

5 September 2013

Steffan Crausaz
Chief Executive
Pharmac
PO Box 10 245
Wellington

By hand

Dear Steffan

Introduction

1. Thank you for the opportunity to meet with you today. Today's meeting focuses on issues with Pharmac's current decision making criteria and processes.
2. The discussion today will focus on:
 - a. matters that NZORD and its advisers consider Pharmac must take into account when making decisions; and
 - b. how the decision criteria need to change to ensure those matters are taken into account.
3. The discussion and this letter are relevant to Pharmac's consultation on its decision criteria, and forms part of NZORD's submission on that document. It is also relevant to your decision regarding the Schedule listing of eculizumab. NZORD is separately writing to you with a fuller submission on your decision criteria consultation paper and that submission will provide NZORD's views on all of the guiding questions recorded in your consultation paper. However, the discussion today is particularly relevant to the following "guiding questions" listed in Appendix 1 of your consultation paper:
 - a. Question 8: "What other criteria should/could PHARMAC consider?"
 - b. Question 12: "What additional criteria would you suggest to reflect fairness or community values and how could these be measured?"

Why has NZORD asked for this meeting now?

4. NZORD has for a number of years made submissions to Pharmac (or assisted patients making submissions to Pharmac) which have stressed the need for Pharmac's decision

making processes to take into account broader factors than those expressly recorded in Pharmac's current decision making criteria.

5. It was not clear to NZORD or its advisers until recently that the factors raised in this letter were not being taken into account by Pharmac in its current decision making processes. Previously, NZORD had assumed these criteria were considered under decision criteria 9 "such other criteria as PHARMAC considers fit". However, it has become apparent to NZORD that criterion 9 has been meaningless. A recent Ombudsman's opinion¹ highlights that:

- Pharmac's view is that it would always carry out consultation if it intended to take such "other criteria" into account (see paragraph 54 of the opinion); and
- "In specifically responding to what consultation might have been required in this case had submissions falling into the "other criteria" category been made to it, Pharmac remarked that it had been unable to identify an instance when this criterion had been used. It considered that if such a factor had been accepted this would probably have led to a permanent amendment to the Decision Criteria." (see paragraph 61 of the opinion).

6. The current consultation document also suggests that the broader factors that NZORD has raised with Pharmac have not to date been considered by Pharmac. The consultation paper mentions some of these broader factors (such as community values and fairness) in discretionary terms, as if the consideration of such factors by Pharmac is purely optional.

The importance of your decision making criteria

7. We wish to acknowledge (as is appropriately acknowledged in your consultation paper) that Pharmac has a crucial role in making decisions about which medicines are publicly funded in New Zealand. Your decisions affect the lives of almost every New Zealander, for many literally meaning the difference between life and death.

8. Given the importance of Pharmac's role, it is of utmost importance that Pharmac's decision making criteria take into account all of the factors that are relevant to those decisions and at a minimum include all of the factors which at law must be considered.

¹See

http://www.ombudsman.parliament.nz/system/paperclip/document_files/document_files/678/original/pharmac_s_decision_not_to_approve_funding_for_myozyme.pdf?1373604677

This is a legal requirement on Pharmac under administrative law. We note that this letter does not discuss other relevant factors which NZORD strongly considers should be considered by Pharmac (see NZORD's other submission).

Court action is an option

9. NZORD is confident that if it sought a declaratory judgment on the correct approach to the interpretation of sections 47 and 48 of the New Zealand Public Health and Disability Act 2000 (the "NZPHD"), the Court would confirm that the matters summarised below are mandatory relevant considerations. Given the importance of Pharmac's decisions, court action remains an option for NZORD.
10. However, it should not be necessary for a charitable organisation such as NZORD to use its limited resources to pursue such a declaratory judgment. Accordingly, NZORD urges Pharmac to change its approach and spare Pharmac and NZORD from the costs and inconvenience of such court action.

Current decision making criteria fail to take into account two factors which at law must be considered

11. Pharmac's current nine decision making criteria are:
 1. The health needs of all eligible people within New Zealand
 2. The particular health needs of Maori and Pacific Peoples
 3. The availability and suitability of existing medicines, therapeutic medical devices and related products and related things
 4. The clinical benefits and risks of pharmaceuticals
 5. The cost-effectiveness of meeting health needs by funding pharmaceuticals rather than using other publicly funded health and disability support services
 6. The budgetary impact (in terms of the pharmaceutical budget and the Government's overall health budget) of any changes to the Schedule
 7. The direct cost to health service users

8. The Government's priorities for health funding, as set out in any objectives notified by the Crown to PHARMAC, or in PHARMAC's Funding Agreement, or elsewhere
 9. Such other criteria as PHARMAC thinks fit. PHARMAC will carry out appropriate consultation when it intends to take any such "other criteria" into account.
12. In our view, the following factors are criteria which Pharmac is also legally required to consider but which are not addressed by your current decision criteria:
- The human rights impacts of individual decisions
 - The consistency of individual decisions with requirements of DHBs
13. We briefly outline below why these factors must be considered by Pharmac and why we believe the current decision making criteria fail to take these factors into account.

The human rights impacts of individual decisions

14. Legislation and case law makes it plain that wherever an enactment can be given a meaning that is consistent with recognised human rights and freedoms, that meaning shall be preferred to any other meaning. Even though Parliament may have considered human rights issues when developing the NZPHD Act, Pharmac must also take these rights into account when making decisions under its legislative framework.²
15. On any given application there may be a number of human rights relevant to the decision to be made by Pharmac. The relevant rights may include rights such as:
- The rights and freedoms in the New Zealand Bill of Rights Act 1990, including:
 - the right not to be deprived of life, except on such grounds as are established by law and are consistent with the principles of fundamental justice (see section 8 of the New Zealand Bill of Rights Act 1990 ("NZBORA") and also Article 6 of the International Covenant on Civil and Political Rights ("ICCPR")).

² NZORD assumes that Pharmac's current thinking is the opposite of this. For example, paragraph 80 of the Ombudsman's opinion stated "Pharmac's view (affirmed to [the Ombudsman]) was that societal values are reflected in the legislative framework, Pharmac acts ethically within that framework and therefore there has been no need to include societal values expressly in the NPPA Policy."

- the right to freedom from discrimination, including on the grounds of disability (including physical illness). (See section 19 of the NZBORA and also Article 26 of the ICCPR.)
 - “[T]he right of everyone to the highest attainable standard of physical and mental health” (see Article 12.1 of the International Covenant of Economic, Social and Cultural Rights (“ICESCR”)).
 - The right of everyone to the enjoyment of the highest attainable standard of physical and mental health (see UN Special Rapporteur on the Right to Health).
 - The right of each person to share in the benefits of scientific progress (see Article 15 of the Universal Declaration on Human Rights (“UDHR”)).
 - The right of a person to a standard of living adequate for the health and well-being, medical care and necessary social services, and the right to security in the event of sickness, disability or other lack of livelihood in circumstances beyond a patient’s control (see Article 25.1 of the UDHR).
16. To realise these rights, positive steps must be taken by Pharmac within the maximum of available resources, to assure all medical service and medical attention in the event of sickness (see Article 12.2 of the ICESCR).
17. It is accepted that, as Pharmac operates within a funding ceiling, it may not be possible “within the maximum of available resources” for these rights to be fully realised in every decision. However Pharmac’s decision making criteria must at a minimum consider in each case the impact on the human rights of each affected New Zealand citizen. In turn, Pharmac must ensure it is taking such steps as are possible within the maximum of available resources to realise these rights. Put another way, the existence of the funding ceiling is not in and of itself a justification for any breach of human rights that results from Pharmac’s decision making.

The consistency of individual decisions with the requirements of DHBs

18. The statutory functions of Pharmac were extended under section 48(e) of the NZPHD Act by the Minister of Health by notice in the Gazette dated 27 September 2001 which stated³

Under section 48 (e) of the New Zealand Public Health and Disability Act 2000, after consulting with the board of Pharmac in accordance with the requirements of that section, I authorise Pharmac to perform the function specified in the Schedule to this authorisation.

This authorisation is effective from the date of signing and shall remain in force until it is revoked by the Minister of Health.

Schedule

Pharmac is authorised to manage the purchasing of any or all pharmaceuticals, whether used either in a hospital or outside it, on behalf of DHBs.

In carrying out this function Pharmac will need to address, at a minimum, the following factors:

- (i) Developing a management strategy;
- (ii) consulting and communicating with DHBs and other interested parties as Pharmac considers appropriate;
- (iii) amending Pharmac's planning, funding, and policy documents to the extent appropriate;
- (iv) compiling and analysing information from DHBs on pharmaceutical volumes, expenditure, and contractual arrangements;
- (v) adjusting the pharmaceutical schedule as necessary; and
- (vi) carrying out purchasing on behalf of DHBs.

19. Under this additional statutory function Pharmac operates as a “purchasing agent” of DHBs. Any purchasing agent (including Pharmac) must act within the scope of the authority conferred on it and owes various binding duties to the principal. At a minimum, this means Pharmac must consider, in respect of any decision it makes for DHBs, the

³ <http://www.dia.govt.nz/MSOS118/On-Line/NZGazette.nsf/6cee7698a9bbc7cfcc256d510059ed0b/c57313b1fcd1e3dccc256d2600600605!OpenDocument>

consistency of the decision with the legal requirements imposed on DHBs and imposed by DHBs.

20. NZORD has identified that the following factors do not currently appear to form part of Pharmac's decision making:

- Consideration of DHBs' statutory objectives, which includes considering:
 - whether Pharmac's decision making on behalf of DHBs exhibits "a sense of social responsibility by having regard to the interests of the people ... for whom it arranges the provision of services" (see section 22(1)(g) of the NZPHD Act);
 - the ethical implications of the decisions made on behalf of DHBs and the ethical standards commonly expected of providers of services and public sector organisations" (see section 22(1)(i) of the NZPHD Act).
- Consideration of "equity of access, reducing inequalities and improving health outcomes for individuals"⁴.

These factors are not being taken into account

21. As noted above, NZORD believes these factors are not currently being taken into account by Pharmac in its decision making processes. NZORD has formed this view based on the statements in the recent Ombudsman's opinion. NZORD considers the human rights implications and the requirements of DHBs are mandatory relevant considerations for all applications, so is surprised that Pharmac is "unable to identify an instance when" criterion 9 has been considered.

22. NZORD also considers the current criterion 9 is misleading. It infers that there are factors additional to those in criteria 1-8 that are being considered by Pharmac, but all it has meant in practice is that it is open to Pharmac to add a new criterion in the future (which Pharmac would have a discretion to do in any event).

What we want Pharmac to do

23. It is not lawful for Pharmac to continue to fail to consider the factors highlighted above, particularly where submissions highlight that these factors are relevant. It would not be

⁴ See clause 3 of the Memorandum of Understanding (MOU) between Pharmac and DHBs which states "Equity of access, reducing inequalities and improving health outcomes for individuals and communities will guide our relationship and decision making".

lawful to delay consideration of these factors until the current process of reviewing Pharmac's Operating Policies and Procedures (OPPs) is completed, as the factors are mandatory considerations.

24. To comply with its legal framework, Pharmac must start taking these factors into account in its decision making processes. For example, NZORD would expect these factors to be taken into account in respect of the current decision-making process in respect of the Schedule listing of eculizumab and in respect of any request by Ms Evans (or other Pompe patients) to reconsider her NPPA application.
25. The reviewed OPPs should expressly include such factors in Pharmac's decision criteria. Until such time as the OPPs can be reviewed, Pharmac should take the factors noted above into account under criterion 9 "Such other factors as Pharmac thinks fit."
26. We appreciate that Pharmac may need to discuss some of the matters raised in this letter with its Board in order to change its current decision making processes. We understand that Pharmac's Board typically meets towards the end of each month. Accordingly, we look forward to hearing from Pharmac by mid-October 2013 with information on how Pharmac will be amending its current decision making process to include the factors raised in this letter.

Other legal issues

27. The meeting today has focused on matters which, at law, we consider Pharmac must take into account. In particular, it has focused on those issues which NZORD considers could be clarified by way of a declaratory judgment process.
28. Pharmac should not assume from this letter that there are no other legal issues raised by its current decision making criteria or processes.
29. For example, Pharmac's current decision making processes, the Ombudsman's opinion and the decision criteria consultation document emphasise that Pharmac holds a view that equity requires Pharmac to treat all cases alike and that Pharmac currently applies the same decision making criteria to all decisions. However, while equity does require treating like cases alike, it also requires that different cases be treated differently. NZORD notes there are references in core accountability documents and purpose statements to reducing inequalities and reducing health disparities. Accordingly, it is clear, that Pharmac needs to take positive steps to ensure its decision making processes address and reduce any inequalities that would arise from addressing all cases on the

same criteria. This is particularly an issue with respect to exceptional circumstances applications under the NPPA Policy. To this end, NZORD supports the Ombudsman's findings that "the decision criteria under the NPPA Policy ought to be clearly differentiated from those under the Pharmaceutical Schedule" (see paragraph 118 of the Ombudsman's opinion).

Conclusion

30. We look forward to receiving from you by mid-October confirmation that these factors will be taken into account by Pharmac in its decision making going forward. NZORD is available to discuss these issues further with Pharmac if that would be useful.

Yours sincerely



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Executive Director, NZORD



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