

MAKING FUNDING DECISIONS

THE FUNDING ENVIRONMENT

None of us can have everything we want; our personal resources only stretch so far. The same is true of healthcare. The budget will never be big enough to cover everyone's preferred medicine or medical device.

In today's world, information about the latest medical treatment travels fast and publicity about the latest 'thing' creates demand. When a new medicine becomes available, it is often presented as doing the job better than older medicines, but it's not always the case. Part of our job is to assess all treatments and fund those that make the most improvement to the health of New Zealanders.

All New Zealanders are, in some way and at some time, affected by the funding decisions we make. To ensure our decisions are as fair and robust as possible we currently use nine Decision Criteria, along with expert clinical advice. From 1 July 2016, PHARMAC will begin using a new decision-making framework, the Factors for Consideration, for funding decisions.

We analyse clinical, economic and commercial issues, and seek the views of users and the wider community through consultation. The processes we generally use are outlined in our Operating Policies and Procedures.

The job of assessing potential health outcomes and allocating a subsidy to a medicine is challenging and complex. The decision making process is shown in the diagram 'Schedule decision making process'.

THE DECISION CRITERIA - UNTIL JULY 2016

The Decision Criteria are not weighted or applied rigidly as the situation for one assessment may require quite different considerations compared with another. Funding decisions are made relative to other options, and the context within which decisions are made is constantly changing. The criteria are:

- the health needs of all eligible people within New Zealand
- the particular health needs of Māori and Pacific peoples
- the availability and suitability of existing medicines, therapeutic medical devices and related products and related things
- the clinical benefits and risks of pharmaceuticals
- the cost-effectiveness of meeting health needs by funding pharmaceuticals rather than using other publicly funded health and disability support services
- the budgetary impact (in terms of the pharmaceutical budget and the Government's overall health budget) of any changes to the Pharmaceutical Schedule
- the direct cost to health service users
- the Government's priorities for health funding, as set out in any objectives notified by the Crown to PHARMAC, or in PHARMAC's Funding Agreement, or elsewhere; and
- such other criteria as PHARMAC thinks fit
- PHARMAC will carry out appropriate consultation when it intends to take any such "other criteria" into account.

During 2013/14 PHARMAC carried out a comprehensive review of its decision criteria, including proposing future changes. We consulted widely across New Zealand as part of this review. The results of the review will be published on our website in the near future.

THE FACTORS FOR CONSIDERATION - FROM JULY 2016

During 2013/14 PHARMAC carried out a comprehensive review of the decision criteria, including proposing future changes. We consulted widely across New Zealand as part of this review. This process led to the development of the Factors for Consideration; PHARMAC's new framework for decision-making. The Factors make more explicit the things we take into account when making funding decisions and support our expanding role.

The Factors cover four dimensions: need, health benefit, costs and savings, and suitability.

THE NEED DIMENSION

Need is about the disease, condition or illness. Within the 'need' dimension we consider the impact of the disease, condition or illness on the person, their family or whānau, wider society, and the broader New Zealand health system.

THE HEALTH BENEFIT DIMENSION

The health benefit dimension will look at the potential health benefits that can be gained from the proposed pharmaceutical. Health benefits are generally considered in relation to an average person with the condition, illness or disease. In circumstances where an individual has unique clinical circumstances, for example for some Named Patient Pharmaceutical Assessment (NPPA) applications, the health benefit may be considered in relation to the individual in question.

Under this Factor, we will consider the health benefits (or harms) to the person receiving the medicine or medical device, the health benefits to their family, whānau and wider society, and the consequences for the broader health system.

THE COSTS AND SAVINGS DIMENSION

This dimension focuses on the costs and savings that would result from a decision to fund the medicine or medical device.

We consider the costs and savings to the person and their family, whānau and to wider society. The cost and savings to the health system covers both the cost and savings to the pharmaceutical budget and to the wider health system.

Where relevant, we may also consider the Factors within this dimension when evaluating the cost-effectiveness of a medicine or medical device.

THE SUITABILITY DIMENSION

This dimension considers the non-clinical features of a medicine or medical device that may still have an impact on health outcomes.

We consider where suitability of the medicine or medical device may impact on use by the person, or their family, whānau or wider society where someone else may be administering treatment. We also consider where non-clinical features may impact on the health workforce, for example reducing the risk of error or accident.

The first funding decisions using the Factors will be made from 1 July 2016.

HOW DOES PHARMAC DECIDE WHICH MEDICINES SHOULD BE FUNDED?

Work on each funding application falls into three broad assessment areas: clinical, economic and commercial. These areas are interrelated in practice but are described separately below to help clarify the considerations within each area.

CLINICAL ASSESSMENT

- What are the existing treatments/alternatives in the area?
- Is this medicine any better than what is available already?
- How do we know it is better?
- How reliable is the clinical trial data? What time period does it cover?
- Is something “proven” or is evidence still emerging?
- Has all available evidence been provided?
- Are there any side effects that need to be considered?
- How big a population will it treat?
- Does access need to be targeted for the medicine to work well?

Our main clinical advice comes from an expert committee of clinicians – the Pharmacology and Therapeutics Advisory Committee (PTAC). In addition, we have a network of 20 subcommittees providing specialised advice on a range of medical areas. Overall, these committees provide us with a resource of over 140 practising clinicians to call upon for advice. Committees also consider the nine Decision Criteria (transitioning to the Factors for Consideration in 2016) when making recommendations.

We also employ people within PHARMAC with clinical expertise – in medical practice, pharmacy, public health or the science of pharmacology – and with links to other health professionals. This expertise is crucial in helping us manage the funding process.

While we are working on how to apply our clinical assessment framework to hospital medical devices, we have established a wound care advisory group to give advice on managing this category of medical devices.

ECONOMIC ASSESSMENT

Economic assessment looks at the costs and benefits of a proposed course of action. It's based on three fundamental concepts that summarise the issues PHARMAC faces daily:

- scarcity - resources will always be insufficient to support all possible activities
- choices - due to scarce resources, decisions must be made regarding how best to use them
- opportunity cost - by choosing to use resources one way, we forgo other opportunities to use the same resources.

The way PHARMAC assesses pharmaceuticals is described in the Prescription for Pharmacoeconomic Analysis (PFPA), a document that is published on the PHARMAC website. Most funding decisions involve spending more for the additional health gains. We use cost-utility analysis to compare these potential funding options on a more-or-less equal basis, and rank them in order of priority. Cost-utility analysis considers:

- effects on quality of life (eg ability to work/perform usual activities, pain/anxiety, mobility) as well as effects on the duration of life
- short and long-term effects
- changes to the cost of pharmaceuticals
- changes to other health sector costs (eg diagnostics, hospitalisations, doctor visits)
- the risk and uncertainties of the evidence available.

COMMERCIAL ASSESSMENT

We all like to get the best deal we can when making a purchase, and as a pharmaceutical funding decision-maker PHARMAC is no different.

We encourage price competition through the use of competitive processes such as tendering for supply (asking for quotes), and reference pricing (applying the same subsidy to all medicines with same or similar effects). PHARMAC does not regulate prices by requiring that pharmaceutical companies supply at a particular price, rather we negotiate subsidies on a 'willing buyer-willing seller' basis.

Commercial assessment means establishing whether funding proposals from pharmaceutical companies represent a good deal. There are many aspects to this such as using economic assessment, comparing prices for existing subsidised medicines in the same therapeutic group and with those that other countries are paying. When we think we have reached a good agreement, we usually then consult with our stakeholders.

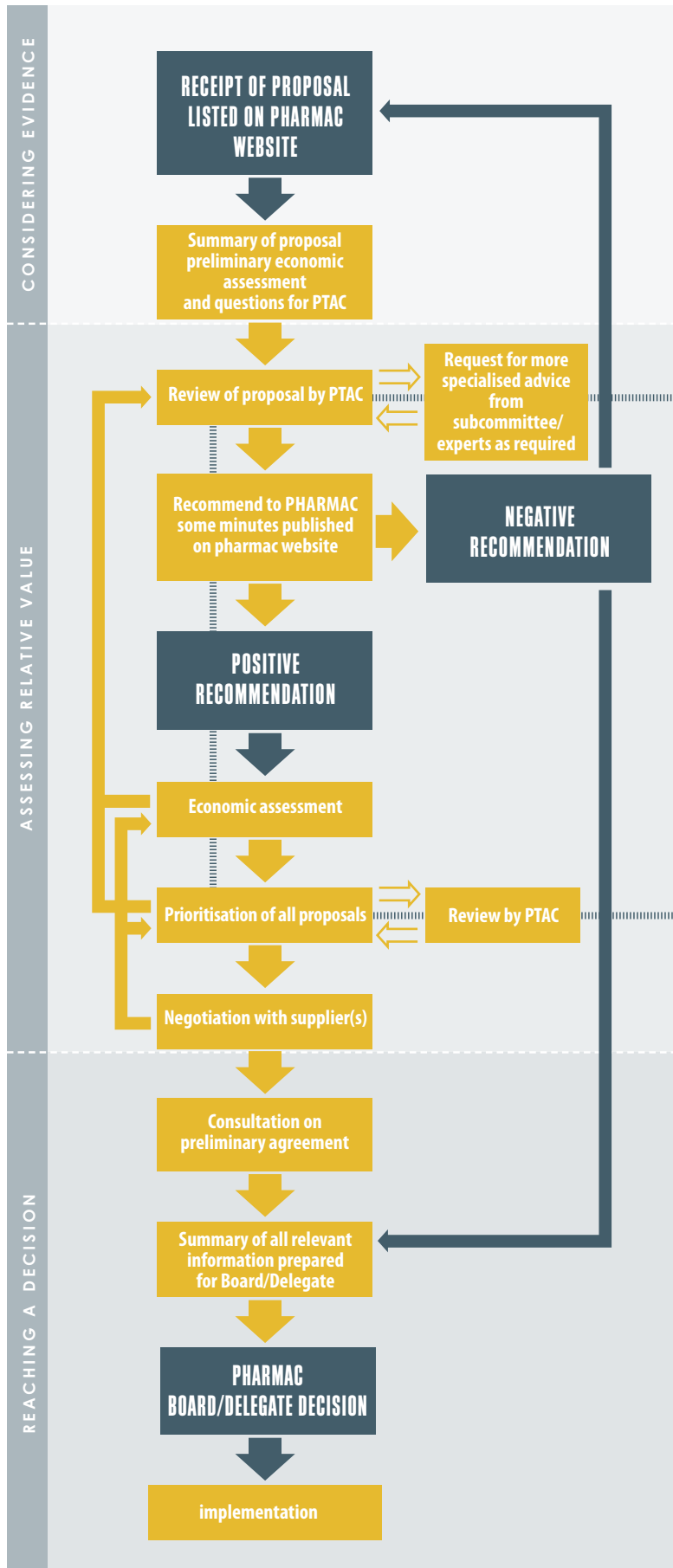
See our Purchasing Medicines information sheet for further information.

CONSULTATION

Before we make a funding decision or make a change to our policies, we want to be sure that we have considered all the possible reasons for and against a decision, and any likely implications. One way we do this is to consult with anyone who is interested in the decision or who may be affected by the decision, to get feedback on our proposed approach and hear their views. We welcome all the views we receive, whether from health professionals, the pharmaceutical industry, consumer and patient groups, Government agencies or the general public.

See the Getting Involved in PHARMAC Decision Making Information Sheet to find out how you can let us know your views.

SCHEDULE DECISION MAKING PROCESS



FUNDING FOR EXCEPTIONAL CIRCUMSTANCES

PHARMAC's Exceptional Circumstance Framework generally considers funding decisions in exceptional circumstances that fall outside of the Pharmaceutical Schedule funding process. This includes:

- Named Patient Pharmaceutical Assessment (NPPA)
- Special Authority waivers
- Hospital Medicine Restriction waivers

NAMED PATIENT PHARMACEUTICAL ASSESSMENT (NPPA)

Sometimes a prescriber will want to use a treatment which isn't on the Pharmaceutical Schedule (either at all or for their patient's clinical circumstances).

The process for applying for an unlisted treatment for an individual patient is called Named Patient Pharmaceutical Assessment (NPPA).

The NPPA policy complements the Pharmaceutical Schedule so considers those funding applications which are not appropriate to be considered through the Pharmaceutical Schedule listing process. This means that NPPA is only intended for people with exceptional clinical circumstances.

Applications can only be made by prescribers due to the clinical information we require to assess them.

More information on how to apply for a NPPA can be found on the PHARMAC website.

SPECIAL AUTHORITY WAIVERS AND HOSPITAL MEDICINE RESTRICTION WAIVERS

Some pharmaceuticals listed in the Pharmaceutical Schedule require conditions to be met before funding will be granted. These conditions generally ensure that funded access is available to those patients who would benefit most from treatment.

Sometimes a person's clinical circumstances may meet the spirit or intent of the conditions within the Schedule, but not meet the technical requirements.

When that happens, PHARMAC may use its discretion to grant:

- a Special Authority waiver for pharmaceuticals used in the community
- a Hospital Medicine Restriction waiver for medicines given by DHB hospitals.

More information on how to apply for a special authority can be found on the PHARMAC website.