PHARMAC's Review of the

Named Patient Pharmaceutical Assessment Policy (NPPA)

- Seeking Your Views

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PHARMAC
Pharmaceutical Management Agency

We're seeking feedback on our Named Patient Pharmaceutical Assessment (NPPA) Policy as part of the rolling review of our Operating Policies and Procedures (OPPs). The NPPA policy has been in place for two years, and in that time it's also been updated to manage hospital medicines.

We're seeking your views on the NPPA Policy, and any other issues you may have with PHARMAC's provision of subsidies for exceptional circumstances.

1. Providing a response

This discussion document includes:

- Information on how to make a response
- Background to the establishment of NPPA and our OPP review
- Information on the NPPA policy
- Questions to help guide your response

1.1 Seeking your views

This document outlines what the NPPA policy is, why we're reviewing it and how you can get involved and have your say. We have tried to describe the NPPA policy with enough detail so you can make an informed response, but nothing in this document is intended to direct your response, or eliminate anything from discussion. We want to know what you think of the NPPA policy, if it achieves the objectives we set out to achieve when we established it two years ago, and if there are any changes you think we should make. Particular questions we would like you to consider are listed at the end.

1.2 Submitting your response

Comments can be submitted via email, fax or letter by 2 May 2014 to:

Rachel Melrose
Email: opp@pharmac.govt.nz
PHARMAC Fax: (04) 460 4995
PO Box 10-254
Wellington 6143

We've also set some time aside to discuss the NPPA review at a consultation event we're holding on Tuesday 15 April 2014. Details of this event can be found on our website. We also invite interested people or groups who cannot make the consultation event to meet with PHARMAC staff to present their views. Please contact Rachel Melrose at opp@pharmac.govt.nz by 2 May 2014 if you would like to arrange a time to meet with us. If a range of groups are interested in meeting with us, we may organise larger group meetings.

1.3 Information requested under the Official Information Act

Feedback we receive is subject to the Official Information Act 1982 (OIA) and we will consider any request to have information withheld in accordance with our obligations

under the OIA. Anyone providing feedback, whether on their own account or on behalf of an organisation, and whether in a personal or professional capacity, should be aware that the content of their feedback and their identity may need to be disclosed in response to an OIA request.

We're not able to treat any part of your feedback as confidential unless you specifically request that we do, and then only to the extent permissible under the OIA and other relevant laws and requirements. If you would like us to withhold any commercially sensitive, confidential proprietary, or personal information included in your submission, please clearly state this in your submission and identify the relevant sections of your submission that you would like withheld. PHARMAC will give due consideration to any such request.

2. Context and review process

2.1 Origins and process to date

We're currently reviewing our Operating Policies and Procedures (OPPs). The OPPs are PHARMAC's framework for how we carry out our role of deciding, on behalf of District Health Boards, which pharmaceuticals and related products are subsidised for use in the community and in public hospitals. They provide guidance to the people and groups we work with, about what to expect when working with us, and they guide PHARMAC staff as we consider funding proposals and policy changes. We last reviewed our OPPs in 2005, and since then our role has expanded into vaccines, hospital medicines and medical devices.

The formal review of our OPPs began with a discussion at the PHARMAC Forum on 20 February 2012. In April 2012, we released a discussion document seeking feedback from the public on what should be included in the OPPs. In response to the submissions we received, in early December 2012, we released notification of:

- The list of topics to be included in the revised OPPs.
- Our intention to re-develop the OPPs as a web-based guide.
- Our intention to begin a rolling review of the substantive content of the OPP topics (and thus PHARMAC practice), starting with a review of our nine decision criteria.

The first round of consultation on the nine decision criteria ran from May 2013 until August 2013, and a second round of consultation on a proposal for change is underway at the moment. In addition to the decision criteria review, PHARMAC has also been consulting on our work to establish a framework for the future management of hospital medical devices. The outcome of this work will also form part of PHARMAC's OPPs.

During the decision criteria consultation we held 12 community forums which, by their nature, covered a wide range of issues that were of interest to the participants. We heard views from some members of the community on PHARMAC's approach to considering patients with exceptional circumstances and, as a result of that feedback, we decided to make NPPA the next stage of our OPP rolling review. Although the

decision criteria review and the medical devices establishment work is still ongoing, we have decided to begin the next phase now to continue the momentum of the review.

2.2 Next steps

After the consultation period closes, we'll carefully consider all of the submissions we've received. If we think any changes to PHARMAC's NPPA policy are needed as a result of this consultation, we'll then run a second round of public consultation on those changes. We'll let you know what the likely timeframe for implementing any changes is, following the end of the second round of consultation.

3. The NPPA Policy

3.1 Origin of the NPPA Policy

Section 48(b) of the New Zealand Public Health and Disability Act 2000 (NZPHD Act) establishes (alongside PHARMAC's management of the Pharmaceutical Schedule 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".*

This legislative provision confers on PHARMAC the function of managing, in exceptional circumstances, funding for patients for treatments that are not available to them on the Schedule. Prior to June 2012, the framework that we used to carry out this function, and guide the exercise of our discretion, was the Exceptional Circumstances (EC) schemes.

The NPPA policy was implemented in June 2012, following a review of PHARMAC's EC schemes. The review was initiated, in part, in response to recommendations in the Report of the High-Cost, Highly-Specialised Medicines Review Panel, commissioned by the Minister of Health in 2009[1], and also in response to the government's *Medicines New Zealand Strategy*[2] and its accompanying action plan. *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'.

The objectives of the review were to:

- Review and clarify the purpose of the provision of funding in exceptional circumstances;
- Review and clearly describe what constitutes exceptional circumstances; and

[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. Available at: http://www.beehive.govt.nz/release/access-high-cost-medicines-report-received

[2] Actioning Medicines New Zealand, available at http://www.health.govt.nz/publication/actioning-medicines-new-zealand

- Ensure the operational arrangements for the administration and provision of funding in exceptional circumstances are optimal.

The Purpose of the NPPA Policy

The outcome of the EC Review was the creation and implementation of the NPPA policy. The policy complements the operation of the Schedule, where PHARMAC lists treatments that are subsidised for population groups. The NPPA policy is an acknowledgement that there are situations where treatment for an individual should be considered outside of the Schedule decision making process.

For PHARMAC to achieve its legislative objective through the maintenance of the Schedule, the operation of the NPPA Policy will, and must, operate in a way that doesn't undermine the Schedule decision making process.

Together the Schedule decision making process and the operation of the NPPA policy ensure there is a pathway for an individual to have their clinical circumstances considered. If an individual has a set of clinical circumstances not covered by the NPPA Policy, the Schedule decision making process is available.

It isn't the purpose of the NPPA Policy to provide access to every treatment not listed on the Schedule. There will always be some treatments that PHARMAC will not be able to provide subsidised access to, either on the Schedule or under the NPPA policy.

Summary of the NPPA Policy

The NPPA Policy identifies two situations where PHARMAC believes it's appropriate to consider funding a treatment for a named individual patient. The NPPA scheme consists of two pathways, one for each of these situations:

- Unusual Clinical Circumstances (UCC) – a pathway for individuals whose clinical circumstances are so unusual that PHARMAC would be unlikely to have considered them when deciding whether to list a treatment on the Schedule. In these situations, we don't expect the patient to be part of a group.
- Urgent Assessment (UA) – a pathway for individuals with serious clinical conditions who would experience a significant deterioration in health or lose the opportunity for a significant improvement in quality of life before the treatment can be considered for Schedule listing (this can take up to a year). This patient may be part of a group of patients with similar conditions.

Each NPPA pathway includes a set of prerequisites that need to be met before an application is considered and assessed against our decision criteria[3]. These include a requirement that the patient has tried and failed all funded alternatives (or it's not clinically appropriate for the patient to try the funded alternatives), and that the

[3] The decision criteria are currently under review. It is currently proposed that any changes to the decision criteria will be equally applicable to the NPPA policy.

treatment hasn't already been assessed and prioritised for funding (for that particular indication). PHARMAC makes final decisions on NPPA applications after receiving clinical advice.

In addition to the two pathways explained above, PHARMAC also considers applications to fund pharmaceuticals for named patients:

- When the pharmaceuticals are less expensive to the health sector than treatments listed on the Schedule.
- In the case of community pharmaceuticals, when the named patient's clinical circumstances do not meet the technical requirements of any relevant Special Authority criteria in Sections B through to D of the Pharmaceutical Schedule, but do meet the intent of the Special Authority provisions.
- In the case of hospital pharmaceuticals, when the named patient's clinical circumstances do not meet the technical requirements of any relevant indication restrictions set out in Section H of the Schedule, but do meet the intent of the restrictions.

The two pathways and three circumstances above make up PHARMAC's framework for performing its legislative function of providing for subsidises in exceptional circumstances for pharmaceuticals not on the Schedule. PHARMAC retains the discretion to consider applications for funding outside of the NPPA Policy.

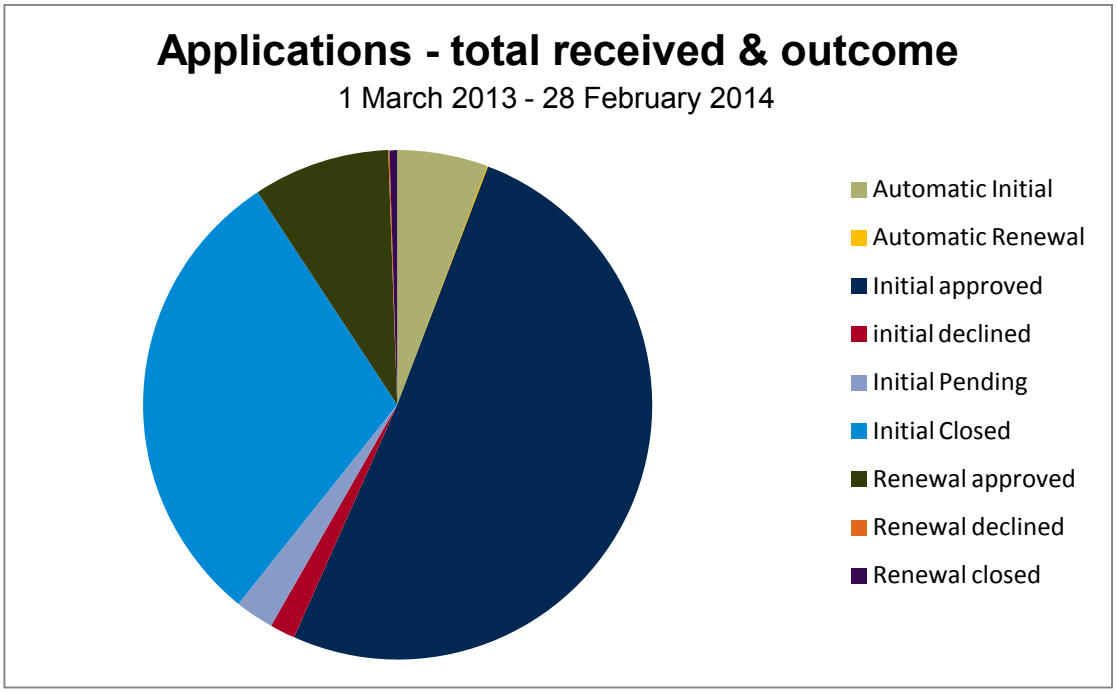
The NPPA policy can be found in full at: http://www.pharmac.health.nz/assets/nppa-policy-2013-07.pdf and in Appendix One.

Operation of the NPPA Policy

Since 1 March 2013 PHARMAC has received 1380 NPPA applications (community and hospital), including renewal applications and automatic approvals.

Of the 1172 initial applications received, 702 (60%) were approved and 22 (2%) were declined. There are 34 of these applications still pending. The remaining 414 (35%) have either been closed because they did not meet pre-requisite criteria or because we didn't hear back from the applicant.

Of the 128 renewal applications received, 120 were approved and one was declined. The remaining 7 were either closed because we didn't hear back from the applicant or they withdrew their application. The remaining 80 applications received were for automatic approvals.



OPP Review of the NPPA Policy

At this time, we're not making any proposals for change. We're seeking your views on the NPPA policy, and any other issues you may have with PHARMAC's provision of subsidies for exceptional circumstances.

While we welcome feedback on any aspects of the NPPA Policy, there are three particular issues we would appreciate you turning your minds to:

1. **Have we achieved the objectives we set out to achieve when we implemented NPPA? Why or why not?**

2. We note that of the 1172 applications we received since 1 March 2013, 33% weren't considered against the nine decision criteria because they didn't meet the pre-requisites, or because we didn't hear back from the applicant. **What does this suggest about the NPPA pre-requisites? Are they confusing? Do they need to be made more specific or clearer? If so, how?**

3. **What circumstances or areas of unmet need does the NPPA policy not currently address?**

Other related matters

We also note that PHARMAC is steadily working towards taking on responsibility for the management of all medical devices used in DHB hospitals. We're considering exceptions as they relate to medical devices as part of our medical devices establishment work, so we're not including medical devices within the scope of this

particular OPP review. Information about our approach to medical devices, including exceptions, will be provided in a discussion document that describes our envisaged approach and seeks feedback on implementation considerations, which is due to be released in the next few months. Any feedback that is received as part of this NPPA review that is relevant to our medical devices establishment work will be captured under both consultations.

We received feedback from the public during our decision criteria review about access to high cost medicines for rare disorders (sometimes called 'orphan medicines'), and the need for differentiated criteria for rare disorders in the NPPA policy. The purpose of the NPPA policy is to ensure that every individual has an opportunity to have their clinical circumstances considered, either through the normal Schedule listing process, or through NPPA. It isn't the purpose of the NPPA Policy to provide access to every treatment not listed on the Schedule.

However, PHARMAC has been successful in transferring 26 medicines that we received NPPA applications for in 2012/13 (and 16 so far in 2013/14) onto the Pharmaceutical Schedule. This has the effect of providing greater access to patients, reducing administrative effort for clinicians, and providing greater certainty for patients and clinicians alike. The agreed funding provision for NPPA is $8 million per annum, although, as stated in our original policy objective, we anticipated this expenditure level would reduce as we listed more medicines on the Schedule. We anticipate that up to $5 million of this funding provision won't be used for NPPA next year, which means this funding is available for other investments.

We've been doing some broader thinking about the issue of access to high cost medicines for rare disorders, and possible uses for the available under-utilised NPPA funding provision. We've released a discussion document to seek further views on the issue. You can find this discussion document at www.pharmac.health.nz/link/high-cost-medicines

Appendix One: Named Patient Pharmaceutical Assessment (Exceptional Circumstances) Policy – July 2013

1. Introduction

Section 48(b) of the New Zealand Public Health and Disability Act 2000 requires PHARMAC to, alongside managing the Pharmaceutical Schedule (the Schedule) and other functions, manage:

> *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.*

This legislative provision confers on PHARMAC the function of managing, in exceptional circumstances, funding for patients for treatments that are not available for them on the Schedule. This Named Patient Pharmaceutical Assessment (Exceptional Circumstances) Policy (NPPA Policy) is the framework PHARMAC has adopted in order to carry out this function and guide the exercise of its discretion.

This framework is required, both to inform applicants of the exceptional circumstances PHARMAC has prospectively identified as warranting consideration for funding outside the Schedule and for PHARMAC to undertake such consideration in a reasonable manner. However, the existence and application of the NPPA Policy does not limit PHARMAC's ability to consider any application for funding treatments outside the NPPA Policy and the Schedule.

2. Named Patient Pharmaceutical Assessment Policy governance

This Policy has been approved by the PHARMAC Board and comes into effect 1 July 2013. Any changes to the Policy must be approved by the Board.

3. Purpose of the Named Patient Pharmaceutical Assessment Policy

The operation of the NPPA Policy complements the operation of the Schedule, in which PHARMAC lists treatments that are subsidised for population groups. The provision for exceptional circumstances is an acknowledgement that there are situations in which consideration of an application for a treatment for an individual, outside of the Schedule decision making process used to consider treatments for patient populations, is warranted. For PHARMAC to achieve its legislative objective through the maintenance of the Schedule the operation of the NPPA Policy will, and must, operate in a way that does not undermine the Schedule decision making process.

Together the Schedule decision making process and the exercise of PHARMAC's discretion to consider funding in exceptional circumstances ensure there is a pathway for consideration of an individual's clinical circumstances. If an individual has a set of clinical circumstances not covered by the NPPA Policy, the Schedule decision making process is available.

It is not the purpose of the NPPA Policy to provide access to *every* treatment not listed on the Schedule. There will always be some treatments that PHARMAC will not be able to provide subsidised access to, either on the Schedule or under the

NPPA Policy. The NPPA Policy, therefore, sets out the framework of exceptional circumstances in which PHARMAC will consider funding treatments.

Details of the factors relevant to PHARMAC's consideration of named patient applications are described in the following sections of the NPPA Policy. At a general level, the clinical circumstances of named patients seeking treatment under the NPPA Policy, and health-related costs and benefits related to the treatment of these, are relevant factors. PHARMAC will not consider named patients' social circumstances or any non-health related costs or benefits arising from treatment.

4. Named patient pharmaceutical assessment

The NPPA process refers to PHARMAC's consideration of applications for named patients seeking approval for funding for treatments not listed on the Schedule, either at all or for the named patient's clinical circumstances.

a. Pathway purposes, explanations and prerequisite requirements

There are two main pathways by which named patients can be considered for funding under the NPPA Policy. A description of the purpose of each of these two pathways, an explanation of each pathway and the prerequisite requirements that applicants need to satisfy for consideration for funding under these pathways is included in the table on the following pages.

PHARMAC will exercise its discretion to determine the most appropriate pathway for an application under the NPPA Policy based on the information that is provided. Thus, if PHARMAC receives an application that does not meet the prerequisite requirements for one pathway, we will consider whether it should appropriately be considered under the alternative pathway.

NPPA pathways – purpose, explanation and prerequisite requirements

Pathway	Purpose	Explanation	Prerequisite requirements
Unusual Clinical Circumstances (UCC)	The purpose of the Unusual Clinical Circumstances (UCC) pathway is to provide a process for consideration for funding for named patients whose clinical circumstances are so unusual that PHARMAC is unlikely, for administrative reasons, to consider listing treatments for these circumstances on the Schedule.	This pathway is for named patients whose clinical circumstances are so unusual that the time and resource required for consideration of a Schedule listing is not warranted given the relative rarity of the unusual clinical circumstances. The pathway is not available for treatments which PHARMAC is considering or has considered for Schedule listing. If PHARMAC has done this, the clinical circumstances have already been considered or are already being considered in the Schedule decision making process and are not so unusual that the UCC process should apply. However, where the treatment has not been considered at all or where the clinical circumstances of the named patient are significantly different from the clinical circumstances for which Schedule listing of the treatment was considered, or is being considered, the UCC pathway will be available.	• The patient has reasonably tried and failed all alternative funded treatments (or alternative treatments have been contraindicated, or there are no other treatments available) or has experienced such serious side effects with all other relevant funded treatments that treatment has been ceased or cannot reasonably be continued; and • The patient is experiencing an indication or set of clinical circumstances that are so unusual that PHARMAC is unlikely to consider listing treatments for these on the Schedule; and • Generally, PHARMAC has not already considered/is not considering, through the Schedule decision making process, the treatment for the patient's clinical circumstances or has not considered the treatment at all.

Pathway	Purpose	Explanation	Prerequisite requirements
Urgent Assessment (UA)	The purpose of the urgent assessment (UA) pathway is to provide a process for PHARMAC (and DHBs in the case of rapid hospital assessments) to consider funding treatments for named patients where PHARMAC is also considering or is likely to consider the treatment for Schedule listing, but the patient's clinical circumstances justify urgent assessment prior to a decision on Schedule listing.	The urgent clinical circumstances covered by this pathway are those where a named patient in serious clinical circumstances would, within a timeframe of up to 12 months, be expected to experience either significant deterioration or miss the opportunity for a significant improvement in clinical outcomes (length or quality of life). The UA pathway is generally not available where PHARMAC has, before approving funding for an application under this pathway, already prioritised or declined the treatment for Schedule listing for the same clinical circumstances presented by the patient. This is because, in this situation, the clinical circumstances of the patient, and other similar patients, have already been considered. However, the UA pathway will be available for named patient applications received after PHARMAC has started to consider the treatment for listing on the Schedule if, before starting that consideration, PHARMAC has funded any patient under this pathway and the named patient applications received subsequently are for the same clinical circumstances. If, however, PHARMAC decides to decline to fund that treatment on the Schedule, the UA pathway will not be available for named patient applications received after this decision if they are for the same clinical circumstances as patients funded before this decision.	• The patient has reasonably tried and failed all alternative funded treatments (or alternative treatments have been contraindicated, or there are no other treatments available) or has experienced such serious side effects with all other relevant funded treatments that treatment has been ceased or cannot reasonably be continued; and • The patient is experiencing an indication or set of clinical circumstances that may be experienced by a population group (either currently or over time); and • The patient has serious clinical circumstances and not receiving the treatment within up to 12 months would lead to either a significant deterioration in a serious clinical condition or the patient would miss the opportunity for significant improvement in clinical outcome (length or quality of life); and • The treatment has either not been prioritised by PHARMAC, or if it has, PHARMAC has funded the treatment under the NPPA Policy for the same clinical circumstances prior to prioritisation. • PHARMAC has not declined to list, on the Schedule, this treatment for these clinical circumstances.

b. Other named patient funding

In addition to the two pathways identified above, PHARMAC (and DHBs on behalf of PHARMAC, in the case of rapid hospital assessments, see section 4f) will, as part of PHARMAC's function to provide for subsidies in exceptional circumstances, also consider applications to fund pharmaceuticals for named patients:

- when the pharmaceuticals are less expensive to the health sector than treatments listed on the Schedule. Relevant factors when assessing such an application would include whether the pharmaceutical being sought was actually cheaper than the funded alternatives (confidential rebates on some products mean that the Schedule price listed for some pharmaceuticals is higher than the price paid) as well as any contractual obligations PHARMAC may have in relation to other suppliers; or

- In the case of community pharmaceuticals, when the named patient's clinical circumstances do not meet the technical requirements of any relevant Special Authority criteria in sections B through to D of the Pharmaceutical the Schedule, but do meet the intent of the Special Authority provisions; or

- In the case of hospital pharmaceuticals, when the named patient's clinical circumstances do not meet the technical requirements of any relevant indication restrictions set out in Section H of the Schedule, but do meet the intent of the restrictions.

The two pathways and three circumstances above constitute PHARMAC's framework for performing its function of providing for subsidies in exceptional circumstances for pharmaceuticals not on the Schedule. PHARMAC (and DHBs, in case of rapid hospital assessments, see section 4f) retains the discretion to consider applications for funding outside the NPPA Policy. However, PHARMAC does not anticipate that it, or DHBs, would receive or approve many applications that fall outside the NPPA Policy.

The Schedule decision making process remains the alternative process for a treatment being sought that does not satisfy the prerequisites for, or is not approved under, these alternatives.

c. Eligible applicants

Any authorised prescriber can make a named patient pharmaceutical application.

d. Treatment categories considered

PHARMAC (and DHBs in the case of rapid hospital assessments, see section 4f) will consider applications for treatments that fall within the following categories:

- medicines or medicinal products (intended for self administration or otherwise delivered in a community [non-hospital] setting); and
- hospital pharmaceuticals excluding medical devices

e. Assessment process for named patient applications considered by PHARMAC

PHARMAC will assess applications made under the NPPA Policy according to the nine Decision Criteria (see section 4g).

PHARMAC will seek clinical advice on named patients when assessing applications.

PHARMAC recognises the need to prioritise those applications that require the quickest decision irrespective of the NPPA pathway that has been applied under. This will be particularly important for applications under the UA pathway. An important consideration in assessing such applications is the benefit that will be forgone from other treatments that will not be funded as a result of funding treatments under UA. Where the cost of a treatment being sought under UA and, therefore, the potential forgone benefit is very high relative to other funding options more analysis including, potentially, prioritisation against other funding options may be required before a decision is made. In such cases, PHARMAC may determine that assessment through the Schedule decision making process is the appropriate pathway for funding consideration.

f. Assessment process for NPPA applications considered by DHBs ("rapid hospital assessments")

Some hospital pharmaceutical applications may be so urgent that it is not feasible for PHARMAC to consider and decide on the application within a clinically appropriate time frame.

If the named patient would, within five working days, be expected to experience either significant deterioration or miss the opportunity for a significant improvement in clinical outcomes (length or quality of life), then a decision on the NPPA application can be made by the relevant DHB. This process is available for NPPA applications made under either the UA or UCC pathways, or the circumstances set out in section 4b.

DHB rapid hospital assessment applications are required to be considered and decided on by a multi-disciplinary panel that consists of at least two individuals, neither of whom are the named patient's prescriber. DHBs may establish regional panels that consist of staff from multiple DHBs, to consider rapid hospital assessments for all DHBs in that region.

DHB panels will consider rapid hospital assessment applications according to PHARMAC's nine Decision Criteria (see section 4g) and are required to inform PHARMAC of the details of the application and the decision outcome, no later than one month after the decision is taken (see section 4j).

This rapid hospital assessment process is not available for Pharmaceutical Cancer Treatments (PCTs). PHARMAC will endeavour to consider urgent PCT NPPA applications as quickly as practicable.

PHARMAC also reserves the ability to notify DHBs of further treatments, indications or circumstances in which the rapid hospital assessment process will not be available. PHARMAC also reserves the ability to permit DHBs to make rapid hospital assessments for additional treatments, indications or circumstances, even if a decision is not needed within five working days.

g. Criteria for assessing named patient applications

PHARMAC and DHBs (in the case of rapid hospital assessments) will assess applications that meet the prerequisites described above according to the Decision Criteria (listed on PHARMAC's website http://www.pharmac.govt.nz/patients/DecisionMakingProcess/DecisionCriteria) before deciding whether to approve applications for funding.

PHARMAC uses the Decision Criteria to assist it to meet its statutory objective, "to secure for eligible people in need of pharmaceuticals the best outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided."

PHARMAC will use the Decision Criteria to assess both the individual clinical circumstances of each NPPA applicant and the implications of each NPPA funding decision on PHARMAC's ability to meet its objective for the population as a whole.

h. Information obtained from Non-PHARMAC Approved Funded Treatment (NPAFT)

PHARMAC will consider applications for named patients who have already received the treatment being applied for where this treatment has not been funded under a PHARMAC approval. However, in considering such applications PHARMAC seeks to ensure that applicants who have not received NPAFT have the same opportunity to obtain publicly funded pharmaceuticals as those who have. PHARMAC will therefore not consider information obtained from NPAFT about the effectiveness of the treatment for the applicant specifically, unless PHARMAC is satisfied that to do so would not undermine equity of opportunity for all applicants, whether or not they have received NPAFT.

i. Decisions on Named Patient Pharmaceutical Assessment applications considered by PHARMAC

Decisions on applications made under the NPPA Policy (excluding rapid hospital assessments, see 4f) will be made by the PHARMAC Board or by staff under delegated authority from the Board. Decisions made under the NPPA Policy relate solely to the named patient who is the subject of the application.

Decisions on applications for treatments that have a relatively large budget impact may take more time than decisions on other NPPA applications due to the need for more comprehensive analysis and/or because the decision may need to be made by the Board.

PHARMAC recognises there is a public expectation that people experiencing the same clinical circumstances should have the same outcome from the application process. PHARMAC will endeavour to take an approach to approving NPPA applications which will achieve consistency over time to the greatest extent possible. However, in considering the Decision Criteria, relevant factors other than the clinical circumstances of the named patient (including evidence of the effectiveness of the treatment and the available budget) may differ over time. It is therefore possible that, due to such factors, PHARMAC may make different decisions for patients with the same or similar clinical circumstances.

j. Decisions on NPPA applications considered by DHBs (rapid hospital assessments)

Decisions on rapid hospital assessment applications (refer to section 4f) will be made by the relevant DHB Board or by staff under delegated authority from the Board. In the case of regional panels, these staff may not necessarily be staff members of the relevant DHB for that particular named patient. Decisions made under the NPPA Policy relate solely to the named patient who is the subject of the application.

PHARMAC recognises there is a public expectation that people experiencing the same clinical circumstances should have the same outcome from the application process. It is possible that different DHBs may make different rapid hospital assessment decisions on patients with similar clinical circumstances.

DHBs are required to inform PHARMAC of the outcome of all rapid hospital assessment decisions, no later than one month after the decision is taken. PHARMAC may choose to review a DHB rapid hospital assessment decision, and to implement a precedent for future applications of a similar nature, to reduce variability in outcomes. PHARMAC may also consider the application for Schedule listing.

q. Information about decision outcome

PHARMAC will provide a summary of all applications made under the NPPA Policy on its website. In the case of rapid hospital assessments made by DHBs, PHARMAC will publish these decisions once it has reviewed the decision, or has determined that a review is not required (refer to 4f). Subject to privacy considerations, information in this summary will include the medication requested, the indication it was requested for and the decision.

l. Resubmission of an application

Declined applications can be resubmitted at any time if relevant new clinical circumstances arise or new evidence becomes available. PHARMAC will treat resubmitted applications as new applications, but will report on new applications and resubmitted applications separately so that demand is not overstated.

m. Decision review

PHARMAC will establish a review process for applicants not satisfied with decisions made under the NPPA Policy. This review process will be available for all NPPA applications, including rapid hospital assessments.

n. Applications for renewal of Named Patient Pharmaceutical Assessment approval

Applications approved under the NPPA Policy may be for a limited time and renewals may need to meet conditions for continued funding. PHARMAC (or the DHB in the case of rapid hospital assessments) will advise the applicant of the duration of the approval (and therefore when an approval renewal application, if necessary, would need to be made) and of any conditions for continued funding.

PHARMAC will examine the original application and assess the newly submitted approval renewal application, including a full clinical update, against any conditions for continued funding stipulated in the original approval.

5. Funding for approved treatments

Funding for approved NPPA applications will either be provided from within the Combined Pharmaceutical Budget, in the case of pharmaceuticals supplied in the community and pharmaceutical cancer treatments (PCTs), or from within individual DHB hospital budgets, in the case of pharmaceuticals supplied by the DHB hospital, other than PCTs.

In the case of rapid hospital assessments, the DHB that makes the approval decision is responsible for funding the treatment. If the patient transfers to another DHB, then the approving DHB is required continue funding the treatment, or to negotiate a funding transfer with the other DHB, if appropriate.

A funding provision for NPPA applications (excluding hospital medicines other than PCTs) exists within the overall Combined Pharmaceutical Budget. The level of this allocation is decided by PHARMAC and DHBs and is reflected in the Memorandum of Understanding Relating to the Working Relationship between PHARMAC and DHBs. PHARMAC and DHBs may agree to amend this provision where required.

Funding for any treatment initially provided under the NPPA policy, and funded out of the Combined Pharmaceutical Budget, that is subsequently listed on the Schedule will be accounted for from the Schedule portion of the Combined Pharmaceutical Budget, rather than the NPPA provision.

PHARMAC is working towards full budget management of hospital pharmaceuticals and there may be future administrative changes to the way the budgets are managed within DHBs. DHBs are not currently able to approve expenditure from the Combined Pharmaceutical Budget (CPB).

6. Schedule decision making for treatments funded under NPPA

PHARMAC will, separately from deciding on an application for a pharmaceutical for a named patient, determine whether it will consider funding the treatment through the Schedule decision making process if it is not already doing so. Considering funding the treatment through the Schedule decision making process will ensure that PHARMAC would also consider the provision of treatments being sought by named patients for listing on the Schedule for the population.

When undertaking a Schedule assessment PHARMAC may undertake more comprehensive analysis of the relevant information than would be undertaken for an NPPA application to determine whether the pharmaceutical is one we would consider appropriate to list on the Schedule and its relative priority compared with other funding options. This information may reveal that the pharmaceutical is a poor option compared with other treatments we are considering for funding. Alternatively, Schedule assessment may indicate that the pharmaceutical is of high value. As with all Schedule funding decisions, the speed of listing products on the Schedule that are being funded for named patients would depend on the relative priority compared with other options, the available budget for new investments and PHARMAC's ability to negotiate a suitable commercial arrangement with a supplier.

Any named patient receiving PHARMAC-managed funding access under the NPPA Policy to a treatment that is subsequently declined for listing on the Schedule would continue to receive funded access as long as they continue to meet any stipulated conditions for renewal of funding approval (discussed in 4n).

7. Transitional arrangements

Any individuals receiving funding for treatments under Community Exceptional Circumstances, Cancer Exceptional Circumstances or the NPPA Hospital Pharmaceuticals in the Community pathway will continue to receive this.

PHARMAC cannot guarantee continued funding of treatments approved under Hospital Exceptional Circumstances as District Health Boards are directly responsible for the provision of such funding.

Applications for renewal of funding for treatments approved under Community Exceptional Circumstances, Cancer Exceptional Circumstances, and Hospital Exceptional Circumstances will continue to be assessed against the criteria for these schemes.

Applications will be considered under the scheme in place at the time PHARMAC receives the application. This means that all applications received prior to 1 July 2013 will be considered under the previous NPPA policy even though the decision may be made after the updated NPPA Policy has commenced.

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