

1 August 2005

To all interested parties

Update of Operating Policies and Procedures

In April 2005, PHARMAC consulted on a draft of the proposed third edition of its Operating Policies and Procedures (**OPPs**). PHARMAC is in the process of assessing the consultation responses received. This letter records PHARMAC's initial response to the submissions received, and seeks to clarify some of the points raised.

30 submissions were received in response to the first round of consultation. The submissions are summarised in the attached table. Please let us know if you do not consider that PHARMAC has accurately reflected your comments in this summary.

A summary of the main issues raised in consultation and PHARMAC's initial response to them is set out below.

PHARMAC's role and objective

Summary of submissions

- There needs to be further debate about PHARMAC's objective (Janssen-Cilag).
- More recognition should be given to balancing fiscal considerations against securing the best health outcomes (NZAF, NZORD).
- PHARMAC's public law obligations should be elaborated on (NZORD).
- PHARMAC should note the statutory and ethical risks inherent in deviating from its core business and seek Ministerial and ethical guidance on these matters (NZORD).
- The Chief Executive's delegated powers should be reviewed to ensure that the PHARMAC Board is performing its statutory functions as set out in the NZPHD Act (GlaxoSmithKline).

PHARMAC response

- PHARMAC's functions and objective are set out in the New Zealand Public Health and Disability Act 2000 (the NZPHD Act). Any change to these functions or objective would involve a Ministerial direction or amendment to the legislation.
- Do you have any suggestions as to how PHARMAC's role, objectives, public law and statutory obligations could be better reflected in the OPPs?

Advisory committees

Summary of submissions

- It would be helpful for membership of PTAC to include a DHB funding perspective (Wairarapa DHB).
- Various amendments should be made to the PTAC Guidelines to ensure that PTAC can operate independently from PHARMAC and in a transparent manner (GlaxoSmithKline).
- A dermatologist should be included on one of PHARMAC's advisory boards (Ian McQuillan).
- PHARMAC should maintain a hospital advisory committee (MidCentral Health, Whanganui DHB, Taranaki DHB, Northland DHB)).

PHARMAC response

- PTAC is a committee of clinicians who have applied directly or were nominated by professional medical bodies, such as the Royal New Zealand College of General Practitioners and the Royal Australasian College of Physicians. Given the wide range of professions, is not expected to be a representative body.
- Vacancies, when they arise, are advertised publicly and PTAC members are appointed by the Director-General of Health following a recommendation by the PHARMAC Board.
- PHARMAC acknowledges the comments in relation to the PTAC guidelines, but notes that the current proposal is to amend the Operating Policies and Procedures, and not the PTAC Guidelines.
- PHARMAC notes that a new HPAC has been convened. It is intended that this committee will meet regularly to provide advice in relation to hospital pharmaceuticals.

Treaty of Waitangi

Summary of submissions

- Clause 1.6 should include considering the impact of PHARMAC's decisions on the health of Maori and demographic features of Maori (Waikato DHB – Maori Health).
- The word “race” in clause 1.6 should be replaced with “ethnicity” (Waikato DHB – Maori Health).
- The principles of the Treaty of Waitangi should be included in clause 1.6 (Waikato DHB – Maori Health).

- Some questions were asked in relation to clause 1.6 (Te Runanga O Kirikiriroa Trust).

PHARMAC response

- The use of the word “race” in the OPPs mirrors the language used in the NZPHD Act.
- PHARMAC welcomes submissions on ways in which the impact of PHARMAC’s decisions on the health of Maori could be considered and the principles of the Treaty of Waitangi could be included.

Decision Criteria

Summary of submissions

- Clause 2.2(c) (“medicines, therapeutic medical devices and related products and related things”) is very broad (Waikato DHB).
- The following additional decision criteria should be added to the OPPs:
 - patient safety (Waitemata DHB);
 - changes in modes of service delivery and alignment to DHB and national priorities (Canterbury DHB);
 - public health consequences of decision-making (Janssen-Cilag);
 - evidence-based decision-making (NZORD, Taranaki DHB);
 - the personal burden on the health status and care requirements of health service users, and on the health status and care requirements of those who support or care for them (NZPORD);
 - financial motivations for companies to bring their medicines to New Zealand (NZORD).
- PHARMAC should advise interested parties and members of the public on what it considers to be the most important criteria in any specific decision or give weightings to the criteria (GlaxoSmithKline, RMI, NZORD).
- The proposed amendments to clauses 3.1 and 3.3.4 should be deleted because inconsistency may breach PHARMAC’s public law obligations of fairness (GlaxoSmithKline).
- The OPPs should clarify that cost-utility analysis cannot be used on its own as a reason to deny an application (NZORD).

- A cooperative consensual approach to limitation of the use of certain pharmaceuticals should be used, rather than decision-making by purchase price (MCNZ).

PHARMAC response

- Section 6 of the NZPHD Act provides that “pharmaceutical” means a medicine, therapeutic medical device, or related product or related thing. The wording in the OPPs is taken directly from this.
- PHARMAC would be interested in further advice on the relative priorities or weightings of the decision criteria in the OPPs.
- Evidence-based decision-making is key factor in PHARMAC processes. Could this be reflected more clearly in the OPPs?
- In relation to weightings to be given the decision criteria, how could this be reflected in the OPPs and implemented?

Strategies

Summary of submissions

- Some of PHARMAC’s strategies, such as reference pricing, parity pricing, sole supply and/or tendering should be reconsidered or re-evaluated (Whanganui DHB, RMI, MCNZ).
- The proposed amendments to clause 3.1 and 3.3.4 should be deleted because inconsistency may breach PHARMAC’s public law obligations of fairness (GlaxoSmithKline).
- The types of risk sharing arrangements that are not appropriate need to be clarified in the OPPs (Janssen-Cilag).
- Pharmaceuticals should only be reclassified where it is clinically appropriate (MCNZ).
- Cross deals or bundling arrangements should only occur when all pharmaceuticals included in a package have been chosen on merit (MCNZ).
- A separate funding pool for high-cost therapies should be introduced (NZORD).

PHARMAC response

- How could the OPPs be amended to take account of any concerns about strategies that are currently used?
- Is there any view about types of risk sharing arrangements are appropriate?

- Do you have a view on how the OPPs should deal with cross-deals or bundling arrangements?
- If a high cost medicine pool was set up, how would it be funded and how large should it be?

Procedure

Summary of submissions

- Procedures for amending the Pharmaceutical Schedule should be clearer (Janssen-Cilag).
- Decisions on new therapies remain slow and cumbersome (NZAF).
- There needs to be a formal process for PHARMAC to be held publicly accountable for the consequences of its decisions (NZAF).

PHARMAC response

- What types of procedures do you envisage us including in the OPPs?
- Given that increased consultation and more detailed processes are likely to delay listing decisions, how could PHARMAC speed up its decision-making?
- What sort of formal process could be introduced to enable PHARMAC to be more accountable for its decisions?

Consultation

Summary of submissions

- There should be increased consultation and/or more time given for comment (Waikato DHB, Northland DHB, GlaxoSmithKline, Janssen-Cilag, FPA, MCNZ).
- PHARMAC should report back to submitters once consultation is complete (Janssen-Cilag, NZAF, DNZ).

PHARMAC response

- What types and periods of consultation do submitters consider is appropriate for different types of decisions?
- How do we balance increased consultation and reporting back to submitters with faster decision-making?

Appeal mechanism

Summary of submissions

- An independent appeal mechanism should be created to hear appeals of PHARMAC decisions (GlaxoSmithKline, RANZCO, NZAF)

PHARMAC response

- How do interested parties envisage an independent appeal mechanism working?
- Please note that an appeal mechanism would not change the total size of the pharmaceutical budget for any given year, therefore it could only rearrange priorities.

Hospital Pharmaceuticals

Summary of submissions

- The incorporation of the hospital procurement process into the OPPs provides PHARMAC with a wider brief than it had previously (Taranaki DHB, NZAF).
- There is concern about applying reference pricing to hospital pharmaceuticals (Taranaki DHB, Southland DHB).
- How and under what circumstances the National Hospital Pharmaceutical Strategy would be updated or amended should be included in clause 3.2.2(a) (MidCentral Health).
- The decision to incorporate provisions relating to hospital pharmaceuticals into the main body of the OPPs is sensible and provides easier access (GlaxoSmithKline, Good Health Wanganui).

PHARMAC response

- The amendments that have been made to the OPPs in relation to hospital pharmaceuticals were simply to incorporate provisions that are currently found in the Hospital Pharmaceuticals Supplement into the main body of the OPPs so that operating policies and procedures for hospital and community pharmaceuticals could be found in one document.
- Bearing this in mind, is there any further comments that parties would like to raise in relation to hospital pharmaceuticals?

Flexibility

Summary of submissions

- The OPPs should not unduly expand the scope of PHARMAC's decision-making discretion or give PHARMAC absolute freedom (GlaxoSmithKline, RMI, Good Health Wanganui, MidCentral DHB).

PHARMAC response

- PHARMAC considers that flexibility in its processes, as set out in the OPPs, help decisions to be made quickly. There is provision for PHARMAC to consult when taking additional decision criteria into account, adopting new strategies, or when a variety of other situations arise.
- In light of this, are there any amendments that should be made to PHARMAC's scope of decision-making?

Future review of OPPs

Summary of submissions

- The OPPs should be reviewed following any statutory or ministerial changes to PHARMAC's objectives and/or functions (GlaxoSmithKline).
- Regular reviews of the OPPs should continue to be a requirement (RMI).

PHARMAC response

- We are happy to consider including a provision for regular reviews in the OPPs. How frequently do you consider these reviews should occur?

Implementation

Summary of submissions

- Consideration should be given to the way in which the OPPs are implemented and enforced (GlaxoSmithKline).
- Transparent processes for ensuring stated policy and procedure is applied appear to be lacking (NZAF).

PHARMAC response

- What measures should PHARMAC take to ensure that the OPPs are implemented, applied and enforced?

- How could PHARMAC improve transparency?

Other

Summary of submissions

- Reference to the Official Information Act should date the version of the Act to which it refers (MidCentral Health).
- There should be a more open and collaborative culture exhibited by PHARMAC staff (Janssen-Cilag).
- The amendments do not address the areas identified by the Minister in public statements (RMI).

PHARMAC response

- The point in relation to the Official Information Act is noted.
- How could we reflect a more open and collaborative culture in the OPPs?

If you wish to comment on any of the issues raised above or in the table of consultations responses, please forward your comments to PHARMAC, to the attention of Stuart Bruce, by **5pm on 30 September 2005**. Please let us know if you would like to meet with us to discuss any of the issues raised by the proposed amendments to the OPPs.

Yours sincerely



Wayne McNee
Chief Executive

Submitter	Submission
District Health Boards	
Waikato DHB	<ul style="list-style-type: none"> • The scope of the statement in part (c) of clause 2.2 is very broad. Clause 2.2(i) might usefully be reconsidered to increase precision. • Clause 4.2 states that “PHARMAC will consult when it considers appropriate...”, which suggests it does not have to consult if it chooses not to. This may not be the intention, as consultation would generally be considered highly desirable in most circumstances.
Waikato DHB – Maori Health	<p>Suggested amendments to clause 1.6:</p> <ul style="list-style-type: none"> • Clause 1.6.2 should include considering the impact of PHARMAC’s decisions on the health of Maori. • Replacing “race” with “ethnicity” (or remove sentence altogether) in clause 1.6.3(a). • Inserting a clause stating that “in order to recognise 1.6.1, PHARMAC will take into consideration the following in its decision making process: <ul style="list-style-type: none"> ○ the health status of Maori regarding the health condition under consideration; and ○ demographic features of Maori including age structure and socio economic status”. <p>This could alternatively be added to the clause 2.2 decision criteria.</p> • Inserting a provision that PHARMAC will consider “the impact decisions made by PHARMAC will have on the health of Maori, and ensuring health equality”. • Including the principles of the Treaty of Waitangi in clause 1.6.1. <p>There is a general concern that the provisions in clause 1.6 do not mean anything in reality and need to be more specific.</p>
MidCentral Health	<ul style="list-style-type: none"> • Clause 5.2 states that PHARMAC <i>may</i> maintain a HPAC. It would be important to hospitals that it definitely maintains this group. • Clause 2.2(i) gives PHARMAC immense power to decide what other criteria it will bring to bear, and needs to be tightened to specify more than an all-inclusive process. • The statement in clause 3.2.2(a) “...or in related documents or in any other strategy developed and notified by PHARMAC” should be tightened to specify <i>how and what circumstances</i> of development, and notification to whom and through what forum. • Reference to the Official Information Act should date the version of

	the Act to which it refers.
Waitemata DHB – Safety and Quality Use of Medicines Group	<ul style="list-style-type: none"> An additional criterion should be added to the clause 2.2 criteria to reflect concerns about patient safety, including where packaging and labelling of a pharmaceutical when replacing one brand with another could place patients at risk of a medication error.
Wairarapa DHB	<ul style="list-style-type: none"> It would be helpful for membership of PTAC, as set out in clause 1.4, to include a DHB funding perspective. This would enable increased communication and understanding between PHARMAC and DHB funders. <p>As such, one of the medical practitioners on PTAC should be a DHB General Manager Planning and Funding.</p>
Wanganui DHB	<ul style="list-style-type: none"> Concerns have been raised by Wanganui DHB clinicians with respect to clause 3.3.1, namely that the application of reference pricing, subsidised at the lowest priced pharmaceutical in the sub-group, may exclude the use of a higher priced more efficacious pharmaceutical. In relation to clause 1.5.2 - hospital representation is vital and should HPAC be disbanded, inclusion of hospital representation on PTAC and sub-committees in an advisory capacity is paramount.
DHBNZ	<ul style="list-style-type: none"> There are only minor changes proposed to the second edition. DHBNZ has no further comment at this time.
Taranaki DHB	<ul style="list-style-type: none"> The incorporation of the hospital procurement process into the OPPs provides PHARMAC with a “wider brief” than previously in relation to purchasing hospital pharmaceuticals. It may provide PHARMAC with a platform to apply the same approach currently operating in the community pharmacy sector. If any changes are to be made these should only follow after establishment of the Hospital Assessment Sub-committee of PTAC. <p>Specific concerns:</p> <ul style="list-style-type: none"> Clause 1.5.2 – “<i>may</i> maintain a Hospital Advisory Committee” should be amended to “<i>will</i> maintain a Hospital Advisory Committee”. It is essential that this area has expert advisory input. Clause 2.1(g) refers to hospital processes when no agreement has been requested via consultation or given regarding hospital processes. Clause 3.2.2 – strategies outlined in 3.2.1 for the community pharmacy setting can be applied to the hospital sector. This may allow the application of restrictive policies and poses a significant area of concern. Clause 3.3.6 signals a clear intention to apply reference pricing to hospital pharmaceuticals. To be effective, reference pricing would require a cumbersome and time consuming claim and

	<p>reimbursement system to be in place.</p> <ul style="list-style-type: none"> • Would like to see wording included in clause 4.1.3 to alleviate a concern that PHARMAC has not taken into consideration specific evidence based clinical trial data. • Clause 4.2.1(e) – in light of the other proposed changes and suggested emphasis on PHARMAC having more restrictive control over the hospital area, consultation may be overridden.
Northland DHB	<ul style="list-style-type: none"> • Clause 1.5.2 should be amended, replacing each occurrence of “may” with “will”. • Clause 4.2.1 – replace “PHARMAC will consult when it considers appropriate...” with “PHARMAC will consult appropriately with the sector, including the public, groups, or individuals”. This is necessary to highlight that PHARMAC must be aware of issues facing DHBs for changes and activities that PHARMAC undertakes.
Southland DHB	<ul style="list-style-type: none"> • Clause 3.3.6 raises the option of applying reference pricing to hospital pharmaceuticals. This is contrary to the National Hospital Pharmaceutical Strategy, clause 5.1. The option to use reference pricing should not be included without a full process of consultation with the DHBs. It is premature to include this in the OPPs without undertaking a review of the NHPS.
Canterbury DHB	<ul style="list-style-type: none"> • The decision making criteria should include the following: <ul style="list-style-type: none"> ○ that PHARMAC decisions recognise and support changes in modes of service delivery; and ○ that PHARMAC decisions align to DHB and national priorities. • The Ophthalmology Department has no significant comments.
HealthPAC	<ul style="list-style-type: none"> • HealthPAC does not anticipate any impact on its technical environments, business processes or operational resource requirements.
Suppliers	
GlaxoSmithKline	<ul style="list-style-type: none"> • PHARMAC should take care in “future proofing” the OPPs that they do not become so general that they no longer provide helpful guidance, or are inconsistent with PHARMAC’s public law obligations. • Removing the requirement to review OPPs once every five years may result in the OPPs not being reviewed at all. They should be reviewed following any statutory or ministerial changes to PHARMAC’s objectives and/or functions. • The proposed changes to clause 2.1 and 2.2 should be deleted as they unduly expand the scope of PHARMAC’s decision-making discretion. Alternatively, they should be altered to refer to PHARMAC’s public law obligations and objectives/functions under

	<p>the NZPHD Act.</p> <ul style="list-style-type: none"> • Clause 2.2 should be amended to state that PHARMAC will advise interested parties and members of the public on what it considers to be the most important criteria in any specific decision, and if those criteria change during the process. • The OPPs should specify that PHARMAC will provide interested parties with a statement of reasons for a decision. • The proposed amendments to clauses 3.1 and 3.3.4 should be deleted because inconsistency may breach PHARMAC's public law obligations of fairness. • An independent appeal mechanism should be created to hear appeals of PHARMAC's decisions, including decisions to amend the Pharmaceutical Schedule. • Various amendments should be made to the PTAC Guidelines to ensure that PTAC can operate independently from PHARMAC and in a transparent manner: <ul style="list-style-type: none"> ○ PTAC and the PTAC sub-committees should be accountable to the Director General of Health and administered by the Ministry of Health, rather than PHARMAC. ○ PTAC should have a separate secretariat, should set its own agenda and take its own minutes. PHARMAC must be able to ask PTAC to consider particular issues, but should not influence the content of the agenda or minutes of PTAC or sub-committee meetings. ○ The appointment of PTAC members should be undertaken independently from the Pharmac executive/Board. Consultation on appointments should be undertaken with the Ministry of Health or with an expert industry body. PHARMAC should not be the only body that is consulted. ○ When PTAC or a sub-committee has been asked by PHARMAC to address a particular issue, interested parties should be made aware of the nature of the request. • Consideration should be given to the way in which the OPPs and the PTAC Guidelines are implemented and enforced. • The broad scope of the Chief Executive's delegated powers should be reviewed to ensure that the PHARMAC Board is performing its statutory functions as set out in the NZPHD Act. • The decision to incorporate provisions relating to hospital pharmaceuticals into the main body of the OPPs is sensible. • The list of proposals in clause 4.2.1 should be expanded to specify that PHARMAC will consult on <i>any</i> proposal to amend the Schedule, whether the proposal is initiated by PTAC, a supplier,
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	another interested party or by PHARMAC itself.
Janssen-Cilag	<ul style="list-style-type: none"> • Clause 1.1 - there needs to be further debate about PHARMAC's objective (in terms of advocating for more funding for pharmaceuticals and PHARMAC under spending its budget). The clause should specify what are "non-core" objectives. • Clause 2.2 – there should be a more specific consideration of public health consequences of decision-making. • Clause 3.2.1(c) – the types of risk sharing arrangements that are NOT appropriate need to be clarified in the OPPs. There is particular concern about the ability of suppliers to audit expenditure on particular products. • Clause 3.2.4(c) – PHARMAC should only take an active role on other issues that impact on supply or demand on the Pharmaceutical Schedule or contracted hospital pharmaceuticals. • Clause 3.3.2 – a therapeutic subgroup should only include products where switching from one member of the sub-group to another results in no adverse consequences to the health of individuals taking those products. • Clause 4.1: <ul style="list-style-type: none"> ○ General details about procedures for making submissions should be available on the PHARMAC website. ○ There should be a defined process for the distribution of PTAC minutes to applicants and interested parties. ○ The information on applications to PTAC and minutes of PTAC meetings published on the website are not current. ○ PHARMAC rarely acknowledged communications or provided a written response to submissions during certain negotiations. This is inappropriate business practice. ○ The management of PHARMAC need to take steps to ensure continuity where there are changes in staff. • Clause 4.2: <ul style="list-style-type: none"> ○ There is a lack of written acknowledgement or feedback on consultation responses. This contributes to an impression that consultations are not genuine. ○ Consultation should be addressed to appropriate clinical experts, consumers and patients to comment. ○ More transparency about who is consulted would improve the process. ○ There must be adequate time given to comment. There may be a case for consultation involving a large number of

	<p>stakeholders to have a longer consultation period.</p> <ul style="list-style-type: none"> ○ Consultations on PHARMAC’s economic analyses are not being sent to appropriate people at DHBs, and should, at a minimum, be sent to the Clinical Directors of the specialist area. ○ There should be more opportunity for suppliers to comment before any analysis goes to DHBs. <ul style="list-style-type: none"> ● Clause 4.2.4: <ul style="list-style-type: none"> ○ It would be good to have a short description of what the consultation is about included in the email alert. ○ PHARMAC needs to take steps to ensure that announcements to the media in relation to its decisions are not inappropriate or misleading. ○ The wording of any press release should be checked with the supplier concerned in advance to ensure that confidentiality is maintained and that no misinformation is promulgated. ● Clause 4.3 – there should be a more open and collaborative culture exhibited by PHARMAC staff.
<p>Researched Medicines Industry Association</p>	<ul style="list-style-type: none"> ● Neither of the two proposed amendments address the areas (including sole supply contracts and Exceptional Circumstances criteria) identified by the Minister of Health in public statements. ● There is now no reference in the draft to any requirement for future reviews. Regular reviews of OPPs should continue to be a requirement. ● The current review is lacking in scope and independence and should instead form part of a wider, independent review that includes, but is not limited to PHARMAC, its policies, operations and impacts. ● The OPPS as written serve to give PHARMAC absolute freedom to act on a case-by-case basis. The reader is unlikely to be able to accurately assess how PHARMAC is likely to act in its processes. <p>For example, the introduction to clause 3.</p> <ul style="list-style-type: none"> ● Reference pricing: <ul style="list-style-type: none"> ○ The linking of subsidy levels to the lowest off-patent molecule in a therapeutic sub-group means innovators are denied a fair return on their investment. ○ PHARMAC may eliminate all subsidies for other medicines in the sub-group, effectively excluding these medicines from the market.

	<ul style="list-style-type: none"> ○ PHARMAC's definition of a therapeutic sub-group means that an entire class of medicines, that may have different chemical structures, are considered to be equipotent. This form of treatment selection fails to provide the range of options necessary to meet the needs of individual patients. ○ Reference pricing has a negative impact on continuity and stability of treatment. Subsidised medicines are switched for no reason other than a new deal has been struck. No provision is made to 'grandparent' patients who would prefer to stay on their current medication. ○ Strategies applied in unison with reference pricing must be considered. For example, the practice of companies offering a price break on another medicine listed on the schedule serves to drive down, through reference pricing, the price of the entire therapeutic sub-group. ● Parity pricing: <ul style="list-style-type: none"> ○ Parity pricing goes against the accepted principles of reference pricing, that a similar price should be paid for those medicines that have the same therapeutic purpose and effect. ○ It allows PHARMAC to reduce the subsidy for a pharmaceutical in one therapeutic sub-group, thus setting the reference price for that sub-group, by setting it at the level of the subsidy for a completely separate sub-group. ● Tendering and sole supply: <ul style="list-style-type: none"> ○ PHARMAC's tendering and sole supply strategies limit clinician choice and cause frequent schedule changes, creating uncertainty for patients. ○ Continuity of supply is compromised as suppliers are unable to carry extra stock due to the cost cutting required to win a tender or sole supply contract. ○ Supply becomes more tenuous towards the end of the contract period as uncertainty mounts as to whether the contract will be re-awarded. ○ Sole supply arrangements can create major difficulties if the supplier is unable ultimately to supply. ○ Frequently, other suppliers are called on to fill the gap when supplies fail, and are expected to start and stop supply within days. ○ Companies can be uncertain whether they have obtained contracts because of the lack of clearly defined response times to contract submissions and tenders. This makes forward planning almost impossible.
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	<ul style="list-style-type: none"> ○ These 'winner-takes-all' strategies serve as a disincentive for suppliers to maintain their whole product portfolio in New Zealand. • The Decision Criteria should include indications of the weightings given to each criterion, and the rationale behind the criteria rankings.
Practitioner groups	
Good Health Wanganui	<ul style="list-style-type: none"> • The inclusion of hospital pharmaceuticals provisions into the main body of the OPPs should improve ease of access and provide a more comprehensive unitary document. • Increased flexibility in the wording and format of the OPPs should expedite their ease of use as administrative tools.
Taupo Health Centre	No suggested alterations.
Family Planning Association	<ul style="list-style-type: none"> • The current OPPs are effective. • FPA encourages PHARMAC to widen its consultation with interested organisations and individuals. Consultation periods should be extended in order to allow organisations and individuals appropriate timeframes in which to reflect, consider and comment on proposals.
Ian W McQuillan Dermatologist	<ul style="list-style-type: none"> • Having a dermatologist on one of PHARMAC's advisory boards would be a welcome reassurance that concerns as to the narrowing of the subsidised products used by dermatologists are being heard, and hopefully acted on.
Dargaville Mobile Nursing Service	<ul style="list-style-type: none"> • Any new drugs (such as Salamol) should be trialled on a focus group before being released to the public.
Pharmacy Guild of New Zealand	<ul style="list-style-type: none"> • Acknowledgement has been made of the amendments allowing for the inclusion of, and distinction of provisions relating to Hospital Pharmaceuticals in contract to Community Pharmaceuticals. • The inclusion of additional text intended for flexibility and recognition of signifying the need for consultation are also acknowledged. • Other than this, the Guild has no comments.
The Royal Australian and New Zealand College of Ophthalmologists	<ul style="list-style-type: none"> • There is no formal appeals process for review of decisions. This may be inherent in PHARMAC's administrative system but is not transparent to stakeholders.
Medical Council of New Zealand	<ul style="list-style-type: none"> • Clause 2.1(d) should only be implemented where reclassification of pharmaceuticals is clinically appropriate. • Negotiations under clause 3.2.1(d) should only occur when all pharmaceuticals included in a package have been chosen on

	<p>merit.</p> <ul style="list-style-type: none"> • Clause 3.2.1(i) should only be invoked when the therapeutic sub-groups are considered equivalent by the relevant branch advisory bodies, and are not necessary as adjuncts or alternatives. • The meaning of “appropriate consultation” under clause 3.3.3 should be clearly outlined. This should include open and transparent consultation with all relevant branch advisory bodies. • Consideration should be given to involving patients in consultation. Confidentiality in relation to commercial issues should not prevent appropriate discussion with professional and consumer groups about therapeutic concerns. • Changeovers of funding should be accompanied by appropriate documentation and follow-up to monitor for any real changes to morbidity and mortality. • A cooperative consensual approach to limitation of the use of certain pharmaceuticals should be used, rather than the blunt instrument of decision making by purchase price.
New Zealand Medical Association	<ul style="list-style-type: none"> • NZMA acknowledge that the main thrust of the revised draft changes are: <ul style="list-style-type: none"> ○ Incorporation of the provisions relating to hospital pharmaceuticals into the main body of the OPPs. ○ More flexibility in the wording to accommodate future additional Ministerial objectives and functions laid down to PHARMAC in order to reduce the need for further amendments or draft supplements. • There is nothing of undue concern in the changes to the wording in clauses one through four to
Patient / interest groups	
Diabetes New Zealand	<ul style="list-style-type: none"> • PHARMAC should consult in good faith and provide feedback to consumer organisations likely to be affected by any amendment to the Schedule. There also needs to be clarity regarding PHARMAC’s responsibilities in providing advice to patients affected by any amendment. Accordingly, there should be amendments to the OPPs along the following lines: <ul style="list-style-type: none"> ○ New clause 2.2(j) stating: “PHARMAC will consult in good faith with any duly constituted consumer organisations representing people likely to be affected by any amendment”. ○ Clause 3.2.4(b) – after the word <i>communications</i>, insert “including patient advice”. ○ Clause 4.2.4 – after the word <i>groups</i>, insert “(including duly

	constituted consumer organisations)".
New Zealand Organisation for Rare Disorders	<ul style="list-style-type: none"> • NZORD would like to meet with PHARMAC to discuss its submission if possible. • Clause 1.2.3 – specific items should be elaborated on, including: <ul style="list-style-type: none"> ○ Spelling out fair process for decision making, including, for example, indicating time-frames for decisions, criteria for possible extension of those time-frames, and the automatic approval of an application if PHARMAC fails to decide within a given time. ○ Making specific reference to Acts such as the Bill of Rights Act and the Human Rights Act, and clarification of how PHARMAC will include those and other relevant legislation in its decision making processes. ○ Elaboration of key common law and ethical principles relating to duty of care relevant to the decision making process, and clarification of how they will be considered. ○ Addressing potential conflict of interest issues arising from PHARMAC’s position as an agent of government. • Evidence-based medicine should be identified in the OPPs as a core criterion in decision making, with some elaboration of how this is implemented in decisions. There should be reasons required of PHARMAC when it decides not to follow PTAC advice. • The OPPS should include specific reference to the tension between budget management goals and securing best health outcomes, and outline a series of measures in relation to this, including: <ul style="list-style-type: none"> ○ ‘Grandparenting” access to existing medicines. ○ Trials of alternatives to establish potential problems. ○ Steps to ensure the needs of specific sub-groups are adequately addressed in tendering and consultation. ○ Risk management strategies to reduce the likelihood of supply problems. • A separate funding pool for high-cost therapies should be introduced to restore equality and reduce disparities for those needing high cost therapies. This should be provided for in the OPPs. • The OPPs should clarify that Cost Utility Analysis cannot be used on its own as a reason to deny an application and that fuller reasoning must be given. • PHARMAC should note the statutory and ethical risks inherent in deviating from its core business (for example becoming involved in treatment decisions and discussion on industry funding of support

	<p>groups), and seek Ministerial and ethical guidance on these matters.</p> <ul style="list-style-type: none"> • The following sections should be added to the Decision Criteria in clause 2.2, to help develop a more transparent decision making process: <ul style="list-style-type: none"> ○ “(j) the personal burden on the health status and care requirements of health service users, and on the health status and care requirements of those who support or care for them” ○ “(k) in making its decisions PHARMAC will disclose the weightings given to these criteria”. • PHARMAC is urged to take note of the recommendations of the 2000 review of the OPPs.
Leukaemia & Blood Foundation	<ul style="list-style-type: none"> • There needs to be a far broader review addressing the fundamental ethos of the organisation. • Delays in evaluating and funding new medicines mean that they are out of reach of patients for much longer than is necessary. • There is a lack of transparency in the process of listing pharmaceuticals on the schedule. There should be a clear model that has all parties confident of the process and progress, including a review process, of each new therapy. • There is concern that new medicines are being evaluated in such a way as to disadvantage the likelihood of them being funded. For example, PHARMAC using a high ‘discount rate’ means new medicines will always appear much less cost-effective and therefore be discriminated against in the ranking against other medicines.
New Zealand Aids Foundation	<ul style="list-style-type: none"> • Decisions on listing new therapies largely remain slow and cumbersome. • PHARMAC appears to prioritise fiscal considerations ahead of clinical need when listing new pharmaceuticals. Not listing new pharmaceuticals will create a disincentive for applying to have a product listed on the schedule. • PHARMAC’s economic analysis only includes costs and benefits within the health sector and does not take into account wider costs and benefits to society • There needs to be a formal process for PHARMAC to be held publicly accountable for the consequences of its decisions. • A formalised appeals process would allow the real impact of PHARMAC decisions to be heard and would contribute to better health outcomes. • NZAF does not support the more restrictive framework of the

	<p>PHARMAC model being extended to hospital provision of antiretroviral therapy. Bringing hospital funding into PHARMAC's realm has the potential to reduce the clinical discretion specialists are able to exercise when using best practice guidelines.</p> <ul style="list-style-type: none"> • There are not strong financial motivations for companies to bring their medicines to NZ. In this context it is important to provide an incentive for pharmaceutical companies to come here. This should be made an explicit consideration in the decision criteria outlined in the OPPs. • The only strategies set out in the OPPs are fiscal. Given that PHARMAC is charged to balance the best health outcomes against budgetary considerations, both sides of the equation should have strategies in place to ensure they are achieved. • There needs to be a process to ensure and prove that objectives are being realised. • There should be some clarification around the accountability of PHARMAC when a surplus is returned. • There should be a formalised process for determining how and when PHARMAC engages in consultation and what happens to public input. Consultation guidelines should include clear provision for PHARMAC to report back to submitters about how the information received in submissions has shaped policy decisions. • There is no process by which affected groups can dispute, challenge or appeal a decision that PHARMAC makes in relation to funding or listing of pharmaceuticals. • Transparent processes for ensuring stated policy and procedure is applied in reality appear to be lacking.
Other groups	
Dr John O'Donnell Canterbury Health Laboratories	<ul style="list-style-type: none"> • In making decisions about funding for pharmaceuticals PHARMAC should make reference to five criteria: <ul style="list-style-type: none"> ○ To what degree is the intervention based on a sound understanding of disease pathophysiology? ○ Is it possible to measure short term benefits from the intervention? ○ Is it possible to measure long term benefits from the intervention? ○ What is the nature and incidence of adverse effects from the intervention? ○ Affordability.
Te Runanga O	<ul style="list-style-type: none"> • The trust has the following questions in relation to clause 1.6:

Kirikiriroa Trust	<ul style="list-style-type: none">○ What other documents (other than the Treaty) do you recognise? Why?○ What relevance do the principles of the Treaty have<ul style="list-style-type: none">▪ on your business ethos;▪ on your practices; and▪ how do you recognise each of the principles?○ What relationship, if any, do you have with Maori? In what way? And for what reason?○ If Maori is a race, how can you rationalize clause 1.6.3(a) and (b) (bearing in mind the special relationship between the Crown and Maori)?
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