

Pharmac Review Panel recommendations – summary of agency comments

Panel recommendation for the Minister	Agency view	Summary of collective agency comments
Governance and accountability		
1. Change the Pae Ora (Healthy Futures) Bill so that Pharmac's best health outcomes objective includes securing equitable health outcomes for Māori and other populations	Agree in principle – current drafting of the Pae Ora Bill achieves this intent	We agree with the Review that Pharmac, along with all health sector departments and Crown agents, should share a common set of principles, should work to achieve equitable health outcomes for Māori and other population groups, and should work collaboratively as part of a single system focused on achieving the best health and equity outcomes. This is an optimal time for the Government to receive the Review report. The Pae Ora (Healthy Futures) Bill has been further developed for passage into law while new health entities, together with their roles and how they will work together, are being established.
2. Make explicit the expectation that in seeking the best health and equity outcomes, Pharmac must work collaboratively with the Ministry, Health NZ, and the Māori Health Authority	Agree in principle – current drafting of the Pae Ora Bill achieves this intent	The Pae Ora (Healthy Futures) Bill, now read back with changes after select committee consideration, provides (albeit differently) for many of the areas for improvement the Panel has identified and made recommendations on. The Bill will transform the health and disability system by providing:
3. Ensure all health system guiding principles in the Bill should apply to Pharmac	Agree – the Pae Ora Bill has been amended so the principles apply to Pharmac	<ul style="list-style-type: none"> a. a shared statutory purpose and principles for the system that gear the system towards prevention, equity, and the government's Treaty obligations b. a new planning and accountability framework that requires a whole-of system approach to achieve common objectives and facilitate sustained interagency and intersectoral approaches c. a clearer balance between national consistency and local flexibility, where responsibilities are distributed appropriately at national, regional and local levels, and where people, communities and whānau are meaningfully involved in determining priorities d. the basis for a shift in emphasis towards prioritising population health and primary and community health services which keep people well, independent and connected to their communities. <p>We agree that Pharmac needs to work collaboratively as part of a single system with shared principles and health and equity outcomes and objectives. Pharmac has capability that can contribute to other health system entities' achievements, and collective aligned work across entities has high potential to improve equity and health outcomes. Securing best and equitable outcomes from pharmaceuticals requires more than having them available – it is also about whether, how and with what else they are used and the value pharmaceuticals create in achieving health outcomes. Pharmac cannot lead all of the whether, how and with what – however nor can any other agency without the strategic intent, expertise, instruments and links that Pharmac can contribute.</p>
4. Amend Pharmac's functions: <ul style="list-style-type: none"> a. Transfer responsible use of medicines to Health NZ and Māori Health Authority b. Enhance its role as the lead advisory agency in security of supply for pharmaceuticals. 	Agree with the intent, with reservations: <ul style="list-style-type: none"> a. Pharmac cannot be solely responsible but does have some responsibility b. Pharmac's role can be enhanced without amendment 	<p>We do not agree that these additional amendments are needed to the Pae Ora (Healthy Futures) Bill – these are practical operational matters and the principles in the Bill, such as to require collaborative working between health entities (including Pharmac) will guide decisions on who is best placed to do these things.</p> <ul style="list-style-type: none"> a. Pharmac having a function to promote responsible use of medicines does not mean it is a sole responsibility or that other entities are prevented from action in that area. Much work across agencies is underway to, for example, improve safety and quality in medicine use, to prevent development of antibiotic resistance and to improve accessibility of medicines for people who need them. While Pharmac is not and should not be responsible for all of this work, Pharmac does have an important role and levers, particularly through the Pharmaceutical Schedule and related activities, that are not available to other entities. Promoting responsible use of medicines is one contribution towards achieving the best outcomes from pharmaceuticals and should be retained. Its retention continues assurance of a broad approach to making pharmaceuticals available in the short and longer term (such as in lowering risks of antibacterial resistance developing in future or in making pharmaceuticals available only to those in greatest need when supply is short). Removing the clause setting out this function could have perverse consequences. s 9(2)(h) b. Regarding security of supply for pharmaceuticals, this is an important issue and one on which a number of agencies are currently working in the context of the current and future pandemics. The Ministry and Pharmac are both providing input to whole of government advice led by the Ministry of Foreign Affairs and Trade on essential supply chain resilience. Pharmac's role can and should be enhanced without requiring legislative amendment.
5. Agree that the membership of the Consumer Advisory Committee should be appointed by the Minister	Agree with the intent for strong consumer voice input, not that Ministerial appointments are the best way to achieve this	<p>The Pae Ora Bill provides for a code of expectations for consumer and whānau engagement in the health sector, being developed by the Health Quality and Safety Commission and near to finalisation. Pharmac, like all health entities, will be expected to abide by this code and for consumer participation to be integral to its work. This code is a mechanism to bring health entities together and to ensure there is robust consumer and whānau input into all levels, across service delivery, policy and governance.</p> <p>Under the Pae Ora Bill, health entity boards are required to have in place consumer advisory committees, and none of these are to be appointed by Ministers; Pharmac would be out of step if this was the case. However, the code will highlight opportunities to enhance consumer participation at all levels, including in Ministerial appointments to Boards.</p>

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		<p>Along with shared principles, outcomes and objectives and the code, there may be an opportunity for shared or over-lapping consumer advisory bodies across sector entities.</p> <p>Agencies have pointed out risks with Ministerial appointments:</p> <ul style="list-style-type: none"> the risk of members being perceived as 'attached' to the Government (as opposed to diverse, impartial and providing balanced public voice), the risk of subsequently confused accountability, and the advantages of public perception of independence among CAC members the risk of misunderstanding/dissatisfaction in the feedback without clear expectations of the role of CAC members that there is no guarantee that the Minister's appointments would guarantee broad representation - without other changes, this may just be shifting the risk the need for clarity of the expected roles of CAC members the need for good balance between clinical expertise and functional consumer experience across the range of advisory input.
6. Direct the Ministry to develop an updated medicines strategy in consultation with stakeholders (including Māori, Pasifika, disabled people) on its contents over the next 12 months	Improving equity and health outcomes through medicines will sit under other higher-level health strategies that should be progressed first	<p>Strategic thinking about how medicines contribute to equity and health outcomes is vital, and can be progressed through a range of outcomes-focused vehicles. The Pae Ora Bill brings in a new suite of strategies that will set direction for Pharmac and other entities and guide the priority areas for investment. Consultation with Māori, Pacifica and disabled people will proceed as part of the development of the new suite of strategies. Engagement with Māori is required to understand Māori health priorities.</p> <p>The existing Medicines Strategy is informing further development of wider health sector services such as clinical pharmacy and medicines review, and elements of it, notably the regulatory scheme, are yet to be realised. Thus, while it is not as important as other new strategies will be in informing Pharmac's work, it continues to have a useful role.</p> <p>Once the Pae Ora Bill strategies are in effect and the new therapeutic products regulatory scheme is in operation, it may be timely to review the need for revision to the Medicines Strategy.</p>
7. Require Pharmac to improve the transparency and accessibility of its systems, processes, resources, and communications to allow disabled people to participate and contribute on an equal basis	Agree	<p>We agree that Pharmac can and should develop a more nuanced approach to the amounts, types and accessibility of information it provides for the public, for special interest groups, for other agencies it is partnering with and for Crown monitors and Government.</p> <p>This way of operating is consistent with the principles and values for the public service set out in the Public Service Act 2020. Pharmac is well placed to establish the advice streams that it needs and to do so in a way that enables participation and informs decisions.</p> <p>As a Crown entity Pharmac will be expected to abide by the newly developed 'Code of consumer and whānau expectations' when engaging with the public. The code is due for sign off by the Minister of Health at the end of June 2022. These have a set of principles including Te Tiriti o Waitangi expectations.</p> <p>Māori make up a significant proportion of disabled populations and it is important to understand and respond to cultural and whānau contexts.</p>
8. Require Pharmac to ensure its contractual obligations do not preclude sharing of commercially sensitive information with key monitoring agencies such as Health NZ, the Māori Health Authority and the Treasury	Agree with reservations – change to principled rather than absolute wording	<p>While Pharmac does have an obligation to protect commercially sensitive information, there are levels of disclosure that are likely to be permissible in particular circumstances. Frameworks for such permissions and processes for recipient handling of confidential information can be developed. We can vouch from experience the problems with commercially sensitive information. The more hands it falls into, the greater the risk. Breaches would have major implications for Pharmac's buying power and trust of the sector – which impacts NZ greatly.</p> <p>The monitor of Pharmac's performance is the Ministry of Health (rather than Health NZ, the Māori Health Authority or the Treasury, though these have a role). The Review report points to a more active monitoring role for the Ministry and in particular assurance that the Board is requesting and seeking the information it needs to have a good overall picture of Pharmac's investments/non-investments and how that picture fits with the Government's overall strategic direction for the health sector.</p>
9. Direct Pharmac and other agencies in the health sector to review how the different operating approaches used in the Covid-19 response could be applied to business as usual, including working collaboratively and speedily, sharing data, and using streamlined processes	Agree	<p>All health entities are being urged to consider what new and better ways of working have arisen out of the pandemic, and how those could be applied more generally while managing any risks that arise.</p> <p>A specific health system response, focused on health system supplies, is to be led by the Ministry of Health to contribute to the wider Government work on supply chain resilience.</p>

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Decision-making		
<p>10. Direct Pharmac to develop an integrated analytical framework for the assessment of pharmaceuticals that incorporates:</p> <ul style="list-style-type: none"> a. Enhanced cost-benefit analysis with strengthened distributional elements b. Strengthened equity analysis in all its decision-making processes c. Reviewing and revising the factors for consideration to ensure a proper analytical framework for their application, which can be demonstrated to make a material impact on the outcomes of funding decisions and advance the agency's equity goals d. More formal structure to consider the prioritisation of the options for investment list currently performed by Pharmac staff, with greater input from its advisory committees e. More generally, role clarity at each step of the decision-making process, including what information should be taken into account when preparing material to support decisions. 	Agree in principle with adjustment in language	<p>We agree that Pharmac's analytical frameworks do need further development, especially to include distributional components to analyses so as to support equity advancement. We note that this would be world-leading work as such methods have not yet been picked up by other health technology assessment bodies internationally. Pharmac will be well-situated to collaborate with New Zealand and international colleagues who are similarly developing measurement tools and analytical frameworks to support the understanding and advancement of equitable health outcomes. This work is likely to require an ongoing programme of testing and further refinement.</p> <p>We also agree that equitable outcomes can be considered more explicitly in many decision-making processes and urge Pharmac to give high priority to this work.</p> <p>We agree with the suggestions in the Panel's report that Pharmac seek to:</p> <ul style="list-style-type: none"> • strengthen its analytical workforce • strengthen the distributional elements of cost-benefit analysis • make its modelling parameters more consistent to improve comparability • build its capacity and capability in equity analysis • improve its ability to connect with real-world, on-the-ground health service delivery • improve assurance processes. <p>Disparities in the quality of health services, disparities in health outcomes and the recognition of mātauranga Māori and the place of rongoā in health policy and services are all important in considering how equitable outcomes for Māori can be achieved, including through pharmaceuticals.</p>
<p>11. Have stronger oversight by the board of pharmaceutical investment decision-making, with a focus on what is not funded alongside what is funded. This should include:</p> <ul style="list-style-type: none"> a. Ongoing quality assurance oversight of the investment decision-making process b. Regular evaluations of the impact of investment decisions and assurance that the pharmaceutical schedule more generally is advancing Pharmac's objectives, including those of achieving equitable health outcomes. 	Agree	<p>Agree that the Board can have stronger oversight, and may wish to assure itself that its delegations and other policies remain fit-for-purpose and provide sufficient clarity for decision-making, and sufficient oversight by the Board of significant decisions.</p> <p>The Board may need to check from time to time that it has the information it needs to have a strategic view of overall performance and risk. For example, a picture of investments and non-investments and how these fit with Government priorities (such as ensuring equity) in accordance with the Pae Ora Bill strategies and the Government Policy Statement on Health.</p> <p>Stronger oversight could involve quality assurance reviews and impact evaluations as recommended, and consider where savings from disinvestment could be reinvested to further equity goals; and could, perhaps in collaboration with other agencies including the Māori Health Authority, consider mechanisms, including limited access, supply and distribution mechanisms, that make pharmaceuticals accessible for those with the greatest potential to benefit and less accessible for those with lower potential to benefit.</p>
Cancer medicines		
12. Agree cancer pharmaceuticals should be considered like other pharmaceuticals. The emphasis needs to be on severity of disease, clinical alternatives and cost for benefit.	Agree in principle	<p>We agree in principle that cancer pharmaceuticals should be considered like other pharmaceuticals; severity of disease, clinical alternatives and cost for benefit are a focus of Pharmac's assessments, alongside other important considerations such as Māori health need and suitability. However, we note that there is currently a different pathway for funding child cancer treatments, and we think this approach should continue while Pharmac continues to review this mechanism with input from other agencies. Pharmac are reviewing the child cancer treatment funding pathway currently.</p> <p>System resources to provide treatments, and how and where they can be safely and effectively delivered, are closely related to outcomes from funding cancer pharmaceuticals. Some mechanisms that allow for the specific service delivery issues related to cancer treatment should continue, as should improvements in accessibility and equity likely to be made through collaborative work involving Te Aho o Te Kahu, Health NZ, the Māori Health Authority, Pharmac and other parts of the system.</p> <p>This partnership has already begun. Pharmac and Te Aho o Te Kahu will continue to work together, with a focus on ensuring additional health system resources that are required to deliver cancer medicines (once funded), such as molecular testing, infusion capacity, additional imaging requirements etc, are also adequately considered and planned for.</p> <p>Pharmac has supported Te Aho o Te Kahu in analysis of cancer medicines availability in Aotearoa, <i>Understanding the Gap: an analysis of the availability of cancer medicines in Aotearoa</i>.</p>
13. Notes the review considered ring-fenced funding for cancer but believed that would lead to prioritising over other conditions.	Agree	
14. Direct Pharmac and Te Aho o Te Kahu to develop a partnership to enable closer integration with the cancer health sector, with a focus on ensuring equitable access to funded cancer medicines.	Agree	

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Rare disorders		
<p>Direct the Ministry to:</p> <p>15. Lead the development of a rare disorders strategy to coordinate efforts to address and improve the lives of people with rare disorders. This strategy will need to:</p> <ul style="list-style-type: none"> a. Agree an official New Zealand definition of rare disorder. b. Be a system view and based on a commitment to ensuring more equitable access to appropriate healthcare services from diagnosis through to treatment and other supports. c. Consider the challenge of funding medicines for rare disorders, taking into account the increasing scale of the problem and the impact that this will have on health services more generally. 	Agree	<p>We agree with the Review that more can be done to improve the lives of people with rare disorders through a strategic approach to addressing the additional barriers that come with rarity. These barriers are for people, practitioners and organisations across the system. They include rare cancers and rare vaccine-preventable conditions, for example.</p> <p>The challenges for Pharmac in funding pharmaceuticals for rare disorders are one type of barrier, and a number of possible approaches to reduce the additional funding barriers of rarity could be investigated. Additionally, barriers that are due not to rarity but to investment size or risk can also be examined with a view to developing more nuanced mechanisms, including limited access, supply and distribution mechanisms, to make pharmaceuticals accessible for those with the greatest potential to benefit and inaccessible for those with low benefit.</p> <p>Improvements need to be systematic including in diagnosis and treatment across health services. The establishment of HNZ will go some way toward improving consistency across districts and communities – this work should not take a narrow view focused on medicines funding.</p> <p>A strategy may not be the most effective response in the short term as previous work has identified good value for money in a register linking practitioners and the public to best practice advice and to services and input. Such an approach is likely to be of interest to Pacific countries who face much greater barriers in being able to provide care for people with rare disorders. Cross-jurisdictional approaches are likely to be of high interest as these barriers will be faced for people in all countries due to scarcity of expertise and resources. It may be possible to develop more practical assistance functions at the same time as a strategy is being considered.</p>
<p>Direct Pharmac to:</p> <p>16. Fully adopt the recommendations of the RFP pilot evaluation:</p> <ul style="list-style-type: none"> a. Pharmac's Rare Disorders Advisory Committee needs to meet frequently enough to undertake and/or consider horizon scanning. b. Pharmac needs to demonstrate it is acting on the recommendation to have in place more regular calls to suppliers seeking applications. 	Agree there should be sufficient meetings to review horizon scanning and that calls for applications should continue to be used among other promotion mechanisms	The pandemic has placed additional requirements on Pharmac, and at times depleted available resources (including both staff and advisory committee members' time). As recovery occurs, Pharmac will increase meetings and active promotion of supply application for rare disorders products. Applications have continued to be received from suppliers since the last call for applications.
17. Support the chair of the Rare Disorders Advisory Committee to ensure the right expertise is invited to provide advice on applications where there is currently no member of the committee covering that specialism. This may mean involving experts from other countries	Agree	We understand that Pharmac has appointed overseas members to the Rare Disorders Advisory Committee (at least one member is an Australian expert) and that Pharmac makes efforts to identify additional expert input and how it can be best obtained to inform advice. There may be circumstances (eg, very rare expertise) in which this cannot easily be obtained. Pharmac will consider how rare expertise is incorporated. Cross-jurisdictional measures may be possible here.
18. Involve the lived experience of patients with rare disorders in the decision-making process	Agree in principle	<p>The Pae Ora Bill will require health entities to use lived experience where appropriate.</p> <p>We suggest Pharmac is asked to consider all of the Review Panel's rare disorders recommendations with a view to improving the quality of inputs to and processes for its decision-making on pharmaceuticals for rare disorders, and to report on which additional measures it will adopt or trial.</p> <p>There is a risk that these measures may result in unintended reductions in applications or trade-offs such as with privacy or effectiveness.</p>
19. Extend the role of the Rare Disorders Advisory Committee to monitor and review pharmaceuticals once funded, to gauge their efficacy. This could be achieved through the development of a register for funded medicines	Agree	
20. Become more transparent about the decision on applications for rare disorders, including under exceptional circumstances	Agree in principle	
21. Formalise the discretion currently applied within the exceptional circumstances process to minimise barriers to access for rare disorders, including greater clinical oversight.	Agree	

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Vaccines		
22. Transition prioritisation of vaccines and their eligibility criteria to the newly established Interim Public Health Agency	Agree in part – both the Public Health Agency and Pharmac should have strong input	<p>We agree that Pharmac should not make vaccine funding decisions in isolation from other parts of the sector and that an increase in collaboration is needed, over both public health and wellbeing priorities and service delivery mechanisms and priorities.</p> <p>Achieving good immunisation outcomes across all of our communities is vitally important to New Zealanders' health. However, which diseases we immunise against and which vaccines we use are only part of the question. To achieve good and equitable immunisation outcomes requires a whole system end-to-end approach with collective efforts and mutual responsiveness across all entities involved.</p> <p>Some other pharmaceuticals have major public health implications and the PHA should be involved in wider decision-making.</p>
23. Direct the Interim Public Health Agency to consider equity as part of the processes they adopt	Agree that equity is important	<p>We propose a joint-agency strategy and oversight mechanism for health outcomes from immunisation, involving the Ministry, Public Health Agency, Pharmac, Health NZ and Māori Health Authority among others. This would set strategy, prioritisation processes and ways for the system to adjust to emerging circumstances. It should consider and give priority to equity in its processes and decisions.</p>
24. Pharmac should continue to negotiate the price, supply and terms of conditions of supply, but should no longer decide which vaccines are listed on the schedule or the eligibility criteria	Agree in part – both the Public Health Agency and Pharmac should have strong input	<p>The PHA should have a strong joint role in deciding priorities as part of a collective strategy and oversight mechanism for health outcomes from immunisation. The collective would involve the Public Health Agency, the Ministry, Pharmac, Health NZ and the Māori Health Authority among others, and would oversee processes and working arrangements that align the activities of all parts of the system and provide for responsive engagement when the priorities of one part of the system change, such as with emerging changes in diseases, workforce or other health and system priorities. This collective end-to-end approach would involve:</p> <ul style="list-style-type: none"> a. a strategy to which the collective entities contribute and for which the Ministry is accountable; b. horizon scanning, expert advice and prioritisation for which the Public Health Agency, Medsafe and Pharmac all contribute and each have accountabilities for different aspects (such as the Public Health agency for disease priorities and vaccine characteristics required, Medsafe for safety and quality and Pharmac for product assessment and public value) and need to be in communication and responsive to each other; c. a joint decision-making requirement for key vaccine decisions, where three parties (the Ministry, the Public Health Agency and Pharmac) collectively agree on vaccines to be added to or removed from the Combined Pharmaceutical Schedule and are bound by confidentiality rules in considering the information underpinning the decisions (noting that Pharmac would be responsible for effecting those joint decisions through maintenance of the Schedule); d. vaccine purchasing and supply management for which Pharmac is accountable and responsive to the collective, and to which others will contribute (such as the Public Health Agency for refining priorities, Health NZ for refining supply management); e. distribution, implementation and service design and delivery priorities for which Health NZ and the Māori Health Authority are accountable and to which Pharmac and other entities, together with many service providers, will contribute; f. review of uptake and effectiveness for which the Public Health Agency and the Māori Health Authority are accountable and to which all entities contribute; and g. a governance structure to oversee the collective work, steer the end-to-end process, give direction as changes emerge (whether in diseases, priorities, availability or uptake) or issues arise that threaten achievement of outcomes, and ensure the required levels of communication and confidentiality. <p>Pharmac should continue to maintain the schedule (with key decisions requiring agreement) – this is necessary in order to continue with a single schedule rather than having a separate budget for vaccines – a separate budget would be likely to limit investment in vaccines and achievement of public health outcomes over the longer term. (However, it may be that, under the immunisation outcomes strategic approach to be developed, there is some flexibility in the budget for emergent needs, as there currently is for pandemic vaccines and therapeutics.) A separate, ringfenced budget and assessment process for vaccines is unlikely to be effective in overcoming the issues of disconnect or poor responsiveness to changing vaccine needs and uptake across the system.</p> <p>Experience with COVID-19 vaccines has confirmed the criticality to negotiations of both commercial leverage and relationship capital with suppliers and other countries.</p>
25. Transition these new arrangements over a sufficient time period to enable the Interim Public Health Agency to establish the requisite capability	Agree that public health and prioritisation capability needs to be built across the system, including in both the PHA and Pharmac	<p>We are concerned that public health and prioritisation capabilities need to grow across the system, in Pharmac and in all other health agencies. The PHA should have a key role in leading and facilitating this growth and all agencies, including Pharmac, should further develop this expertise and contribute to system growth.</p> <p>An important consideration is meeting our obligations under te Tiriti o Waitangi for partnership and kaitiakitanga – this is more likely to be successful when conducted in wider partnership with health system entities and Māori, focused on what Māori want from health and immunisation outcomes and prioritisation of a National Immunisation Programme including how purchasing can better support equitable outcomes.</p>

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26.	Direct the Ministry, the Interim Public Health Agency and Pharmac to revise the memorandum of understanding to reflect clear roles and functions, including the primacy of the Interim Public Health Agency in ensuring the vaccine schedule is up-to-date and relevant to the health needs of New Zealanders	Agree the memorandum of understanding be revised in line with the immunisation strategy to reflect the contributions of all agencies to end-to-end prioritisation of vaccines, supply, distribution, immunisation and other services	The memorandum of understanding does require revision, in particular to reflect the differing roles, responsibilities and processes according to the current situation. These need to vary in public health outbreaks and emergencies, whether these are local or global or related to particular population or risk groups. Examples include meningococcal (Northland), measles (national), rheumatic fever or HIV (in future).
27.	Allocate responsibility for overseeing the entire vaccine supply chain to Health NZ.	Agree that further work on supply and distribution is needed to support the strategic approach and effective utilisation and equitable outcomes, and needs input from all agencies.	Supply and distribution of vaccines is required to adapt, be assured, maintain safety and minimise wastage with changing circumstances, especially in outbreaks or pandemics, with short-dated stock and/or significant demand. Much has been learned about improving this management during COVID-19 and this learning is being consolidated and translated by the several agencies involved. This requires the input of all agencies involved, including contributing to the inter-agency work led by MFAT on options for strengthening resilience of New Zealand’s supply chains.
28.	Direct Health NZ to undertake detailed policy work to design the system needed to ensure comprehensive, real-time monitoring of vaccines along the supply chain		
Medical devices			
29.	Transfer cataloguing and contracting medical devices from Pharmac to Health NZ, which is better placed to manage procurement and supply chain for medical devices.	Agree that Health NZ has a role in collaboration with Pharmac and other agencies	<p>Like with vaccines and responsible use, a single agency cannot control the end-to-end process alone – joint work across agencies is critical to achieve efficient distribution, assured supply and good outcomes.</p> <p>Health NZ has major work ahead, developing a fully costed multi-year health plan and progressing consistency and standardisation across clinical services including with device use. Taking on additional functions at this time would increase system risk. However, the move from 20 DHBs to a single Health NZ should have considerable positive impact on enabling standardisation and consistency to be developed.</p> <p>Pharmac is managing medical devices supply effectively, safely, collaboratively and with financial prudence. A transfer of this function would involve a number of risks, including:</p> <ul style="list-style-type: none">a. Financial - Pharmac has a strong track record of financial management and probity. This has not been universal in the health system to date; one of Health NZ’s first challenges will be to lead development of a fully costed multi-year Health Plan that it then lives within. Pharmac’s financial management is built on an overall approach of getting maximum value from investment, and the evidence base it assembles can contribute to other agencies’ financial control, including where Pharmac is not the sole or final decision-maker.b. Public health and safety - Risks to public health and safety from poor choices or use of pharmaceuticals can be high. Until new therapeutic products legislation comes into effect, there is no premarket approval or assessment of medical devices, and pre-procurement assessment is all the more important. Pharmac is at present the quasi-regulator of quality and that no counterfeit and substandard devices are used in the health system. Risk to public health and safety would be raised were the medical devices assessment and procurement function to transfer to an agency with less experience in product safety and quality.c. System capability - Pharmac has made greater strides in developing an assessment approach for medical devices than has any other agency and in so doing has gradually developed expertise and capability that would be difficult to replicate elsewhere. There would be risks of capability loss to the system with any transfer of functions, especially at a time of uncertainty with new system structures in New Zealand and opening up of opportunities elsewhere in the world. <p>Pharmac is currently working with Health NZ and other agencies on a health system procurement and supply chain work programme, and is contributing well.</p> <p>Health NZ’s view is different from other agencies’. Health NZ considers it should be given this function from the outset, with a transfer of staff from Pharmac, so that its entire procurement and supply chain work is directly managed.</p> <p>Medical devices are a broad category of product and as work is done on where responsibility for these products should sit it may be useful to consider whether different categories of product should be treated differently (eg, products that are more consumables, products that are implanted and people carry for many years, or products that involve large capital investments in technology with ongoing maintenance requirements). The complexity of this issue speaks to it being given more thought and decisions being taken over time, and to the importance of a strategic prioritisation framework being in place and supported by operational guidance.</p>

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30. This transition should happen at the speed Health NZ determines.	Such a change if considered in future would require Government decisions	Risks with transfer of this function may reduce in time and would require Government policy decisions were that to occur. Risks would be unlikely to reduce sufficiently until after the new therapeutic products regulatory scheme is fully operational for medical devices. (A Bill to provide for this scheme is planned for introduction this year.) By that time, the landscape for medical devices may have changed somewhat, given current trends for these products to become more biological and individualised and increasingly used in community settings.
31. Direct Pharmac to work with Health NZ to complete the work to design the health technology assessment process	Joint work is already underway, direction not required	Health NZ, technicians and clinical staff are key stakeholders in assessment.
32. Any ongoing role for Pharmac in medical devices (for example in technical evaluation or as a purchasing agent) is a matter for Health NZ to consider and agree with Pharmac.	Both Pharmac and Health NZ should be involved, along with MHA and others – any change if considered in future would require Government decisions	This remains a niche area. However, there are a range of products that could fall in or out of scope, and it is probably sensible that this area is looked into in more detail over time. This should be a joint process, involving the Ministry, the regulator (likely to be Medsafe for all therapeutic products), Pharmac, Health NZ and the Māori Health Authority together with other interested agencies.
Responsible use		
33. Agree Pharmac's role in optimising the use of medicines should focus on ensuring medicines are assessed with an equity approach and undertaking any agreed activities that follow on from the proposed medicines strategy and associated action plans.	Agree that Pharmac should assess pharmaceuticals with an equity approach and also should be jointly involved in influencing and reviewing how pharmaceuticals are used and how utilisation affects health and equity outcomes.	To achieve the best equity and health outcomes from pharmaceuticals requires contributions from all health system agencies and others. Pharmac continues to have a significant role and as part of core business supports good prescribing and use such as for medicines changes and new medicines. In developing more nuanced mechanisms to improve equitable access, Pharmac can contribute greatly to best practice utilisation, as can a number of other health system entities and practitioner, provider and consumer groups. This needs to be collective and collaborative work and include medicines review activities. Collaboration can usefully involve agencies more broadly, including for example the whānau ora commissioning agencies who deal with a wide range of issues and hauora responses in their communities and will have critical insights on enabling equitable access.