



25 March 2011

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PHARMAC
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Review of Exceptional Circumstances Policy

Thank you for the opportunity to provide feedback on this proposal.

This regional response is from Hazel Rook (ADHB), Paul Baines (NDHB), Lynanne Stanaway (CMDHB), and Tim Wood and I (WDHB), on behalf of our Organisations and stakeholders.

This submission was compiled by:

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1. What are your views on the proposal that the purpose of EC is to provide a scheme for considering funding in those situations the Schedule process is not most appropriate?

We support this concept.

2. What are your views on the proposal that the Named Patient Pharmaceutical Assessment scheme considers applications for funding for individuals rather than patient populations?

We support this concept.

3. What are your views on the proposed purpose of the Unique Clinical Circumstances pathway?

We accept that this category is for rare clinical circumstances, but we feel it may be too restrictive. We are concerned that a clinical circumstance that PHARMAC 'would not anticipate seeing... in more than one patient' (an incidence of 1:4 million) is exceedingly rare. We question how many patients would fulfil this criterion with diseases that are generally considered as being very uncommon.



4. What are your views on the proposed purpose of the Urgent Assessment pathway?

We broadly agree with the purpose of this pathway and support the concept that this mechanism may provide funding for previously unfunded therapies for a wider group of patients.

However, we have concerns about equity and consistency, i.e. a funding consideration could be approved for a patient via this pathway, but following an assessment for inclusion in the Pharmaceutical Schedule, funding for subsequent patients with the same clinical circumstances might be refused. We think this is unfair. It is also unclear in the proposal what would happen to patients already receiving treatment in this scenario; would it be stopped? We acknowledge PHARMAC's intention to improve the EC decision making process, which is prone to apparent inconsistencies because funding, priorities and available evidence may vary year to year. We hope the proposal leads to an improvement in this area and suggest that the process around this needs to be absolutely clear to avoid conflict.

We understand that the indication/medicine does not need to be under assessment by PHARMAC for funding to be considered, irrespective of the medicine's status, e.g. unregistered, registered, etc, and we support this approach. Given that for some inexpensive medicines (e.g. paediatric liquid formulations) the cost of seeking a Schedule listing is the reason why companies do not apply, and yet these medicines are of proven effectiveness and there is established clinical need, we would support this intent.

5. What are your views on the proposed purpose of the Hospital Pharmaceuticals in the Community pathway?

We support the purpose of this pathway and endorse the trial of the three month and \$500 maximum discretionary limit. We ask for clarification if this limit includes the expenses around the administration of parenteral medicines, e.g. the use of consumables.

We understand that the indication/medicine does not need to be under assessment by PHARMAC for funding to be considered, irrespective of the medicine's status, e.g. unregistered, registered etc, and we support this approach.

6. What, if any, additional situations do you consider the Schedule process does not best cater for that PHARMAC should consider under the Named Patient Pharmaceutical Assessment process?

Patients with a condition that is not rare or unique, but who have a set of individual circumstances that lead to a clinical situation that is rare and difficult to treat.

7. What are your views on the proposed prerequisites for the Unique Clinical Circumstances pathway?

We consider that this pathway as described will be too restrictive.

This pathway should provide access to a funded product to patients who have an allergic or idiosyncratic response to a funded product, or patients whose condition in itself may not be unique, but who have a unique combination of circumstances surrounding clinical aspects of treatment.

We are concerned that the criteria require in part that the standard treatment 'has been ceased'. There are circumstances where the standard treatment has significant adverse effects on a patient, but that the adverse effects are less threatening than the withdrawal of treatment. These circumstances should not require exposing the patient to the risk of



complete withdrawal in order to gain approval for funding for an alternative treatment that might be better tolerated. An example would be (before its recognition by PHARMAC) an

ACE inhibitor-induced cough that is now accepted as a reason to fund angiotensin receptor blockers.

8. What are your views on the proposed prerequisites for the Urgent Assessment pathway?

We consider the proposed prerequisites to be appropriate, although there are no clear objective criteria around 'significant deterioration in health or significant improvement in quality of life'.

Our concerns about the 'has been ceased' criteria (see Q7) also apply here.

9. What are your views on the proposed prerequisites for the Hospital Pharmaceuticals in the Community pathway?

We consider the proposed prerequisites to be appropriate.

10. What are your views on the proposal to assess Named Patient Pharmaceutical Applications against PHARMAC's decision criteria?

Use of PHARMAC criteria provides consistency in the decision making process for both Exceptional Circumstances and Pharmaceutical Schedule listing decisions.

We note that applications that satisfy the prerequisites would subsequently be assessed according to PHARMAC's decision criteria before a decision is made about whether the pharmaceutical being applied for would be funded. Whilst the decision criteria are clearly laid out, we would request that the reasons for an application being rejected relating to these criteria are transparent and available to applicants.

Please note that the flow diagram on page 17 is not clear. It can be interpreted to mean that hospital clinicians do not have access to the UCC or Urgency pathways.

11. What are your views on the proposal that an NPPA application (other than within the UCC pathway) triggers PHARMAC's consideration of listing the treatment being requested on the Pharmaceutical Schedule?

We support this approach, but there doesn't seem to be any explicit expectation that the companies will submit the medication for a schedule listing, even though this is implied elsewhere in the document. Can this please be clarified?

12. Do you favour wider access with the appearance of inconsistent decisions that this may bring, or a more restrictive but consistent approach?

The Northern Region DHBs would favour consistency, even though this may be more restrictive.



13. What are your views on removing the distinction between cancer and community treatments under the proposed NPPA scheme?

We support this approach.

14. What are your views on the proposed approach to funding for treatments approved under the NPPA scheme?

We agree with the proposal that funding treatments approved for named patients under the UCC and Urgent Assessment pathways be allocated in the same manner as the funding currently is for EC.

We agree that there should be a nationally consistent approach to funding for medications, and that a high-cost medication for a rare condition should be funded from a national pool rather than imposed upon the budget of a small DHB. The “top-slicing” proposal seems to ensure this.

However, we suspect spending on EC is likely to increase, especially under the Urgent Assessment pathway. The proposal may shift the balance of funding towards funding more pharmaceuticals for individuals prior to a Schedule assessment via the Urgent Assessment pathway as well. We recognise the clinical benefit of this, but we would appreciate some modelling of cost impact if possible and a proposal from Pharmac for managing any budget over-runs.

15. What are your views on the proposed operational arrangements for the NPPA scheme?

We agree that transparency on the reasons that an application was funded, or rejected, is of critical importance, and would support PHARMAC providing an explanation for the decision to the applicant.

We strongly support the concept of a Review or Appeal process where applicants would be able to request a review of their application if they were not satisfied with the decision. There will need to be a process to ensure there are genuine grounds for appeal because of resource implications associated with this type of review.

We support the proposal that a summary of all applications under NPPA would be available on the PHARMAC website.

We would recommend that the reviews of patients during the assessment process be undertaken by experts in that particular field. We would prefer the decision to take a little longer if necessary to ensure that the relevant specialists are included in the assessment.

Any electronic system for managing applications, renewals or re-applications must be user friendly and include search functionality, e.g. with the current SA electronic access system there is no capacity to search to find a SA number or expiry date.

Within hospital systems staff apart from SMOs should have the ability to submit applications (on behalf of the lead SMO).

We request clarification around the maximum time it will take for an EC application to be considered. From the proposal it would appear that the majority will have a decision within one month. We would prefer to see a definite timeframe specified in the proposal.



16. What information do DHB hospitals routinely collect and how would this satisfy the information needs we have identified as necessary from DHB hospitals wishing to participate in the trial described in section 6(a)(ii).

The Northern DHBs can track the cost of dispensed medicines under Discretionary Community Supply and Hospital Exceptional Circumstances; we can meet the requirements outlined in this document.

17. What is your view of the proposal to stop funding treatments that are not related to exceptionality through EC?

We agree with the proposal to stop funding non-exceptional treatments through “Exceptional Circumstances” because of technical reasons.

There are ongoing issues around accessing non-registered (Section 29) products which need to be resolved.

In addition, the concept that any medicine requiring administration by infusion is necessarily a Hospital Pharmaceutical needs to be reconsidered. With the move towards accessing more complex care within the community, the ability to provide medicines by infusion by listing them in the PS is important (e.g. infliximab).

Thank you for considering this feedback.

Yours sincerely,

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WAITEMATA DISTRICT HEALTH BOARD