differences in the frequency with which controls need to be run, can in practice make the difference between batching and not batching tests, thus leading to very different turnaround times, even though both instruments can technically be claimed to be "random access" (ie, capable of uploading additional assays while other assays are already underway).

For specialised diagnostic instruments such as these, the needs of different laboratories are very different. Community laboratories serving primary care may only need high throughput assays such as chlamydia and gonococcus whereas our laboratory - which functions as a national referral centre and serves Christchurch and Burwood hospitals - currently performs over 45 different PCR assays.

In New Zealand, there is no one size fits all when it comes to complex diagnostic instruments, neither should there be. The country is so small that as just one instrument of a particular kind may be all that's needed nationwide. As it is, nearly all the specialised molecular testing is currently in the hands of just 2 to 3 public laboratories in New Zealand and even within this group, the type of platforms needed will be very different depending on (at the very least) differences in the nature, diversity and volumes of the assays provided.

Therefore, deciding on the right molecular testing platform is not something that can appropriately or safely be delegated to a national advisory committee (at least in the more specialised public laboratories) even if the committee is comprised of genuine experts in the field. Because there are so many complexities and local factors to consider, a 'one-size fits all' solution shouldn't be assumed. Furthermore, the bewildering variety of platforms on the market don't fit neatly into groups of 'interchangeable' equivalents in the same way that more simple, single purpose medical equipment or medications do. There are invariably numerous technical differences between superficially similar instruments that make a world of difference to the functionality that is practically attainable.

I'm uncertain whether similar issues apply to instruments used in other branches of pathology such as haematology, biochemistry and histopathology, but I suspect they do to some extent. I wonder whether there may possibly also be issues when it comes to radiology and IT solutions (but this is well beyond my expertise).

Given the above issues, I think the range of devices in scope needs to be critically re-evaluated so that highly specialised diagnostic or therapeutic instruments with complex and multi-purpose functionality, and for which only one or two may be required nationally, should be excluded from scope. Such instruments won't have the benefits of economies of scale, so the financial gains from taking a national purchasing approach are likely to be negligible anyway, and the risk of achieving a perverse or unhelpful outcome is significant.