Questions for Consultation

Pharmac is asking for input to help better understand the complex issues related to the Framework and its processes, including the NPPA Policy. This section outlines key issues and questions for feedback.

Exceptional Circumstances Framework

Pharmac's role includes considering whether to fund pharmaceutical treatments for people with **exceptional circumstances** when those treatments are not currently available for them on the Pharmaceutical Schedule.

This role reflects the legislative function outlined in section 69(1)(b) of the Pae Ora (Healthy Futures) Act 2022:

[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.

General Exceptional Circumstances Framework Questions:

What is your experience of the Framework?
Comment:

What do we need to change?
Comment:

What improvements would you consider?
Comment:

Do you feel the current system supports equitable access to medicines for all New Zealanders?
Yes/No
Comment:

Is the current information on Pharmac's website easy to understand and navigate?
Yes/No
Comment:

Named Patient Pharmaceutical Assessment

Pharmac uses its Named Patient Pharmaceutical Assessment (NPPA) policy to consider whether to fund a treatment for an individual patient whose clinical circumstances are exceptional.

The NPPA policy has three principles.

1. The NPPA policy provides a pathway to consider those whose clinical circumstances cannot be met through the Pharmaceutical Schedule at a given point in time
2. The NPPA policy complements the Pharmaceutical Schedule and the Schedule decision-making process
3. The NPPA policy is designed for individual assessment.

All three principles must be met for an application to be progressed for a decision.

What is your experience of NPPA?
Comment:

Do you consider the three principles to be fit for purpose?
Yes/No
Comment:

If you consider one or more of the principles to be not fit for purpose, what would you like to see changed?
Comment:

How confident are you in interpreting the NPPA principles?
Not at all confident Slightly confident Moderately confident Very confident Extremely confident

NPPA application policy questions to interpret the principles.

The following questions are used by Pharmac staff to help interpret the principles of the NPPA Policy:

1. Does the person have exceptional clinical circumstances?
2. Has the person tried all existing funded alternative treatments?
3. Has Pharmac considered the treatment for funding previously?

In your view, do these questions provide clear and useful guidance for interpreting each of the three NPPA principles in practice?
Comment:

Can you provide a specific example of a situation where the NPPA policy has been difficult to interpret? *(withhold any identifiable information)*
Comment:

Application and decision

After Pharmac receives the application, we assess whether it meets the principles of the NPPA Policy.

If the principles are not met, Pharmac will contact the clinician who made the application. Pharmac may invite them to provide more information. If the principles are met, Pharmac will then consider the application against the FFC (see Appendix one). Pharmac may also seek clinical advice from the NPPA Advisory Panel to help apply the Factors.

Do you have any comments on the application process itself?

Comment:

Are you confident accessing the correct forms and completing the submission?

Not at all confident Slightly confident Moderately confident Very confident Extremely confident

Were you kept informed about the progress and outcome of the application?

Yes/No

Comment:

Is the current information available on the Pharmac website regarding NPPA easy to understand and navigate?

Yes/No

Comment:

NPPA Rapid Assessment Pathways

In clinically urgent situations, Health NZ hospitals can access medicines through one of three pathways: ***NPPA rapid assessment*** by Pharmac, ***in-hospital rapid assessment*** by Health New Zealand, or the ***emergency-use rule*** for immediate treatment access, by Health New Zealand.

Clinicians use a NPPA rapid assessment application when:

- treatment is to be administered to an inpatient of a Health NZ hospital
- the situation is clinically urgent.

As a guide, if the treatment needs to start within 5 working days because of clinical urgency, then NPPA rapid assessment by Pharmac may be appropriate. Where Health NZ hospitals have a specific rapid assessment process, an in-house rapid assessment can be completed. The application still needs to be assessed using the principles of the NPPA policy. Health NZ hospitals report the outcomes of these assessments to Pharmac.

Pharmac (rather than the hospital) must assess any rapid assessment applications for:

- any pharmaceutical cancer treatment
- rituximab, infliximab, tocilizumab, bevacizumab.

Emergency use rule

Health NZ use their usual hospital protocols (rather than a Rapid pathway) if these three conditions are met:

- there is an immediate (life threatening) clinical need
- the medicine is not listed on the Schedule for use in that indication
- the medicine is available in the hospital.

The Framework also provides a mechanism for Pharmac to fund treatments for specific patients outside of the Pharmaceutical Schedule and separate to the NPPA Policy. These pathways are currently classified as 'others' in the Framework and include Special Authority Waivers and a few bespoke pathways created in response to a brand change.

What is your experience with the Rapid Assessment pathways?

Comment:

When do you consider using hospital rapid assessments vs the emergency use rule and why?

Comment:

Is it clear which pathway to use in an urgent situation?

Yes/no

I have a clear understanding of the NPPA rapid assessment process

No understanding | Minor understanding | Moderate understanding | Full understanding

I have a clear understanding of the in-hospital rapid assessment process

No understanding | Minor understanding | Moderate understanding | Full understanding

I have a clear understanding of the current emergency use rule

No understanding | Minor understanding | Moderate understanding | Full understanding

Bespoke exceptional circumstances

Please share your experience with the bespoke exceptional circumstance's pathway, including any challenges or areas of clarity.

I have a clear understanding of the bespoke exceptional circumstances assessment process (e.g. alternative brand application)

No understanding | Minor understanding | Moderate understanding | Full understanding

The information available on Pharmac's website regarding bespoke exceptional circumstances is easy to understand and navigate.

Strongly disagree | Disagree | Neutral | Agree | Strongly agree

Bespoke exceptional circumstances pathways have been created to support brand changes. These pathways in general have their own application form, and criteria for assessment that are specific to the pharmaceutical. There are no set criteria across these pathways for assessment of alternative brand requests.

Special Authority waivers and Hospital Medicine Restriction waivers

Some pharmaceuticals that are listed in the Schedule require certain conditions (Special Authority criteria) to be met before funding is granted. These conditions generally ensure that funding is targeted to those patients that would benefit most from treatment.

If a patient's clinical circumstances align with the intent but not the exact criteria of Special Authority waiver or Hospital Medicine Restriction waiver, prescribers can apply.

Please share your experience with the Special Authority waivers or Hospital Medicine Restriction Waivers including any challenges or areas of clarity.

Comment:

I have a clear understanding of the waivers

No understanding | Minor understanding | Moderate understanding | Full understanding

The information available on Pharmac's website regarding the waivers is easy to understand and navigate.

Strongly disagree | Disagree | Neutral | Agree | Strongly agree

Additional questions

Do you see the need for additional exceptional circumstances framework pathways? If so, what?

Comment:

Do you consider that different clinical groups would need their own exceptional circumstances pathway?

Comment:

Are there any current pathways in the Framework you would like to remove or see changes to? If so, provide more information.

Comment:

What improvements would you suggest for the application form or IT systems?

Would more detailed reporting (e.g. reasons for 'principles not met' (PNM) decisions) help you decide whether to apply?

Comment:

Do you have other comments?

Your feedback may be shared

When you give feedback on a consultation, your feedback becomes official information that Pharmac holds. Pharmac has legal responsibilities for how we manage this official information, under laws such as the Official Information Act and Privacy Act.

Pharmac may receive a request from people for official information, which could include your feedback. Legally, Pharmac must consider whether your feedback should be released.

We will consider your views when assessing whether the feedback has to be released. Tell us if there is anything about your feedback that you would prefer wasn't released.

If your feedback is proposed for release, then Pharmac will contact you, unless there is a legal reason that we can't.

Note that Pharmac collects and holds your information in line with our **Privacy Statement**.[10]

10 https://www.pharmac.govt.nz/about-this-site/privacy-statement