Attachment Two: Named Patient Pharmaceutical Assessment (NPPA) Policy Changes

We are proposing a number of changes to the NPPA policy, to enable the policy to manage both hospital and community exceptions. Some of the key proposals are discussed below, and the revised NPPA policy is provided at the end (additions to the current policy wording are shown in bold, and deletions are shown as strikethroughs).

Proposed Changes

The revised NPPA policy would apply to both hospital and community exceptions. It differs from the existing NPPA policy (which applies to community and hospital cancer pharmaceuticals only) in the following ways:

1. Changes have been made to the wording of the policy to reflect the inclusion of hospital pharmaceuticals.
2. One of the prerequisites for the Urgent Assessment (UA) pathway is that the patient has serious clinical circumstances, and not receiving the treatment within six to 12 months would lead to a significant deterioration in their condition. The wording of this prerequisite has been changed to 'up to 12 months', to reflect the original intent of the policy.
3. The HPC pathway has been removed. The original rationale for the HPC pathway was to allow DHBs to prescribe hospital medicines for use in the community, if doing so was clinically appropriate or cheaper than administering them in the hospital setting. An exceptions policy was needed to allow for this, because DHBs are not currently able to prescribe non-Schedule medicines for use in the community, and hospital medicines are not currently listed on the Schedule.

   As hospital medicines will now be included in the Schedule (Section H), this pathway is no longer needed. As outlined in attachment one, it is proposed that the Schedule rules include a provision that allows most pharmaceuticals from the hospital list to be administered in either the community or the hospital.
4. An alternative assessment process has been included for applications that are particularly urgent (hereafter referred to as the "acute assessment process"). This process allows the DHB to make decisions on NPPA applications, when it is not feasible for PHARMAC to consider the application in a clinically appropriate time frame (see section 4f of the revised policy for more detail).

Implementation of Acute Application Process

The revised NPPA policy does not include detail on how the changes, and in particular the DHB acute assessments, will be implemented. This is somewhat deliberate, because the purpose of the policy is to provide a framework and to set out the intent of the NPPA policy. PHARMAC and DHBs would retain the flexibility to implement the policy as appropriate.

After consultation, we will give further consideration to implementation and DHB guidance. However, it is important to give some thought to implementation now, to

ensure the policy is achievable, appropriate, and provides for a range of implementation options. In regards to acute applications, successful implementation will be critical to ensuring the policy intent is achieved, and the risks are minimised.

Feedback is sought from stakeholders on the implementation assumptions that have informed the proposed policy, which are as follows:

- If the named patient would, within a time frame of 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 the application could be considered by the relevant DHB.
- DHBs would be required to report to PHARMAC on the outcome of all acute assessment applications, no later than one month after the decision is taken.
- PHARMAC would monitor the implementation and make adjustments to operational practice or policy as necessary. PHARMAC would also have the ability to review any acute assessment decisions, and to implement a precedent for future acute assessments of a similar nature, to reduce variability in outcomes. If appropriate, PHARMAC would also consider the application for possible Schedule listing.
- 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 in the DHB hospital, other than PCTs.

The intention is that DHBs would be required to make decisions that are consistent with PHARMAC's NPPA Policy and Schedule decisions. It may be difficult for DHBs to do this for a number of reasons, and consideration will be given to the ways in which PHARMAC can support DHBs.

Background

The last round of consultation, in July 2012, sought feedback on:

- Removing the Hospital Pharmaceuticals in the Community (HPC) NPPA pathway.
- Allowing DHB committees to make NPPA decisions for hospital pharmaceuticals in some circumstances.

Responses to the consultation were mixed. Some organisations were of the view that exceptions should be managed centrally wherever possible, to ensure consistency of outcomes. DHBs generally accepted the need for rapid decision making in some circumstances, but raised some concerns with the committee proposal, including the following:

- added workload for DHBs;
- divergence of decisions for similar cases;
- inefficient use of scarce resources by having multiple committees;
- lack of experience in DHBs performing this function; and
- potential tensions when NPPA patients are transferred between hospitals.

Questions for Discussion

Feedback is sought from stakeholders on all of the proposed changes outlined in the revised policy. Some additional specific questions are also provided below:

- Should there be only one NPPA policy that applies to both hospital and community pharmaceuticals, rather than two individual policies?
- Are there any features of the HPC pathway that need to be retained?
- Are there any other ways in which the hospital setting requires a different approach?
- Should the review process (refer section 4m of the policy document) be extended to include NPPA decisions taken by DHBs?
- Who within the DHB should be made ultimately responsible for the acute assessments (assuming that the responsible body or individual will delegate this authority to a panel, but will be held responsible for the performance of that panel) – DHB Board, Board DHB Chair, CE or someone at the hospital level?
- What support will DHBs need to implement a process for acute assessments?
- Should the general discretion (refer to section 1 of the policy document) provided for in the NPPA policy, to consider applications that do not meet the criteria for UA or UCC, also be extended to DHB acute application decisions?

Named Patient Pharmaceutical Assessment (Exceptional Circumstances) Policy

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 on 1 March 2012. Any changes to the Policy must be approved by the Board.~~
To be updated once approved.

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 ~~three~~ 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 ~~three~~ 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~~s~~.

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 limited direct **financial** impact on ~~the Combined Pharmaceutical Budget~~ **DHBs** due to 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 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 ~~six~~ **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, even 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 ~~six~~ **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.
~~**Hospital**~~	~~The purpose of the Hospital~~	~~Under this pathway, it is the funding of the treatment~~	~~• The patient has reasonably tried and failed all~~

Pathway	Purpose	Explanation	Prerequisite requirements
~~**Pharmaceuticals in the Community (HPC)**~~	~~Pharmaceuticals in the Community (HPC) pathway is to allow District Health Board hospitals to fund a medicine for a patient in the community if this is more affordable for the DHB than paying for the treatment that would otherwise need to be provided. PHARMAC's approval is required for any such funding given DHBs' legislative obligation to act consistently with the Schedule.~~	~~outside the Schedule, not the clinical circumstances of the patient, which is exceptional. This pathway is not generally intended to enable long-term DHB funding of treatments for chronic conditions that are not available on the Schedule.~~ ~~As PHARMAC administers the funding for all cancer treatments (in-hospital and community-based), the HPC pathway does not apply to treatments of cancers. Applications for treatments of cancers can be made through the UCC or UA pathways.~~ ~~PHARMAC will implement a process by which DHBs may approve funding, without application to PHARMAC, for all treatments that meet the prerequisites for the HPC pathway and cost $500 or under. This process will only be available for DHBs that can provide PHARMAC with adequate data regarding the use of the process.~~	~~alternative cheaper funded treatments (or these alternative treatments have been contraindicated) or has experienced such serious side effects with all other cheaper relevant funded treatments that treatment has been ceased or cannot reasonably be continued; and~~ • ~~The application is for a DHB hospital to fund a treatment for use in the community for a patient under the care of a DHB hospital clinician (in-patient or out-patient); and~~ • ~~The treatment is not being used to treat a cancer; and~~ • ~~The treatment costs less for the DHB than the most likely alternative intervention or outcome; and~~ • ~~The treatment is being sought for a short-term episode of care (around three months) and is not generally for the treatment of a chronic condition.~~

b. Other named patient funding

In addition to the ~~three~~ two pathways identified above, PHARMAC will, as part of its function to provide for subsidies in exceptional circumstances, also consider applications to fund pharmaceuticals for named patients in the following circumstances:

- 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

- when the named patient's clinical circumstances do not meet the technical requirements of any relevant Special Authority criteria in the Schedule but do meet the intent of the Special Authority provisions.

The ~~three~~ two pathways and two circumstances above constitute PHARMAC's framework for performing its function of providing for subsidies in exceptional circumstances for pharmaceuticals not on the Schedule. PHARMAC retains the discretion to consider applications for funding outside the NPPA Policy. However, PHARMAC does not anticipate that it 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 ~~may~~ **can** make a ~~named patient pharmaceutical~~ **NPPA** application ~~under the UCC pathway and the UA pathway.~~

~~District Health Board clinicians may make named patient pharmaceutical applications under the Hospital Pharmaceuticals in the Community pathway.~~

d. Treatment categories considered

PHARMAC 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 ~~cancer~~ treatments ~~(including those administered by infusion in hospital)~~.

~~PHARMAC is in a transition phase with respect to the management of non-cancer hospital medicines. While PHARMAC will generally not consider in-hospital treatments under the NPPA Policy, PHARMAC may consider applications for therapies for chronic conditions which are delivered outside the community setting.~~

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 ~~4f~~**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. Rapid decisions 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 (acute 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.

DHBs will consider acute 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).

Any approval under this mechanism by one DHB would need to be continued by any other DHB to which this particular patient transfers. It is expected that in these instances, the relevant DHB would be consulted.

~~*f*~~***g****. Criteria for assessing named patient applications*

PHARMAC **and DHBs (in the case of acute assessments)** will assess applications that meet the prerequisites described above according to ~~its~~ **the** Decision Criteria (listed on PHARMAC's website http://www.pharmac.health.nz/medicines/how-medicines-are-funded/decision-criteria) 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.

*~~g~~**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.

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

Decisions on applications made under the NPPA Policy 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 (acute assessments)

Decisions on acute applications (refer to section 4f) will be made by the relevant DHB. 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 acute assessment decisions on patients with similar clinical circumstances.

DHBs are required to inform PHARMAC of the outcome of all acute applications, no later than one month after the decision is taken. PHARMAC may choose to review a DHB acute 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. It is therefore not anticipated that more than one acute assessment would need to be made by DHBs for patients in the same clinical circumstances.

*~~i~~**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 acute assessments made by DHBs, PHARMAC will publish these decisions once it has reviewed the application for Schedule listing (refer to 4j).** Subject to privacy considerations, information in this summary will include the medication requested, the indication it was requested for and ~~PHARMAC's~~ **the** decision.

*~~j~~**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.

*~~k~~**m**. Decision review*

PHARMAC will establish a review process for applicants not satisfied with decisions made under the NPPA Policy.

*~~l~~**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** 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.

~~Renewal applications for the HPC pathway will not generally be approved as the purpose of HPC is not to provide for long-term funding of community treatments.~~

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.

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.

~~A funding provision for approved NPPA applications (other than HPC approvals, which continue to be funded by DHB hospitals) is made within the overall quantum provided for the Combined Pharmaceutical Budget. The level of this allocation is decided by PHARMAC and DHBs and 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 subsequently listed on the Schedule will be accounted for from the Schedule portion of the Combined Pharmaceutical Budget rather than the agreed NPPA provision.~~

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 (4)(**n**)). ~~Because PHARMAC does not manage funding for treatments approved under the HPC pathway, this commitment does not apply to these treatments.~~

7. Transitional arrangements

Any individuals receiving funding for treatments under Community Exceptional Circumstances ~~or~~ 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 TBC will be considered under the previous NPPA policy even though the decision may be made after the updated NPPA Policy has commenced.**