

Pharmaceutical Management Agency
Review of Exceptional Circumstances
Seeking Your Views
August 2010



Contents

Providing a response	3
Background to this discussion phase	4
Providing for Exceptional Circumstances	5
The criteria for considering funding in Exceptional Circumstances.....	6
Funding for Exceptional Circumstances	8
Operational arrangements for Exceptional Circumstances	9
Additional comments.....	10
Appendix one: Questions to guide submission	12
Appendix two: PHARMAC decision making	13
Appendix three: Relevant provisions of the OIA 1982.....	16

Providing a response

This document includes:

- information on how to make a response
- the background for PHARMAC's review of Exceptional Circumstances
- information on PHARMAC's role and the current Exceptional Circumstances Schemes; and
- questions to help guide your response (listed throughout the document and collated in Appendix one).

This discussion document and a letter from PHARMAC's Chief Executive inviting your response are also available on our website at www.pharmac.govt.nz/ecreivew.

Submitting your response

Please submit comments via an email, fax or letter by **5pm Friday, 3 September** to:

Bryce Wigodsky
PHARMAC
PO Box 10-254
Wellington 6143

Email: ecreview@pharmac.govt.nz
Telephone: (04) 460 4990
Fax: (04) 460 4995

We also invite interested stakeholders to meet with PHARMAC staff to present their views in response to our request for information. Please contact Bryce Wigodsky by Tuesday 17 August 2010 if you would like to meet with us. If a range of stakeholder groups are interested in meeting, we may organise larger group meetings.

Please contact Bryce Wigodsky if you require further information about any other aspects of this review.

Information requested under the Official Information Act

Please note that your response and all correspondence you have with PHARMAC may be the subject of requests under the Official Information Act 1982 (the OIA). PHARMAC will generally omit your personal details (name, contact details and any other personally identifying information) from your response, before making it available as part of any request under the OIA, if you make it clear that you wish such information to be withheld.

If there is any other part of your response or correspondence that you consider could properly be withheld under the OIA, please include comment to this effect along with reasons why you want the information withheld. The provisions setting out reasons for withholding information under the OIA are attached in Appendix three for your information.

Background to this discussion phase

PHARMAC is seeking your views on the purpose of the Exceptional Circumstances (EC) Policy, the appropriate EC criteria, operational arrangements for EC, and any other related issues.

PHARMAC's review of EC is being undertaken with the close involvement of the Ministry of Health and District Health Boards (DHBs). Our aims are to:

- review and clarify the purpose of the provision of funding in Exceptional Circumstances;
- review and clearly describe what constitutes exceptional circumstances; and
- ensure the operational arrangements for the administration of Exceptional Circumstances, including funding, are optimal.

Currently, we manage three EC Schemes. While we include detail of each Scheme in this document, we encourage you not to be constrained by current arrangements when providing your views on the appropriate purpose, criteria and operational arrangements of EC.

The three current Schemes are:

- Community Exceptional Circumstances (CEC) - allows funding, in some circumstances, for community-based pharmaceutical treatments not covered under the provisions of the Pharmaceutical Schedule.
- Cancer Exceptional Circumstances (CaEC) - provides District Health Board-funded access, in some circumstances, to oncology treatments outside of those funded through the Pharmaceutical Schedule.
- Hospital Exceptional Circumstances (HEC) - allows for access, in some circumstances, to otherwise unfunded community treatments to allow a patient under DHB treatment to be discharged from a hospital or to avoid hospitalisation.

PHARMAC also considers any requests for funding for an individual for whom funding is not provided through the Pharmaceutical Schedule or through the three formalised EC Schemes described above. Further detail on the three EC Schemes, and the other circumstances in which funding is considered, is provided in the following section.

At this time, we are not making any proposals for change. We are seeking your views on the purpose, criteria, operational implementation, and any other issues you may have with PHARMAC's provision of subsidies for Exceptional Circumstances. Once we receive and analyse all feedback, we will develop proposals for improving EC, which we will consult on later this year.

Origins of the review

This review of EC has been initiated, in part, in response to the recommendations in the report of the High-Cost, Highly-Specialised Medicines Review Panel, commissioned by the Minister of Health in 2009.¹ Amongst other actions, the Panel recommended that the three EC Schemes be combined into one.

While this review of EC does not specifically focus on funding for, and access to, what may be regarded as 'high-cost' or 'highly-specialised medicines', some treatments for which funding is approved by PHARMAC under EC could be considered to be 'high-cost' and/or 'highly-specialised'. Consequently, this review of PHARMAC's EC Policy may have implications for access to these treatments.

¹ P McCormack, J Quigley and P Hansen. *Review of Access to High-Cost, Highly-Specialised Medicines in New Zealand*. Report to Minister of Health, Hon Tony Ryall, 31 March 2010.

This review is also part of our ongoing work to continue improving our service to New Zealand and is in response to the government's *Medicines New Zealand* strategy and its accompanying action plan, *Actioning Medicines New Zealand*.² Particularly relevant to the EC Policy, *Medicines New Zealand* aims to ensure that, 'taking account of and balanced against other health priorities, the medicines system is responsive to individual variation, within a population focus.'³

Providing for Exceptional Circumstances

Legislative requirements

Section 48(b) of the New Zealand Public Health and Disability Act 2000 (NZPHD Act) establishes, alongside PHARMAC's management of the Pharmaceutical Schedule (described further below) and other functions, PHARMAC's role in managing:

incidental matters arising out of [maintaining and managing a pharmaceutical schedule], including in exceptional circumstances providing for subsidies for the supply of pharmaceuticals not on the pharmaceutical schedule.

The legislation is clear that alongside managing the Pharmaceutical Schedule that applies consistently throughout New Zealand (including determining eligibility and criteria for the provision of subsidies), PHARMAC must consider the need for funding medicines outside of the Schedule. The NZPHD Act is silent on what constitutes 'exceptional circumstances', and how the provision is to be implemented.

The Pharmaceutical Schedule is key to PHARMAC achieving its statutory objective of securing 'for eligible people in need of pharmaceuticals, the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided.'⁴

The Schedule lists:

- pharmaceuticals available in the community and subsidised by the government (through the DHBs) with funding from the Community Pharmaceutical Budget; and
- pharmaceutical cancer treatments available in the community or hospital which are subsidised by DHBs; and
- some pharmaceuticals purchased by DHBs for use in their hospitals, specifically those hospital pharmaceuticals for which national prices have been negotiated by PHARMAC.

Approximately 2,000 brands of pharmaceuticals available in the community are subsidised by DHBs through PHARMAC's administration of the Schedule. Most are available to all eligible people⁵ in New Zealand on prescription by an authorised prescriber. Some pharmaceuticals are listed in the Schedule with guidelines or access criteria, such as a requirement for a prescriber to complete a Special Authority application to ensure the medicine is funded only for patients who are most likely to benefit from them. More information on the Schedule listing process is provided in Appendix 2.

Exceptional Circumstances and the Pharmaceutical Schedule

The current EC Policy provides a formal mechanism for considering funding for individual patients, for pharmaceuticals that are not listed in the Schedule, or in circumstances where a patient is in a

² *Actioning Medicines New Zealand*, available at <http://www.moh.govt.nz/moh.nsf/indexmh/actioning-medicines-nz?Open>

³ *Medicines New Zealand*, available at <http://www.moh.govt.nz/moh.nsf/indexmh/medicines-nz>

⁴ New Zealand Public Health and Disability Act 2000, section 47(a).

⁵ See <http://www.moh.govt.nz/eligibility> for more information on the eligibility criteria for publicly funded health and disability services in New Zealand.

different population group to that which was considered when a pharmaceutical was listed in the Schedule.

For PHARMAC to achieve its strategic objective through the maintenance of the Schedule, it is essential that the EC Policy does not undermine the Schedule listing process. There are a number of reasons why a pharmaceutical may not be funded at all, or not funded for a particular indication (medical condition or symptom), including that PHARMAC:

- may not be aware of the need for a pharmaceutical and has not assessed it for funding;
- may not have assessed a pharmaceutical for funding for a particular use;
- may have decided to fund a pharmaceutical for a limited group of patients, for example using Special Authority criteria;
- may have assessed a pharmaceutical and decided not to fund it;
- may have assessed a pharmaceutical and considered that it should be funded but that it cannot be afforded in the current year; or
- may be in the process of assessing a pharmaceutical.

The range of medicines that could be funded will always exceed PHARMAC's ability to pay for them. The Schedule funding process determines which medicines, out of all the available options, provide the best health outcomes as assessed by PHARMAC against its 9 Decision Criteria⁶. The result of this process is that some people may not have access to funded treatments that they wish to access. Using the EC Policy as a mechanism to fund these treatments as a matter of course is not desirable as the reality of limited resources, and the need to make choices within this, remains.

To assist our review of the purpose of providing subsidies in exceptional circumstances, we are seeking your response to these questions:

1. How would you define the term 'exceptional circumstances'?
2. What do you think is the purpose of the statutory requirement that PHARMAC provide subsidies in exceptional circumstances?
3. What, if any, other comments do you have on the purpose of the provision of subsidies in exceptional circumstances?

The criteria for considering funding in Exceptional Circumstances

As explained above, PHARMAC currently manages three Exceptional Circumstances Schemes. Each Scheme has different criteria which govern access to funding under that Scheme. In addition, PHARMAC considers any requests for funding for treatments for individuals that fall outside these Schemes.

The current criteria for the three Schemes described below reflect the approach PHARMAC has taken to date to defining the term 'exceptional circumstances'. As discussed earlier, our primary focus in this document is on learning your views on what the EC Policy should be. The following discussion of the individual EC Schemes is intended to provide further information about the current arrangements, but is not intended to constrain your response.

Community Exceptional Circumstances

⁶ See the *Making Funding Decisions* information sheet in Appendix two for the list of decision criteria.

The current criteria for Community Exceptional Circumstances (CEC) funding have not changed from those originally used by the Regional Health Authorities (RHAs) and the Health Funding Authority (HFA) who managed the Scheme before the NZPHD Act gave the role to PHARMAC in 2001.

CEC provides funding for community pharmaceuticals that are either not listed on the Schedule, or that are listed with access conditions, allowing funding to be given only to certain patients rather than to the population as a whole.

In order to qualify for CEC funding one of the following criteria must be met:

1. the condition must be rare, or
2. the reaction to alternative funded treatment must be unusual, or
3. an unusual combination of clinical circumstances applies.

As a guide for applying health professionals, PHARMAC currently considers the criteria to be met in applications for CEC funding for patients in circumstances where there are approximately ten or fewer individuals in the same clinical situation in New Zealand.

Where one of the above criteria is met, CEC applications are then further examined taking into account the following supplementary considerations:

- the suitability of the pharmaceutical for which funding is sought;
- the clinical benefit;
- the cost effectiveness of the treatment; and
- the patient's ability to pay for the treatment.

Where the cost of a treatment being applied for exceeds \$15,000 for the total course of treatment, PHARMAC's 9 Decision Criteria are also considered.

Cancer Exceptional Circumstances

Like Community EC, Cancer EC (CaEC) allows DHB funding, in some circumstances, of a cancer treatment that has not been considered for funding on the Schedule. Applications for treatments that have been considered and declined for funding on the Schedule, but are being sought for a different patient sub-group, can also be considered under CaEC.

The current criteria for CaEC funding are based on the principles of peer review within DHB hospitals. They enable DHB hospitals to fund treatments where all of the following conditions are met:

- the proposed use is evaluated and approved using established DHB review mechanisms involving experienced clinicians;
- the DHB hospital providing treatment has agreed to fund it;
- the condition is considered unusual (and thus a decision to treat is unlikely to result in access inequalities across DHBs);
- the proposed use has not been, or is not currently being, considered by PHARMAC for funding;
- specification is provided of the:
 - product to be used
 - dose and treatment schedule
 - duration of treatment
 - indication
 - total cost
- the total cost is less than \$30,000 over a five year period. If the application is for a treatment of \$30,000 or more, a cost-utility analysis may also be undertaken to inform a decision.

Hospital Exceptional Circumstances

HEC allows for DHB hospital funding of community-based treatments for patients currently in DHB hospitals who are awaiting discharge, or to prevent an admission of a patient, where there is no provision for funding the treatment in the community through the Schedule.

Cost-effectiveness to the DHB hospital when compared to the most likely alternative intervention or outcome is the sole criterion applied to HEC applications. As such, HEC applications must provide evidence demonstrating that funding the pharmaceutical for a specific patient is more cost-effective for the relevant DHB hospital in the region in which the patient resides than the most likely alternative intervention or outcome.

Other exceptional circumstances

PHARMAC considers all requests for funding for an individual, outside of listings on the Schedule, even if these do not fit under the three Schemes described above. The circumstances in which funding is most commonly provided outside of the Schedule funding process and outside of the three Schemes, but from within the Community Pharmaceuticals Budget, are:

- minor deviations from special authorities – where an individual's clinical circumstances do not meet the technical requirements of the special authority criteria, but do meet the intent of the special authority provisions.
- where we are unable to fulfil the requirements for a Schedule listing (for example where there is no supplier in New Zealand) but wish to make a treatment available for patients.

To assist us in our review of access criteria for Exceptional Circumstances funding, we are seeking your response to these questions about the overarching EC Policy:

4. What do you think should be the criteria on which any Exceptional Circumstances funding requests are assessed and approved?
5. How do these criteria support your description of the purpose of the provision of funding in exceptional circumstances, in response to Question 1?
6. What, if any, other comments do you have on the criteria for Exceptional Circumstances?

Funding for Exceptional Circumstances

The funding arrangements for Community Exceptional Circumstances differ to those for CaEC and HEC.

Community Exceptional Circumstances

For community pharmaceuticals listed on the Pharmaceutical Schedule, each DHB funds the actual pharmaceuticals used by its patients.

Funding for pharmaceuticals for CEC is allocated from a notional budget as agreed to by PHARMAC and DHBs. This budget is set aside each year from the overall Community Pharmaceuticals Budget. The more funding that is allocated to individuals through CEC, the less funding there is available for increasing access to pharmaceuticals through the Pharmaceutical Schedule.

The notional CEC budget is contributed to by each DHB based on its respective share of the national population, not on the actual usage of pharmaceuticals granted funding under CEC in the DHB region. Thus, the notional budget acts as a risk pool for DHBs, spreading the financial risk of funding CEC applications across all DHBs. The size of the notional budget is \$3 million, based on the current EC Policy.

This budget is notional as the money provided for CEC is determined by the volume and nature of the approved applications. If expenditure is likely to exceed the agreed budget PHARMAC must seek agreement from the DHBs to spend additional money. Actual CEC spending is currently about \$2.5 million per year.

Hospital and Cancer Exceptional Circumstances

Whereas PHARMAC manages the administration and review of applications for CaEC and HEC, funding for both these Schemes comes from the hospital budget of the DHB region where the patient resides. In the case of CaEC, the DHB has to agree to fund the treatment prior to an application being made. For HEC, the DHB can choose to fund, at its discretion, an approved application.

To assist us in our review of the funding arrangements for Exceptional Circumstances, we are seeking your response to these questions:

7. How do you think funding for Exceptional Circumstances should be allocated and managed?
8. How do you think PHARMAC can best manage the trade-off between funding for increased access to pharmaceuticals listed on the Schedule, and providing funding for Exceptional Circumstances?
9. What, if any, other comments do you have on the funding for Exceptional Circumstances?

Operational arrangements for Exceptional Circumstances

For all three Schemes, relevant health professionals complete application forms which seek clinical information on the individual patient that will be considered under the criteria for the EC Scheme. Applying health professionals are notified of the outcome of their application by a letter from PHARMAC staff.

One EC Panel interprets the criteria carefully for each Scheme, as described below, and applies them consistently to make judgments based on their clinical and Panel experience.

Community Exceptional Circumstances

Applications for CEC funding are received by the Exceptional Circumstances Coordinator and typically referred to the Exceptional Circumstances Panel (the Coordinator has delegated authority in a small number of circumstances to determine whether an application can be approved). Where possible, a decision is made within two weeks of receipt of a CEC application. Decisions can be made more urgently if needed, and the EC Panel sometimes requests further information to inform its decision.

Currently, the EC Panel has the authority to approve CEC funding applications up to \$15,000 for the full course of treatment. This amount is set by the PHARMAC Board as it is the amount over which the investment is significant enough to warrant further analysis. This threshold is subject to review and change by the Board. If the Panel recommends that funding be made available for a patient

where the full course of treatment is over \$15,000, PHARMAC staff may undertake a more detailed analysis and the Board or its Delegated Authority makes a decision, taking into account our 9 Decision Criteria. This process may take up to two months.

CEC applicants can ask the EC Panel to review any Panel decision on a CEC application. If, following review, the decision remains unchanged it can also, upon request, be reviewed by a separate EC Review Committee. This EC Review Committee is made up of the chair of the Pharmacology and Therapeutics Advisory Committee (PTAC)⁷ and three senior clinicians. The Review Committee reviews all information considered by the EC Panel and can direct the EC Panel to reconsider its decision if, in the Committee's view, all relevant material was not properly considered. PHARMAC staff are also able to review the Panel's decision processes. The EC Review Committee cannot overturn the Panel's decision, it can only send the application back to the Panel for reconsideration.

Cancer Exceptional Circumstances

DHB clinicians making applications to CaEC must seek prior DHB approval of funding, and obtain peer review of their application. CaEC applications are made on a tick-box system and are then considered by PHARMAC staff, including the CaEC Panel Co-ordinator, relevant Therapeutic Group Manager and the Medical Director. Where the criteria are clearly met, the CaEC Panel Co-ordinator approves the application. Where there is any doubt about whether the criteria are met or the application is more complex, the application is referred to the EC Panel for advice. Decisions on most CaEC applications are made within 72 hours of receipt of a CaEC application.

DHBs are responsible for considering the financial implications of applications. Where the total cost of an application for a treatment is over \$30,000, PHARMAC staff may undertake a cost-utility analysis to inform PHARMAC's decision on the application.

Hospital Exceptional Circumstances

Applications for HEC must provide evidence demonstrating that funding the pharmaceutical for a specific patient is the most cost-effective option when compared to the most likely alternative intervention or outcome (taking into account the clinical benefit of the treatment) for the DHB hospital in the region where the patient resides. Where this is demonstrated, the HEC application is approved and the DHB can choose to fund, at its discretion, an approved application. As with CaEC applications, DHBs fund pharmaceuticals approved under HEC so are responsible for considering the financial implications of applications.

To assist us in our review of the operational arrangements for Exceptional Circumstances, we are seeking your response to these questions:

10. What are the important factors to consider regarding the operational arrangements for EC?

11. What, if any, other comments do you have on the optimal operational arrangements for EC?

Additional comments

We have attempted to keep this discussion document on PHARMAC's Exceptional Circumstances policy brief in order to leave the response process as open-ended as possible. While we have provided you with some questions throughout this document (which are also collated in Appendix 1) to guide your thinking and response, we are interested in any other comments you may have about the EC Policy and our operational processes. Please feel free to include in your response any comments, concerns or questions that are not addressed by our guideline questions.

⁷ PTAC is a clinical advisory committee to PHARMAC consisting of expert clinicians.

To assist us in considering all issues relevant to the review of Exceptional Circumstances, we are seeking your response to these questions:

12. What additional comments, concerns or issues do you have with the current provision, criteria, operational arrangements or other matters relating to the EC Schemes?

The next steps

As noted, submissions are due to PHARMAC by **5 pm on 3 September**. Following this, we will review and analyse all submissions (and feedback from any meetings) to inform our development of a proposal for a revised EC Policy.

We intend to publicly consult on that proposal later this year. Any feedback you have will be considered when the Board makes its decision about EC in early 2011. Depending on the outcome of the review, any relevant changes to the EC Policy will be implemented as appropriate.

Appendix one: Questions to guide submission

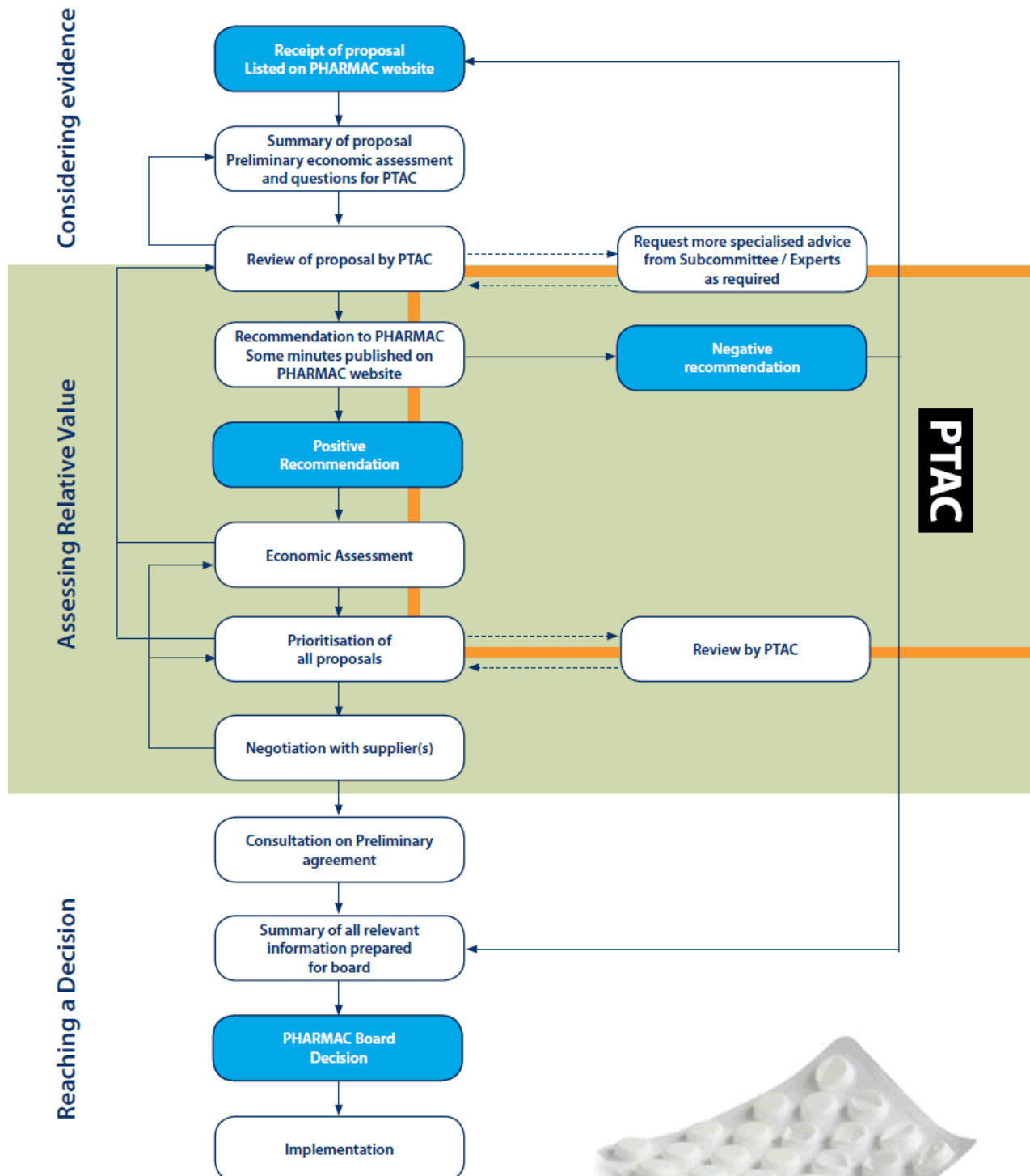
1. How would you define the term 'exceptional circumstances'?
2. What do you think is the purpose of the statutory requirement that PHARMAC provide subsidies in exceptional circumstances?
3. What, if any, other comments do you have on the purpose of the provision of subsidies in exceptional circumstances?
4. What do you think should be the criteria on which any Exceptional Circumstances funding requests are assessed and approved?
5. How do these criteria support your description of the purpose of the provision of funding in exceptional circumstances, in response to Question 1?
6. What, if any, other comments do you have on the criteria for Exceptional Circumstances?
7. How do you think funding for Exceptional Circumstances should be allocated and managed?
8. How do you think PHARMAC can best manage the trade-off between funding for increased access to pharmaceuticals listed on the Schedule, and providing funding for Exceptional Circumstances?
9. What, if any, other comments do you have on the funding for Exceptional Circumstances?
10. What are the important factors to consider regarding the operational arrangements for EC?
11. What, if any, other comments do you have on the optimal operational arrangements for EC?
12. What additional comments, concerns or issues do you have with the current provision, criteria, operational arrangements or other matters relating to the EC Schemes?

Appendix two: PHARMAC decision making

Decision making process



The process set out in this diagram is intended to be indicative of the process that may follow where a supplier or other applicant wishes a pharmaceutical to be funded on the Pharmaceutical Schedule. PHARMAC may, at its discretion, adopt a different process or variations of the process (for example, decisions on whether or not it is appropriate to undertake consultation are made on a case-by-case basis).



Making funding decisions



The medicine funding environment

None of us can have everything we want; our personal resources only stretch so far. The same is true of healthcare, and medicines. There will always be a greater demand for funded medicines than the available resources allow.

Rapid sharing of information leads to heightened public desire for new medicines to be funded. Further, when a new medicine becomes available, it is often presented as doing the job better than older medicines. But newer isn't necessarily better and part of our job is to assess all medicines and fund those that make the most improvement in the health of New Zealanders.

All New Zealanders are, in some way and at some time, affected by the decisions we make. To ensure that the funding of medicines is as fair and robust as possible, we use nine Decision Criteria and an established process that includes expert clinical advice, and internal analysis by PHARMAC of clinical, economic and commercial issues. We also seek the views of the wider community through consultation.

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

The "Decision Criteria"

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

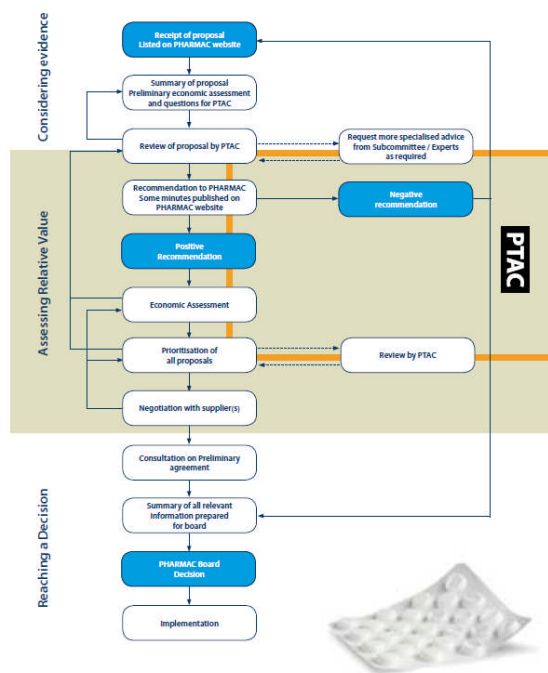
- the health needs of all eligible people within New Zealand;
- the particular health needs of Māori and Pacific peoples;
- the availability and suitability of existing medicines, therapeutic medical devices and related products and related things;
- the clinical benefits and risks of pharmaceuticals;
- 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.

How does PHARMAC decide which medicines should be funded?

We undertake a range of work for each funding decision, which falls into three broad areas: clinical, economic and commercial assessment. These work areas are all interrelated in practice but are described separately below to help clarify key considerations within each area.

Decision making process



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, there is a network of Subcommittees providing specialised advice on a range of medical areas. Overall, these committees provide us with a considerable resource of over 50 practicing clinicians to call upon for advice. Committees also consider the nine decision criteria when making recommendations.

We also employ a number of 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.

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; and
- opportunity cost - by choosing to use resources one way, we forgo other opportunities to use the same resources.

The way that PHARMAC assesses pharmaceuticals is described in the Prescription for Pharmacoeconomic Analysis (PFPA). Most funding decisions involve spending more for the additional health gains. “Cost utility analysis” enables us to compare these potential funding options on a more-or-less equal basis, and rank them in order of priority. Cost-utility analysis includes consideration of:

- effects on quality of life (e.g. 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 (e.g hospitalisations, doctor visits)
- the risk and uncertainties of the evidence available.

Assuming that the impact on the other decision criteria is identical, the more cost-effective an intervention is the more likely it is to be funded.

Commercial Assessment

We all like to get the best deal we can when making a purchase and as a medicine funder, PHARMAC is no different.

We encourage price competition through the use of competitive processes such as tendering for supply (asking for quotes in effect), 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.

Commercial assessment means establishing whether funding proposals from pharmaceutical companies represent a good deal. There are many aspects to this such as using our economic assessment, comparing prices for existing subsidised medicines in the same therapeutic group and with those that other countries are paying (see our Purchasing Medicines information sheet for further information).

When we think we have reached a good agreement, the next step is to consult with our stakeholders.

Consultation

Before we make a medicine 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.

PHARMAC is the Government agency that decides, on behalf of District Health Boards (DHBs), which medicines get subsidised so that they are more affordable for New Zealanders and available nationally. The subsidies PHARMAC sets are funded from a fixed budget that is part of DHB funding. PHARMAC also promotes the optimal use of medicines, carries out some procurement for DHBs, and manages special access programmes for some medicines.

Information Sheets on various PHARMAC topics are available from our website: www.pharmac.govt.nz/patients/infosheets

If you have specific areas of interest (such as consultations, committees or vacancies), visit our website and subscribe to news feeds in the area(s) of interest to you: <http://pharmac.govt.nz/feeds>

Contacting Us

Call us on 0800 66 00 50 (between 9am and 5pm, Monday to Friday), or on 04 460 4990 (between 8am and 5.30pm, Monday to Friday).

Write to us at: PHARMAC, PO Box 10 254, Wellington
– we respond to all letters

Email us at enquiries@pharmac.govt.nz – we respond to all emails

newzealand.govt.nz

PHARMAC
Pharmaceutical Management Agency

Appendix three: Relevant provisions of the OIA 1982

9. Other reasons for withholding official information
- (1) Where this section applies, good reason for withholding official information exists, for the purpose of section 5 of this Act, unless, in the circumstances of the particular case, the withholding of that information is outweighed by other considerations which render it desirable, in the public interest, to make that information available.
- (2) Subject to sections 6, 7, 10, and 18 of this Act, this section applies if, and only if, the withholding of the information is necessary to –
- (a) protect the privacy of natural persons, including that of deceased natural persons; or
 - (b) protect information where the making available of the information –
 - (i) would disclose a trade secret; or
 - (ii) would be likely unreasonably to prejudice the commercial position of the person who supplied or who is the subject of the information; or
 - (ba) protect information which is subject to an obligation of confidence or which any person has been or could be compelled to provide under the authority of any enactment, where the making available of the information –
 - (i) would be likely to prejudice the supply of similar information, or information from the same source, and it is in the public interest that such information should continue to be supplied; or
 - (ii) would be likely otherwise to damage the public interest; or
 - (c) avoid prejudice to measures protecting the health or safety of members of the public; or
 - (d) avoid prejudice to the substantial economic interests of New Zealand; or
 - (e) avoid prejudice to measures that prevent or mitigate material loss to members of the public; or
 - (f) maintain the constitutional conventions for the time being which protect –
 - (i) the confidentiality of communications by or with the Sovereign or her representative;
 - (ii) collective and individual ministerial responsibility;
 - (iii) the political neutrality of officials;
 - (iv) the confidentiality of advice tendered by Ministers of the Crown and officials; or
 - (g) maintain the effective conduct of public affairs through –
 - (i) the free and frank expression of opinions by or between or to Ministers of the Crown or members of an organisation or officers and employees of any Department or organisation in the course of their duty; or
 - (ii) the protection of such Ministers, members of organisations, officers, and employees from improper pressure or harassment; or
 - (h) maintain legal professional privilege; or
 - (i) enable a Minister of the Crown or any Department or organisation holding the information to carry out, without prejudice or disadvantage, commercial activities; or
 - (j) enable a Minister of the Crown or any Department or organisation holding the information to carry on, without prejudice or disadvantage, negotiations (including commercial and industrial negotiations); or
- (k) prevent the disclosure or use of official information for improper gain or improper advantage.