

**Submission by vaccines member companies of Medicines New Zealand to:
PHARMAC's Decision Criteria, Proposal for Change
March 2014**

We appreciate the opportunity to provide feedback on this consultation.

This submission should be read in conjunction with the overall submission from Medicines New Zealand and the wider group of external stakeholders convened to provide input to the OPP review.

Overall comment

We would like to express our concern that there is inadequate information about how PHARMAC proposes to evaluate vaccines according to the proposed “factors for consideration”.

As with our main submission, we prefer the terminology “decision criteria” and will use this throughout our response when referring to what PHARMAC has termed “factors for consideration”.

Although we support standardising the decision criteria being used across all technologies (vaccines, medicines and medical devices) we believe that where there are meaningful differences, these should be highlighted as part of the definition of the criteria. Failing this, it will be unclear to the public, stakeholders and decision-makers themselves how the criteria are intended to be interpreted in the face of the complexity that arises from comparing these different technologies. We are concerned that PHARMAC proposes to use decision criteria that are open to wide variation in interpretation, without an adequate definition of their intended interpretation to guide applicants and decision makers alike. To facilitate the potential to develop such definitions, we propose the vaccine-specific aspects of the definitions that should be used.

Proposed definitions of the decision factors

As with our main submission, we propose that PHARMAC develop and consult on a set of definitions for the decision criteria to guide applicants and decision makers about the intended meaning of the criteria and aid their application in practice in a consistent manner. With the complexity that arises from comparing different technologies, it is important to have the intended meaning clearly defined.

We have included our initial proposed definitions here as well as the vaccines specific proposals in italics and bolded for clarity.

Need

The health need of the patient population under consideration relative to all eligible people in NZ

- The extent of illness (or health deficit) within the group of patients for whom the treatment is being considered. This measure includes how many people are affected as well as how severely they are affected on average and compares this to the expected (normal) life expectancy and quality. Aspects of relative severity of the illness; urgency of need and the degree to which that need is unmet will be measured under this criterion. The expected benefit of the treatment being considered is excluded from this criterion as it is covered in the “benefits of the medicine” criterion.
- ***Includes the extent of illness (or burden of disease) that would be expected in the future based on epidemiological evidence and statistical models of disease for vaccine preventable illnesses.***

The principles of the Treaty of Waitangi

- Definition in “Supporting Information” is sufficient.

The impact on the health outcomes of population groups experiencing health disparities including Maori and Pacific peoples.

- The expected benefit of providing access to the medicine or medical device that would accrue to a specific population group (geographic, ethnic, demographic or socioeconomic) because of there being a pre-existing worse level of health within that population group.
- ***Includes the expected impact of prevention of illness on groups such as children, the elderly and other population groups that may be vulnerable to worse health outcomes by virtue of a dependence on family or other means of support.***

The availability and suitability of existing medicines, medical devices and treatments for the clinical use under consideration.

- Whether the existing treatments that are publicly funded for the condition under consideration fully treat the condition for all patients and whether (and to what extent) the new treatment under consideration improves the expected benefit for any of the group of patients.
- ***Includes the availability of any preventative intervention such as vaccination and school based programmes of early diagnosis and treatment.***

Supporting Government Health Priorities

- Where a treatment has evidence of being effective in a condition that forms part of the Government's stated health priorities this would increase the level of priority attributed to funding the treatment under consideration.
- ***Includes ensuring that any overall Government or Ministry of Health priority given to preventative programmes over other forms of treatment flows through into access to preventative technologies such as vaccines.***

Benefits

Clinical benefits and risks of the medicine or medical device to the patient and health outcomes

- The measurable improvement in health (measured in QALYs) that the treatment under consideration is expected to provide compared to the treatment which it would replace in clinical use. Where any positive benefit should be balanced against any expected risk attributable to the new treatment.
- ***Includes the projected benefit to those who receive treatment (e.g. a vaccines) as well as any wider benefit to communities from such treatment (e.g. herd immunity).***

Benefits and risks to the health sector of the medicine or medical device

- The measurable overall change in health service utilisation (e.g. hospital admission days; DHB personnel utilisation and other resource use within the health sector) or costs that would be expected to accrue to any part of the health sector if the treatment under consideration is funded.
- ***Includes projected overall change in health service utilisation by those who receive treatment (e.g. a vaccines) as well as by the wider communities who benefit from such treatment (e.g. herd immunity).***

Costs

Out of pocket costs to the patient using the medicine or medical device

- The costs that a patient using a treatment would incur due to the use of that treatment, including any overall increase or decrease in such costs to a patient and their family.
- ***Include evidence of any beneficial impacts on future out of pocket costs to the patient and their family or carers that would accrue due to a preventative intervention such as a vaccine.***

Cost of the medicine or medical device

- The cost effectiveness (dollars per unit health gain) of the treatment under consideration, including assumptions of how many people would use it and what existing treatments would be replaced by the new treatment.
- Costs are compared across treatments for different disease groups, patient types, health technologies.
- The timing of the costs is also taken into account, comparing both immediate and future costs and cost offsets (including prevention compared to treatment).
- Note it is unclear whether this criterion is also intended to include the annual budget impact of the treatment under consideration and if so, should include the definition currently under “statutory objective” below.

Flow on costs of the medicine or medical device to the rest of the health sector

- All costs and savings incurred by any agency funded by Vote Health that would be expected from the decision to make the treatment under consideration available.
- ***Includes costs and savings that accrue in the future beyond the PHARMAC budgeting period.***

Note also that there are specific issues with the economic evaluation of vaccines that need to be taken into account, Advice is available from WHO on these issues and they were covered in detail in our previous submission.

Suitability

Suitability of the medicine or medical device to the patient

- The degree to which the attributes of the treatment under consideration are considered beneficial to the patients who would be using it in terms of ease of administration, need for training and overall acceptability of the medicine. Such attributes and benefits will relate only to those with a beneficial impact on health and not simply to stated preferences without a positive benefit to health.
- ***Includes the suitability to the parents, family or carers of the people eligible for preventative intervention, acknowledging that such perceptions of suitability are strong influencers of appropriate use of vaccines and have flow-on effects on public health outcomes.***

Suitability of the medicine or medical device to the health sector

- The degree to which the attributes of the treatment under consideration are considered beneficial by the prescribers who would be using it in terms of ease of administration, need for training and overall acceptability of the medicine. Such attributes and benefits will relate only to those with a beneficial impact on health and not simply to stated preferences without a positive benefit to health.
- The degree to which the treatment under consideration meets best clinical practice guidelines.

Statutory objective

Does the proposal or decision help PHARMAC to secure for eligible people in need of pharmaceuticals the best health outcomes reasonably achievable from pharmaceutical treatment and within the amount of funding provided?

- Would the funding needed to make the treatment under consideration available to the population for whom it is being considered fit within the short term (annual) and long term (3 year) budget?
- The quantity of health gain relative to other investment opportunities is measured in the “Clinical benefits and risks” criteria.
- The definition of “pharmaceuticals” in this context refers to medicines, medical devices, vaccines and related things.

Vaccine-specific issues for further consideration

In the next section we discuss our concerns about how PHARMAC has not given adequate consideration to our proposals for aspects relevant to vaccines to be included in the decision criteria. We acknowledge that this is a field that PHARMAC is newly applying its decisions to and would like to ensure that the differences between PHARMAC’s prior work and its new responsibility for an important component of public health are fully appreciated. It is widely acknowledged that where possible in healthcare, “prevention is better than cure”, but we are concerned that this preference is not transmitted into the decision criteria as currently proposed.

Issues raised in original submission	Change Needed	Further discussion
<p>Vaccines are generally preventative versus treatment based – this may require emphasis on prevention of disease (and human suffering) in decision-making.</p>	<p>Pharmac’s Decision Criteria need to give due consideration to desirability of prevention of disease.</p>	<p>Prevention of disease (versus treatment of disease) does not seem to rate any special attention in the document.</p>
<p>Vaccines may prevent illness in others not only in those vaccinated</p> <ul style="list-style-type: none"> ○ Herd immunity effect ¹ ○ May result in disease being eradicated altogether ○ Antibiotic resistance may be prevented 	<p>Wider impacts of vaccination need to be included in Pharmac’s Decision Criteria to take account of these issues for vaccines.</p>	<p>This issue is specifically mentioned as being considered under benefits and risks to the patient. “PHARMAC also takes into account how clinical benefits and risks of a given treatment may have an impact on the wider New Zealand population. This becomes particularly relevant when considering, for example, vaccines where effective vaccination has clinical benefits for the wider population in terms of lowering the risk of the spread of contagious disease.” The factors for consideration should therefore be specific about the fact that Pharmac is not only considering health effects on existing patients but members of society (not ordinarily considered as being patients).</p> <p>Under the guiding documents, international treaty obligations need to be taken into account. Specific mention of vaccines being used for disease eradication as part of a worldwide initiative would highlight the importance of this.</p>

<p>Public health considerations may take precedence over other factors when making decisions about vaccines.⁵</p>	<p>Overseas experience indicates that public health considerations may need to take precedence over cost-effectiveness when considering vaccines. Pharmac’s Decision Criteria need to be amended to reflect this.</p>	<p>Pharmac’s document states that all decision criteria are considered for each decision and different criteria will get more weight for particular decisions, within the confines of the legislative framework. Public health issues would presumably be included within this.</p>
<p>Vaccine use may be part of an international strategy in which New Zealand’s participation is desirable (e.g. with leadership by WHO).</p>	<p>This needs to be considered in Pharmac’s Decision Criteria.</p>	<p>Aspects outside government health priorities appear to have been specifically excluded. The removal of Criterion 9 also means that other issues (where relevant) may not be included in decision making. PHARMAC should include reference to international attempts to eradicate vaccine preventable diseases as recommended by the World Health Organisation (WHO). Such reference should form part of the “<i>PHARMAC’s legal framework and guiding documents</i>” section of the OPP.</p>
<p>Vaccines require a <u>proactive approach</u> to acquisition and development so that health priorities are addressed. This may require surveillance of disease incidence and prevalence and vaccine uptake.</p>	<p>The current process for medicines is reactive – the process for vaccines needs to be proactive to ensure timely reaction to or pre-empting infectious disease threats.</p>	<p>The document separates out process issues into something that will be considered in the next stage of the OPP review.</p>

<p>Due to their public health significance, vaccines may need strategies to encourage uptake.</p>	<p>Strategies to encourage uptake of vaccines need to be planned and implemented to ensure the full benefits are realised. The role of Pharmac versus current players in encouraging uptake needs to be defined as this may conflict with Pharmac’s (current) budgetary management focus.</p>	<p>This issue does not appear to be considered specifically. Where companies provide evidence of enhanced adherence to treatment/prevention regimes, either due to product attributes or specific adherence programs associated with the supply of the medicine/vaccine, this should be considered favourably in the overall decision.</p>
<ul style="list-style-type: none"> • There is a strong argument that analyses of vaccines should use a societal perspective because of the burden associated with family care and work loss for childhood vaccines; outcome related productivity gains from physically and cognitively healthy adults;¹³ behaviour related productivity gains arising from reduced child mortality; ¹³ and because community externalities such as herd immunity and reduced antibiotic resistance may need to be included.¹³ There is increasing evidence that EQ-5D does not reflect loss of earnings and that these need to be specifically included in the analysis. This is particularly relevant when disutility occurs in children and productivity loss affects their parents.²⁰ 	<p>Cost-effectiveness should remain one of Pharmac’s Decision Criteria when considering vaccines</p> <p>However, the economic evaluation of vaccines will require amendment of PFPA to reflect special requirements.</p> <p>It is unclear whether vaccines should be considered comparable with other medicines given the special considerations.</p> <p>Vaccines may be more appropriately benchmarked against other preventative health care or public health strategies.</p>	<p>This issue does not appear to be considered specifically. It is not mentioned in the commentary about economic evaluation.</p>

Answers to questions posed

1. How helpful is a high-level summary in better explaining what PHARMAC takes into account?

It does not provide any better explanation of what Pharmac currently takes into account or intends to take into account specifically in relation to vaccines.

2. How well would the proposed terminology 'factors for consideration' reflect how PHARMAC does or should think about its funding decisions?

What other options can you suggest for describing these?

The proposed criteria do not adequately address vaccine specific aspects, see substance of submission above.

3. How would the presentation of a decision-making matrix provide clarity over what PHARMAC considers when it makes a funding decision?

No specific impact of the matrix compared to a list of criteria.

4. Should the decision-making matrix be applied to all PHARMAC's decisions including Schedule, Named Patients and implementation decisions? Why or why not?

If it is not amended to incorporate aspects discussed above (at the very least in how the criteria are defined), it should not apply to vaccines.

Where PHARMAC may benefit from some flexibility in applying the decision criteria between different technologies, there needs to be some predefined limit within which this flexibility occurs to avoid the risk of widely divergent interpretations being used when it is expedient to do so.

5. Are there other dimensions that you would include? Are there any dimensions that you would leave out? Why?

See details above for dimensions that we believe have not yet given adequate consideration.

6. What alternatives to the proposed decision-making matrix could PHARMAC use for presenting what it takes into consideration?

The matrix is sufficient as long as other aspects included in our submission are implemented.

7. What factors for consideration could be omitted or what further ones could be included to inform PHARMAC's decisions?

See details above

8. How useful is it to frame the factors for consideration within the broader operating environment that PHARMAC operates within?

It is helpful to provide context to the decisions that PHARMAC makes, although does little to explain the criteria themselves. There needs to be further explanation of the way in which the various elements in the framework impact on PHARMAC decisions.

9. What key strategic or legislative obligations would you omit or include? Why?

New Zealand's obligations under international treaties need to be included. For example, New Zealand's obligations to comply with international guidance of the WHO relating to international efforts to reduce or eradicate vaccine preventable illness. This is important as international obligations may need to predominate in decision making where these exist.

10. What would be achieved by broadening the health disparity factor to include any population groups experiencing health disparities?

This opens the opportunity to more favourably consider improving health outcomes for groups such as children or others who may depend on carers for support and healthcare. Where these groups have worse outcomes from difficulties accessing health interventions, it is beneficial to focus on preventative strategies.

11. How is the Treaty of Waitangi best reflected in the proposed framework? Why?

No specific concerns with how this is achieved.

12. What would be the impact of removing the current decision criterion 9 ("such other criteria as PHARMAC thinks fit")?

There is concern about the removal of this if there is no allowance made for the inclusion of factors that apply specifically to vaccines. Aspects such as international attempts to eradicate vaccine-preventable disease under the guidance of the WHO and responses to pandemics need to be considered.

13. What is your view on the proposed rewording of the factors for consideration?

As they stand in the proposal by PHARMAC, their intended meaning is not clear and we strongly recommend that definitions of their intended meaning be developed and consulted on. In the absence of PHARMAC providing definitions, we have proposed our own and tried to ensure these are consistent with the “Supplementary Information” (appendix 5) in the consultation.

14. Which factors, if any, are unclear or confusing?

All of the criteria require more specific definitions, but of particular concern to the vaccines suppliers is the term “Suitability of the medicine or medical device to the patient”. As vaccines are often administered to young children, it is essential that their parents’ or caregivers’ views on the suitability are considered.

15. How helpful would the inclusion of a supporting information document be? How would the draft document (appendix 5) provide more clarity and transparency?

We believe that the inclusion of definition of each criterion is essential to enable consistent and transparent application of the criteria. The current appendix 5 however was not intended to serve as definitions of the criteria and therefore is inadequate, should be redeveloped with this purpose in mind and consulted on.

16. What are the pros and cons from using the same decision-making matrix decision criteria for medicines and medical devices? Why?

Specific criteria or factors for consideration need to be included for vaccines. These do not seem to have been included in the “Proposal for Change”

Without inclusion of vaccine-specific definitions or criteria, it is unlikely to be possible to make meaningful comparisons between the technologies described.

17. What additional considerations relevant to medical devices could be captured in the proposed decision-making matrix?

NA

18. Does the proposed approach reflect your views on ‘community values’? Why or why not?

No. Currently PHARMAC practices an unstated preference for a utilitarian framework of resource allocation and yet PHARMAC says it isn’t possible to include community values.

We believe that it is not only possible, but extremely important for PHARMAC to be guided by the views of the community it serves. Without making an explicit decision on the community values that guide PHARMAC, it will continue to focus more on cost containment than optimal access to treatments for people who need them.

19. What aspects of your ‘community values,’ do you feel are not captured in this proposal?

Equity considerations include universality, accessibility to and access to services for the most vulnerable population groups and strategies to reach target groups for vaccinations.

Ethical Issues include consent, confidentiality and the value of life extension with and without disabilities.

Legal considerations might include use of the vaccine in a schedule different from that recommended by the manufacturer (e.g. reducing the number of doses) and the occurrence of severe adverse events.

20. Is there other rationale that PHARMAC hasn’t considered that could be employed to justify PHARMAC considering factors related to non-health outcomes? What is this?

See main body of response above – there are a whole set of issues for vaccines that deserve separate consideration.

Thank you for the opportunity to submit on this consultation.

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