SUMMARY OF SUBMISSIONS

This *Summary of Submissions* document provides a summary of the submissions we received. The views that stakeholders expressed in their submissions are described in general terms. For the purposes of this document, PHARMAC staff paraphrased and shortened respondent's comments. It is important to note that this summary is not intended as a replacement for the individual submissions themselves, all of which stand in their own right. All submissions were individually provided to and considered by the PHARMAC Board, as part of the decision making process.

Preparing submissions often takes considerable time and effort and we were grateful that stakeholders took time to provide their views on this important topic. In total, we received nine responses during the three month consultation period. Submissions were made by:

- A member of the public
- Access to Medicines Coalition (ATM)
- Researched Medicines Industry (RMI)
- Pharmaceutical Society
- New Zealand Medical Association (NZMA)
- Janssen-Cilag
- Another pharmaceutical supplier
- Lakes DHB
- Hauora Taranaki PHO

In addition, one submitter drew our attention to a related document that was released after the closing date for submissions as a consultation response to the draft Medicines Strategy. While we did not treat that document as a formal submission, we proactively sought a copy and summarised a portion of it as related to high cost medicines issues and wider PHARMAC-related issues for the Board to consider along with the formal submissions.

We have analysed the stakeholder submissions and present a summary of the information contained in these under the following five categories:

- Considering the topic of decisions about funding high-cost medicines
- Review process
- PHARMAC's framing of the review questions
- Expert reports on PHARMAC's decision-making processes
- Decisions about funding high-cost medicines

Considering the topic of decisions about funding high-cost medicines

Some submitters commented that they thought that it was important to consider the topic of high-cost medicines funding decisions. It also was noted that high-cost medicines funding is an issue of international interest and contention.

Some submitters commented on the complex and challenging nature of funding decisions about high-cost medicines. The view was expressed that the issues raised by these decisions engender strong feelings and that people will often not like the outcomes.

Some submitters considered it inappropriate that PHARMAC was undertaking the high cost medicines review. Reasons for this included that submitters considered PHARMAC's role as an operational agency was simply to undertake resource allocation decisions, and that the strategic direction for funding high-cost medicines should be set by government policy (led by the Ministry of Health). In addition, some submitters commented that the broader policy should be set in the

context of the development of the Medicines Strategy. These submitters advised that they would feed their submissions into the Ministry of Health's medicines strategy process in addition to responding to PHARMAC's consultation process.

Review process

One submitter commented that the timing of PHARMAC's announcement of the review was planned to ameliorate public criticism of some funding decisions. This submitter also considered that PHARMAC's inclusion of its preliminary view on decisions about funding high-cost medicines, which were included in consultation material, called into question the authenticity of the consultation. In addition, this submitter noted the length of the review process.

PHARMAC's framing of the review questions

Some submitters expressed the view that the review questions did not correctly frame the issues. One submitter considered the focus on the characteristic (high cost) of the medicine within the tools and techniques for rationing decisions was inappropriate. This submitter commented that the issue should have been considered from a more strategic perspective, including by considering the characteristics and needs of populations affected by diseases that are treated by high-cost medicines; the application of the objectives of the Health and Disability Act to this population group; and the objectives of DHB's and PHARMAC's role in assisting DHBs to achieve these. In addition, this submitter suggested that international initiatives to support the development and registration of, and access to, high-cost medicines should be considered alongside advice from patient organisations on how governments should respond to rare diseases.

Another submitter expressed the view that the review questions assumed PHARMAC's systems for funding other medicines were effective and equipped to introduce modern and innovative new medicines. This submitter suggested that a more appropriate question to ask is whether New Zealand needs a different approach to funding all medicines. This submitter also considered that a discussion of budget-setting is essential when considering whether the New Zealand system is robust enough to accommodate high-cost medicines, and noted that PHARMAC had not sought views on this topic.

A further submitter suggested that the first consultation question was an over-simplification of the issues involved in funding high-cost medicines. This submitter suggested that an independent review should be undertaken to determine how decisions have been made in the past and how they should be made in the future.

Expert reports on PHARMAC's decision-making processes

Some submitters commented positively on the reports that PHARMAC had commissioned and provided to inform consultation responses. These submitters considered that the reports were thought-provoking, and included valuable opinion and debate on the economic issues relevant to the prioritisation of medicines and health interventions in general.

Decisions about funding high-cost medicines

Submitters responded to the consultation questions with a range of views on how, and on what basis, PHARMAC should make decisions about funding high-cost medicines. In addition to commenting on whether high-cost medicines require a different approach compared to other medicines, submitters suggested improvements for the decision-making process, and identified the criteria they thought should be considered in funding decisions. Submitters' views on these topics are summarised in this section.

Do high-cost medicines require a different approach?

Submitters provided a range of views on whether a different approach is required for making decisions about funding high-cost medicines, compared with decisions about other medicines.

Some submitters agreed with PHARMAC's preliminary conclusion that the same framework should be used for all medicine funding decisions – regardless of whether the medicines are high-cost or not.

One submitter expressed the view that while decisions about high-cost and other medicines should ideally be made in the same way, they are currently not. This submitter considered that lobbying pressure and media attention appears to have changed the consideration given to some medicines. This submitter also commented that all medicines do not appear to be treated the same, as there is a group of medicines about which decisions are never made.

Other submitters did not support PHARMAC's preliminary conclusion that the same funding approach should be used for all medicines. One submitter considered that instead, equal priority should be given to cases of equal seriousness.

The view was also expressed that PHARMAC's processes were not adequate for any pharmaceutical funding decisions, whether for high-cost medicines or not.

One submitter commented that cost-effectiveness does not currently guarantee funding. The view was expressed that medicines that pose a higher net cost to the Pharmaceutical Schedule struggle to achieve funding, and those medicines that have relatively high costs per patient or costs per quality-adjusted years of life (QALYs) are even more unlikely to achieve funding.

All submitters, regardless of their view of the appropriateness of a single process for all medicine funding decisions, suggested improvements for PHARMAC's decision-making processes. These are detailed in the following section.

Suggestions for PHARMAC's decision-making processes

Some submitters identified process improvements that they considered PHARMAC should make to its budget-setting and decision-making processes. Not all of the suggestions proposed by submitters were directly related to high-cost medicines. However all views are reflected in the following summary for completeness.

Some improvements suggested by submitters had been included in the expert reports that PHARMAC commissioned and made available to submitters. Some submitters expressed the view that PHARMAC appears to have ignored the suggestions contained in these reports.

<u>The pharmaceutical budget</u>

It was recognised that PHARMAC's role is to fund within a budget, and that funding is not unlimited.

One submitter suggested that PHARMAC lobby the Government for an increased allocation from Vote:Health to fund new medicines. The view was expressed that PHARMAC's current policy of funding new medicines out of existing savings is self-limiting. This submitter further suggested that additional funding could be used to fund new expensive medicines.

Another submitter commented that budget-setting should involve a methodology that establishes the optimal level of investment in pharmaceuticals. This submitter considered that the budget should be based on factors including cost-effectiveness (which should take into account the benefits that accrue across the health system), meeting patient needs and health priorities, equity and social objectives and affordability to the tax-payer.

A further submitter commented on a problem with a specific aspect of New Zealand's tax regime and suggested that the resolution of this could result in more money being available for pharmaceutical funding.

Transparency

Some submitters commented on the need for PHARMAC's decision-making processes to be open, explicit, and transparent. Some submitters considered that the weighting of individual criteria in decision-making should be more transparent; in particular PHARMAC should be explicit about its list of priorities; the budget-setting process should be explicit, and that fuller information should be made available on all funding decisions.

It was also suggested that PHARMAC should be clear when it has made a decision about an application, and decline those applications it does not intend to fund. Greater clarity about who makes decisions and how independent advice is integrated was also requested.

It was suggested that transparency about PHARMAC's investment priorities and what will not be funded would provide greater certainty, and inform people about the trade-offs PHARMAC has to make. The view was expressed that this would also assist suppliers' to develop their commercial strategies.

Consultation on decisions

Some submitters considered that PHARMAC needed to improve its consultation processes to ensure the views of a wide range of stakeholders are involved in the decision-making process.

One submitter suggested specifically that PHARMAC distribute papers explaining reasoning behind the decisions when consulting on decisions. It was considered that this would benefit public understanding and debate as well as increasing transparency.

Appeals mechanism

Some submitters considered that an appeals mechanism should be introduced to enable challenge of decisions and ensure that people feel their perspectives have been heard. The view was expressed that an appeals Committee should directly inform the PHARMAC Board.

Consideration of criteria

Some submitters commented that PHARMAC's decisions need to be made according to explicit criteria. The view was also expressed that these criteria must be inclusive, reasonable, responsible, publicised, and open to scrutiny.

Some submitters supported the use of implicit judgments or non-technical methods to weigh criteria, in a context of explicit moral values. In contrast, another submitter commented that PHARMAC should consider using more formal methods for determining the relative importance of its decision criteria, rather than the intuitive approach that the submitter believes is currently used.

Some submitters supported the use of a four-step approach, as described in one of the expert reports, to make decisions. The view was expressed that this framework could be used to consider the cost/QALY of a medicine alongside its impact on health disparities. One submitter commented that they were considering such an approach for funding interventions in their DHB to allow a flow of budget between pharmaceutical and personal health services budgets. However, this submitter noted this approach would be very complex and potentially costly.

Some submitters considered that there needed to be a greater focus on ethical considerations and social values. The view was expressed that PHARMAC should publish an ethical framework and use this to supplement and clarify the current decision-making framework. One stakeholder suggested that PHARMAC should seek the assistance of an allocation committee, which would have the same status as PTAC but would advise on social values.

One submitter suggested that PHARMAC's approach to weighing criteria should prioritise the funding of medicines that would have a disproportionately greater benefit for populations that experience inequalities in health outcomes. The submitter commented that this approach is consistent with the DHB operating framework which requires efforts to address inequalities in health. This submitter also considered that a Rawlsian (described in the expert reports), rather than utilitarian approach would better support PHARMAC to weigh criteria in the manner they suggest.

One submitter identified a range of reforms that they considered were necessary to ensure that PHARMAC's processes could cater for all (not just high-cost) medicines funding decisions. The suggestions involved different groups considering different criteria in order to reach decisions on different aspects of an application. It was proposed that clinical decisions and therapeutic substitution decisions be separated from procurement decisions and that cost-effectiveness decisions be separated from funding decisions. This submitter also considered that an independent body should make decisions about the relative merit of medicines.

Decision criteria

The view was expressed that the current decision criteria are sound and appropriate for decisions about high-cost medicines. One submitter expressed support for what they considered to be a narrow view of benefit that focuses on health and not on other factors that deliver utility. Other submitters thought that PHARMAC should tighten its criteria and consult with stakeholders more fully about what the criteria should be.

Some submitters suggested a range of criteria that they thought should be considered in decision-making, including:

- numbers needed to treat and/or numbers not needed to treat
- impact of the treatment on life expectancy, morbidity and mortality
- the implications of funding a class of drug on other groups which will consider themselves disadvantaged
- implications of funding decisions on areas outside of health (for example, the effect on the patient's dependants), although submitter recognised that this approach could give rise to human rights issues
- clinical efficacy and effectiveness
- impact of funding on health disparities
- the cost per QALY of a medicine
- cost
- cost-effectiveness
- patient need
- health priorities
- funding priorities

- technical performance
- safety
- organisational implications
- social consequences
- legal considerations
- ethical considerations
- a specifically New Zealand set of values

A view was expressed that cost-effectiveness should not be the only consideration in funding decisions. In addition, one submitter was of the opinion that cost-effectiveness analysis favours pharmaceuticals that offer a small benefit for many, over those that offer a significant benefit for a few.

Quality of process

One submitter commented that PHARMAC needs to use a robust process, as well as explicit criteria that are publicly accessible, to ensure that its decisions are defensible. Another submitter considered that there should be an agreed set of standards for different aspects of the decision-making process. The view was also expressed that PHARMAC needs to be accountable for following its criteria when making decisions.

Speed of decision-making

One submitter expressed the view that delays in listing and restrictions on access are used to help reduce expenditure. The view was expressed that the effect of these delays is that timely and appropriate access to new medicines, especially high-cost medicines, is significantly compromised.

PHARMAC's role

One submitter commented that PHARMAC should embrace the debate generated by difficult decisions and not try to protect itself from the criticism that arises from these decisions.

Rebates

One submitter suggested that PHARMAC could assist generic suppliers by not using confidential rebates within three years of patent expiry and/or include provision in its contracts for disclosure of the net effective price by 30 June of the year in which the relevant contract expires.

SUBMISSIONS

Attached are copies of the individual submissions. Some material has been withheld in accordance with the Official Information Act 1982 (OIA) to protect the privacy of natural persons (section 9(2)(a)).

ATM

Access to Medicines NGO Coalition

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19 March 2007

High Cost Medicines Review
Pharmac
PO Box 10-254
Wellington

This is a response from the Access to Medicines Coalition to your consultation paper on high cost pharmaceuticals.

This is a very important area for public policy. There are many high cost medicines being developed and we are pleased that you have taken some steps to initiate discussion about it. However we cannot support your preliminary conclusion that high cost medicines should be treated no differently to other medicines, and the implied solution that such medicines are unlikely to be funded in New Zealand.

Our coalition's view is that it is not acceptable for Pharmac to decide whether to fund an essential medicine on the basis of an operational decision making framework. There needs to be significant input into such matters at a political and Ministry level to decide such things, including the ethical, budget setting and decision making matters that need to be factored in.

Our view is that your investigations of this matter have not been adequate.

We start by drawing your attention to one of the phrases in the NICE guidelines that were appended to your report. At Page 9 they say that "the results are very sensitive to the way questions are framed". This is a trap we think you have fallen very deeply into with your papers, and it is indicative of the significant, even fundamental, flaw in the reports and in the conclusions you draw from them.

By framing the question so narrowly you have missed many important things that should have been considered in a document that was intended by the Ministry and government to be a contribution to a medicines strategy for New Zealand. We emphasise the word strategy. Unfortunately you have focussed on just one part of the operational matters that should come into play only once the strategic framework

has been established and a number of key decisions taken at a higher level about vision, principles, objectives, action plans and budgets.

Your emphasis has been on the characteristic of the medicine (i.e. its high cost) and the mechanisms used for decision making about them. The narrowly defined questions have resulted in two expert reports that have in general failed to look beyond those same characteristics of the medicine, and consider them almost exclusively within the tools and techniques for rationing decisions (primarily the crude utilitarian tool of cost utility analysis).

There are nine review reports commenting on the two expert reports. Though some of them have noted points of concern about the likely consequences of an excessively CUA focussed approach, and have offered various other suggestions for improving decision making, none take a strategic look at the issues, and they all appear blindsided by the restricted framework set for them by the questions asked and the initial reports made.

Were the two main report writers even aware that the document was intended to be part of a strategy development process, as opposed to an operational review of Pharmac's own decision making processes? We doubt this considerably. Pharmac's briefing to the incoming Minister in 2005 shows that Pharmac had already initiated this work before the government was formed and a Medicine Strategy announced, and it was confirmed at a meeting with your former CEO and your Medical Director in August 2005, that the two main reports had been prepared many months earlier and were undergoing review.

Using reports prepared for analysis of CUA implementation and redirecting them into the medicines strategy discussion has been a serious mistake and leads to a most inadequate analysis. There are several important points this work should have covered if it was to take a truly strategic look at the issues, but has unfortunately failed to deal with. These include:

1. Relating the issue of high cost therapies to the diseases they are intended to treat and the characteristics of the populations affected by those diseases.

2. Considering the needs of those population groups within the context of the purposes of the NZ Health and Disability Act - in particular the objectives of improving health, providing best care, and reducing health disparities.

3. Assessing the issues in the context of the specific objectives of DHBs and your role as their agent in helping to achieve them - in particular, the objectives of improving and protecting the health of people, improving health outcomes, and reducing health outcome disparities of population groups.

4. Addressing the functions of DHBs and your role as their agent in helping them do health needs assessment of population groups (and in this context we clearly mean the medicine needs of the population), and the associated requirement to publicly consult on those plans.

These four points seem to us to be part of essential prerequisites to any chance that you could ever carry out your primary objective "to secure for eligible people in need of pharmaceuticals, the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided".

We are aware there would be some limitations on your ability to do this work in the first years they became your joint obligations with DHBs after the passing of the Act in 2000, but we read your discussion papers with despair at the lack of strategic content and lack of any declared intention for Pharmac and DHBs to carry out this important work that is mandated by the Act.

Additional work that we consider to be essential to a good quality discussion on the strategic implications of high cost therapies, is work that analyses the international situation and how other governments and agencies are responding to these issues. You have not addressed:

1. Guidance from the World Health Organisation on essential medicines and the implication for New Zealand's current medicine strategy development of their recommendations, and in particular issues such as cost sharing, total investment and equity. These items in the WHO guidelines are most relevant to the issue of subsidy for high cost medicines.

2. Policy initiatives currently in place or under discussion in Australia, Canada, USA, the European Union and other countries, designed to improve the pace of discovery and licensing of new medicines for orphan diseases, and develop mechanisms to protect patients against the catastrophic costs of those medicines.

3. Policy statements from patient organisations such as the International Genetic Alliance, giving advice on how governments should respond to the needs of rare diseases, including the public health implications, and how issues such as equity could influence a good comprehensive policy response from governments.

While there are a range of such initiatives in place, some are at early stages of development, and some of the high level guidance documents are quite broad in their scope. However, discussion on medicine strategy in New Zealand, and your contribution to it, is seriously deficient if such initiatives and trends are not analysed and discussed when the strategy is developed.

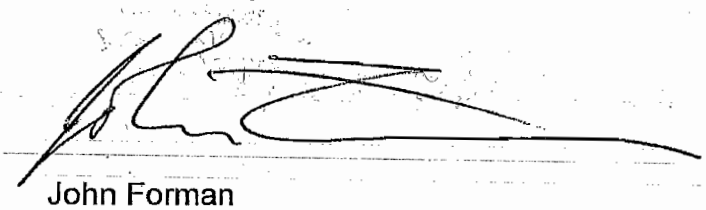
Responding to the specific questions you have posed in your document, and your preliminary conclusions reached, we comment:

1. The answers given by the reports you commissioned are of little value because the questions and the context were wrong.
2. Your preliminary conclusions are therefore wrong.
3. The expert reports should have given more weight to a specifically New Zealand set of values in considering the ethical arguments.
4. The correct conclusion in the ethical consideration is that equal priority should be given to cases of equal seriousness.
5. Pharmac should recognise the need for a paradigm shift in the approach to high cost medicines. The correct approach requires strategic policy decisions to be made about meeting the health needs of specific population groups, prior to operational decision making about resource allocation. Political input may also be required and should be expected in any circumstances that essential medicines are to be denied to any segment of the population.
6. Pharmac should seek guidance from the Ministry of Health and government, as well as from significant stakeholder groups, about the strategic approach that should be taken to high cost therapies (among many other important issues that should be determined in the Medicines Strategy development process).

ATM considers there has been a significant failure by Pharmac to produce a suitable contribution to this part of the Medicines Strategy development process, perhaps consistent with your history of focussing narrowly on operational budget management and rationing functions. We feel it is more appropriate to direct all further comment on your papers and all other medicines strategy matters, to the Ministry and to government.

There are significant issues relating to ethics, good health strategy development, compliance with the purposes and objectives of the Act, and proper public sector decision making and governance, including Pharmac's roles and responsibilities, that we will refer to the Ministry and government for appropriate decisions to be made. Our consultants' reports will be included with our submission to the Ministry consultation document.

Yours sincerely,



John Forman
Spokesperson, Access to Medicines Coalition

HAUORA Taranaki

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11 January 2007

Matthew Brougham
Acting General Manager
Pharmac
PO Box 10 254
Wellington

Dear Matthew

I submit the following comments in response to the request for suggestions concerning the funding of high cost pharmaceuticals. The issue Pharmac raises is of international interest and decisions not to fund new medicines will always be contentious and challenged. The recent Editorial in the Australian Prescriber December 2006 highlights the issue across the Tasman.

I am aware that Pharmac is required to operate within a budget which it does well and additional funding will only come from Central Government and is dependent on government policies at the time. Funding for health is not unlimited so the pharmaceutical budget has to compete for other sectors within Vote Health. There will also be a lot of emotion around the perceived need to supply new expensive drugs for specific patient groupings which may be small numerically but could benefit from new drug therapies.

New medicines used appropriately by general practitioners have been shown to reduce the number of hospital admissions and re-admissions. An Ischemic Heart Disease Pilot Project we undertook by the current GPs within the Hauora Taranaki PHO in 2002 demonstrated this. (references available on request). The One Heart Many Lives Programme currently promoted by Pharmac is comparable. The current policy of Pharmac to fund new medicines from existing savings is self limiting. Adequate provision should be made in budgeting forecasts to increase the allocation within Vote Health for medicines to accommodate the funding of new medicines outside of the current savings. This additional funding could be used to fund new expensive medicines. Pharmac needs to actively lobby government in this respect to at least maintain or increase their percentage of the Vote Health Budget.

The current decision criteria principles used by Pharmac within its Operating Policies are sound and should also be followed when considering applications for funding new expensive medicines.

I consider relevant issues to consider regarding applications for new medicines are;

1. Numbers Needed to Treat (NNT) or alternatively Numbers not Needed to Treat

2. Impact on life expectancy, morbidity and mortality.

3. Is the drug likely to effect a cure or will it just improve quality of life.
4. Social implications of funding one class of drug by other groups which will consider consider themselves now disadvantaged.

5. Number of lives affected by the decision e.g. treatment of a young parent with dependent children could be given priority under special circumstances. (I am aware that this does raise some political social and Human Rights issues).

6. If the medicine has been proven to be effective treatment should be commenced as soon as possible.

Yours sincerely

Brian Irvine
Clinical Facilitator
Hauora Taranaki PHO

8 March 2007

Matthew Brougham
High Cost Medicines Review
PHARMAC
P.O. Box 10-254
WELLINGTON

Dear Matthew

High Cost Medicines Review

I agree with the proposition put forward by PHARMAC – that high cost medicines should be treated no differently to other medicines. However, I wonder if this is actually PHARMAC's current practice. Based on the information that is publicly available, it appears to me that pharmaceutical funding applications fall into three categories following PTAC's assessment:

1. Those that are progressed to listing on their own merit (these are very few – perhaps half a dozen per year).
2. Those for which there is a strong lobby/media attention (which usually end up getting funded).
3. Those about which PHARMAC's Board may never make a decision or may take years to do so (the vast majority).

Given that most applications which fall into the second category are for high cost pharmaceuticals (that is, either a high cost per person or an overall large investment), one would have to be certain that the lobby pressure/media attention did not influence the outcome of the process in order to say with any certainty that PHARMAC currently subscribes to the proposition upon which it is now consulting.

Furthermore, if high cost medicines are to be treated no differently than other medicines, then ALL medicines must be treated the same. I would have thought that this would mean all pharmaceutical funding applications would be assessed against PHARMAC's Decision Criteria. However, the existence of category three suggests otherwise.

Therefore, from an external perspective, it appears that PHARMAC would need to amend its funding prioritization process in order to ensure that all medicines, including high cost medicines, are treated the same in terms of funding decisions. I believe that greater transparency around this aspect of the process would improve public acceptance of PHARMAC's budgetary position, and assist suppliers in determining commercial strategy.

I believe that PHARMAC should decline the applications it does not intend to fund, rank the rest according to their merits under its Decision Criteria, publicly declare the order of investment priorities, and implement the decisions (as it is able to) in that order.

A requirement to decline, within a specified timeframe, any applications for which PHARMAC does not consider there to be justification for funding would eliminate situations like we have with tramadol and Epipen (where the applications were submitted years ago and no funding decision has yet been made), and provide a much clearer picture of what may or may not be funded in this country.

Explicit ranking of the remaining possible investments according to their relative merits under PHARMAC's Decision Criteria, and public disclosure of this ranking (even without PHARMAC's assessment) would allow more informed public debate about the trade offs PHARMAC must make under a fixed notional budget.

Clearly, under the current budgetary structure, PHARMAC cannot invest in any new pharmaceuticals unless it can be sure that it will not exceed its budget by doing so. It must also be sure that it can afford to continue to fund that pharmaceutical into the future. This constraint might gain more acceptance if stakeholders were aware what the next investment might be, and what it would cost.

Furthermore, the uncertainty around the budgetary position appears to drive PHARMAC's business practices in a way which impacts significantly on suppliers. When PHARMAC is unconcerned about exceeding the budget, it appears to become less interested in what generic suppliers like ourselves can offer – namely low prices. Therefore, PHARMAC's budgetary position impacts on our business strategy. Greater transparency around PHARMAC's investment intentions and constraints would assist our planning and our ability to work with PHARMAC to achieve its goals.

Unrelated to the issue of prioritization, I have one further concern about PHARMAC's current practices with respect to its commercial dealings with branded products. PHARMAC frequently funds new investments under confidential rebate arrangements. While this is quite understandable, and of little concern to me in the early years of the products' patent lives, it can impact on the ability of generic suppliers to enter the market. There have been examples where PHARMAC has delayed investment in a new treatment until there are only a few years remaining until it has generic competition. In other cases, PHARMAC has extended existing confidential rebate provisions until beyond the patent expiry date. This puts generic suppliers at a considerable disadvantage when it comes to bidding for these markets in a tender or offering an alternative commercial proposal.

I consider that PHARMAC should refrain from using confidential rebates within three years of patent expiry and/or include provision in its contracts for disclosure of the net effective price by 30 June of the year in which the relevant contract expires.

Yours sincerely

MANAGING DIRECTOR

JANSSEN-CILAG

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16 March 2007

Matthew Brougham
Acting Chief Executive
Pharmaceutical Management Agency
PO Box 10-254
Wellington

By fax to (04) 460 4995

Dear Matthew,

Re: Consultation on High Cost Medicines Review

Thank you for the opportunity to comment on the High Cost Drugs Review documents. They provide an interesting and thought-provoking range of views on decision-making at PHARMAC.

We believe that the first question asked in the consultation (i.e. How should PHARMAC approach the trade-off between funding the treatment of very small numbers of patients with very expensive medicines (for very rare conditions) against the treatment of large numbers of patients with less expensive medicines (for more common conditions)?) is an oversimplification of the issues involved.

As many of the commentators pointed out, it is important to understand how complex decisions about whether to list a product for a certain purpose on the publicly funded Pharmaceutical Schedule are taken or should be taken. We do not believe that the current system is transparent enough to allow current decision-making to be adequately evaluated.

For this reason, we would support an independent review of how decisions have been made in the past as well as how they should be made in the future for or by PHARMAC. We believe that there are several problems with the way that decision-making occurs currently that require scrutiny. A few of the key deficiencies we have observed are as follows:

- A lack of transparency around how individual decisions by PHARMAC weigh existing Decision Making Criteria.
- A lack of clarity around who actually makes decisions and how independent advice is integrated.
- A lack of transparency about whether a decision has actually been made.
- The lack of integration of a wide range of stakeholders into decision-making.
- The poor quality of inputs into decision making at PHARMAC.

We will be addressing these points to the Medicines Strategy Review as we think it is important to have wider debate on such issues. To this end, the papers commissioned by PHARMAC have been useful in providing perspective and informing this debate. We would welcome the opportunity to discuss these issues further.

Yours sincerely

DAVID PASCOE
Marketing Director
Janssen Cilag

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1 March 2007

000227

High Cost Medicines Review
PHARMAC
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To Whom It May Concern:

This is Lakes District Health Board's response to the PHARMAC paper requesting input on how high cost medicines should be funded.

In parallel to responding to this document Lakes District Health Board is also responding to the Ministry of Health's consultation on the formation of a medicines policy. Lakes District Health Board recognises that to a great extent the matters under consideration in each of these consultation processes are relevant to both processes. The response provided here addresses some issues more fully than would be required if Lakes DHB was simply providing feedback on High Cost Medicines in isolation from thoughts around the overall strategy.

PHARMAC's questions are:

1. How should PHARMAC approach the trade-off between funding the treatment of very small numbers of patients with very expensive medicines (for very rare conditions) against the treatment of large numbers of patients with less expensive medicines (for more common conditions).
2. Do you agree with PHARMAC's preliminary conclusion that there are no persuasive arguments for treating the funding of "high cost medicines" differently to other medicines.

Addressing both questions together: Lakes District Health Board agrees with PHARMAC's assessment that there is no compelling argument to treat high cost medicines different from other medicines.

The consultation paper notes that PHARMAC is also open to receiving input about their wider operations. The papers provided by PHARMAC contained valuable opinion and debate about relevant ethical and economic issues relevant to the prioritisation of medicines, and health interventions in general. Lakes District Health Board intends to address such issues in its response to the Ministry of Health's proposed medicines policy and has carried out some internal consultation on our response.

This internal consultation has received input from a range of senior managers, clinicians and board committee members via discussion by our planning and funding team, Pharmaceutical Advisory Committee, Community and Public Health Advisory Committee and some members of the executive management team.

Lakes District Health Board believes that it is desirable for PHARMAC to determine and publish an ethical framework within which decisions will be made. Such a framework would be useful in augmenting and clarifying the current framework within which decisions are made. The new framework might be similar in nature to that published by the UK National Institute for Health and Clinical Excellence (NICE). Many aspects of any New Zealand framework will need to be different from the detail of the NICE framework. For example, we believe that a PHARMAC ethical framework will need to include the need for fiscal constraint, within the agreed budget. Also a New Zealand based framework needs to pay attention to the special relationship between Māori and the crown and needs to go some way in describing what "good-value" means e.g. by addressing Utilitarian versus Rawlsian balance.

We believe that it would be valuable for PHARMAC to publishing papers explaining the reasoning behind decisions (similar to the public summary documents produced by PBAC in Australia) and include those papers in consultation rounds. This would assist in informing sector and public debate and would add to the transparency of decision making.

Lakes District Health Board recommends that it is not reasonable to fund medicines solely for particular groups within society (e.g. Māori, pacific or the socio-economically deprived). However we believe it is valuable to prioritise the funding of medicines that will have a disproportionally greater effect on these populations higher than they would, all other things being equal. The reason that we believe this is that the framework within which District Health Boards operate requires us to address inequities in population health with a focus on these groups. This justifies an approach more Rawlsian than Utilitarian.

While we believe that weighting in favour of these groups is required we are supportive that decisions be made using non-technical methods, utilising QALY's as only one input into the decision. We believe that technical methods, such as that proposed in the Hansen review may be useful as an audit tool at this point but should not be used as the method by which decisions are made. Our opinion in this matter aligns with that expressed by Gillon, in his review, that implicit judgements be made while making explicit the moral values considered to be relevant.

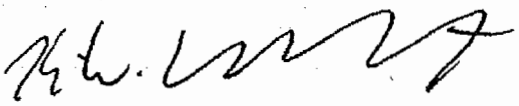
We support PHARMAC's approach in taking a narrow view on benefit, that focuses on health and not on other factors that deliver utility.

We believe that where a decision to fund a medicine is made due to government direction and where such a decision would not otherwise have been made, that funding additional to that which DHBs would ordinarily have received should be provided.

We believe that a four step approach, similar to that described in the Hansen review, would be of value. The projected effect of funding a medicine on increasing health inequity, where that medicine's overall benefit falls below a $/QALY hurdle, could be counted as a factor counting against its entry onto the pharmaceutical schedule. Where the medicine's benefit falls above the hurdle but health inequity is expected to be reduced by its funding then we believe that funding should be more likely.

Lakes District Health Board are cautiously interested in exploring processes by which other, non-pharmaceutical, interventions could be considered in such a four step process in order to allow for a flow of budget between pharmaceutical and personal health budgets. However this interest is tempered due to the likely complexity and cost of such an initiative.

Yours sincerely



Keith Wright.
Portfolio Manager - Referred Services
Lakes District Health Board

New Zealand Medical Association

000684

16 March 2007

Dilky Rasiah
High Cost Medicines Review
Pharmac
PO Box 10 – 254
Wellington

By email: highcostmedicines@pharmac.govt.nz

Dear Dilky

Review of Funding of High Cost Medicines

Thank you for providing us with the opportunity to comment on this matter.

NZMA has decided not to address the specifics of how these medicines should be funded as it is not our area of expertise. Instead, our comments are directed at a higher policy level.

Firstly, it is our view that the implications of funding high cost medicines are so significant that they are likely to have high policy and political repercussions. We would therefore expect to see the principles governing this issue to be set by government in a high level strategic document (for example, in the document "Towards a New Zealand Medicines Strategy"). We believe it is critical that the policy governing funding of high cost medicines is established by government which in turn then guides the funding agency as to how the money should be spent. In our view it is not for the funding agency to determine the policy. Given our concerns in regard to we will be annexing a copy of this submission to our submission on the consultation document "Towards a New Zealand Medicines Strategy".

Secondly, we believe it is important that whatever approach is ultimately decided upon in funding such medicines the process adopted is highly transparent with full reasons given for any decision made in regard to a particular drug.

Yours faithfully

Lucille Curtis
Policy Advisor

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PHARMACEUTICAL
SOCIETY
of New Zealand Incorporated

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19 March 2007

O1 02 04

High Cost Medicines Review
PHARMAC
P O Box 10-254
WELLINGTON

HOW SHOULD HIGH COST MEDICINES BE FUNDED?

The Pharmaceutical Society of New Zealand is the organisation that represents the professional interests of pharmacists in this country, and their role in the provision to the public of medicines and medicines management services that achieve the best use of those medicines.

The Society acknowledges the complex and ethically challenging nature of the decisions that have to be made around funding medicines that are of high cost and/or reserved for treating rare conditions affecting small numbers of people. As is advocated by the authors of the two full reports, and the nine reviewers' reports, all reproduced in the PHARMAC consultation document, PHARMAC must approach such decision-making using explicit criteria that are publicised and open to scrutiny, that are seen to be followed, that are inclusive, reasonable, responsive and for which PHARMAC is accountable. Judgements about which medicines to fund generally must not be made just on the basis of QUALYs or cost-utility analysis (ie, economics-based). Other values, judgements and ethical positions need to be included in final decision-making.

The Gillon and Hansen papers express these matters more logically and robustly than the Society can, and largely the papers' reviewers are in support of the conclusions reached - that as well as economic-based/cost criteria, other values-based decision-making must be included. The criteria must be specific and the decision-making processes open and transparent, and based on appropriate evidence and information. In addition, reasons for decisions must be publicly-accessible, and there must be provision for challenge and dispute resolution. The Society supports this approach. PHARMAC has to make these difficult decisions, which more often than not, people will not like. Providing the decisions have been made in a robust way, taking account of criteria about which people know, then PHARMAC should be able to defend its decisions and justify how it reached them.

The nature of the democracy in this country is such that PHARMAC must expect, and the public and interest groups have every right to voice, vigorous appeal against decisions they do not like. As stated, PHARMAC's role is to defend the decisions and embrace the debate, and not to seek to shut it down or protect itself from criticism.

The Society considers there is merit in Gillon's recommendation that PHARMAC's judgement should be made with the aid of an allocation committee, especially where contentiousness is anticipated. This should be a separate advisory committee, on a par with PTAC but in the domain of social values. This would allow the values of the public to be incorporated into the decision-making process. This, along with appeals mechanisms, would give people a sense of being heard, and being treated fairly, even when disappointed by a decision not to fund a high cost medicine (or any other medicine for that matter). Such an allocation committee should report directly to the PHARMAC board so that in making final decisions, the board is informed by PTAC on clinical effectiveness, by an allocation committee that looks at ethical matters and social judgements, and by cost utility and other economic considerations.

Provided decision criteria is specific, decision processes are transparent and evidence based, and there is opportunity for appeal; then the Pharmaceutical Society accepts that PHARMAC should treat the funding of high cost medicines within the same framework as all other medicines; strengthened (as recommended by Gillon) with the advice of an allocation committee.

Yours sincerely

Richard Townley
Chief Executive Officer
Pharmaceutical Society of New Zealand

Researched Medicines Industry

Researched Medicines Industry Association
Submission on PHARMAC High Cost Medicines Review

1. Preamble

1.1 The Researched Medicines Industry Association of New Zealand (RMI) is the professional and trade organisation of New Zealand's research-based pharmaceutical industry. Its 18 member companies are engaged in the research, development, manufacture and marketing of prescription medicines and the ongoing improvement of medical and scientific knowledge about their products.

2. Background

2.1 In November 2005 PHARMAC announced in the media that it had, in March 2005, sought the advice of two experts to review its decision making processes for high cost medicines[1]. The newspaper reported Wayne McNee, PHARMAC CEO, as saying that the review was initiated "because the Board was uncomfortable having to turn down treatments for small numbers of people who missed out because there was no easy alternative." McNee went on to say that "the economist had suggested other ways high cost drugs could be assessed and his advice was being peer reviewed".

2.2 It is our view that PHARMAC's announcement of this review in 2005, some eight months after it had been initiated, was deliberately timed to coincide with the announcement of the establishment of the Access to Medicines patient group coalition. As such it was designed to fend off the increasing level of public criticism during 2005 regarding the agency's failure to fund important medicines. PHARMAC could therefore say that it has engaged two independent experts to offer advice and that they were serious about addressing this issue.

2.3 Ultimately however it took PHARMAC nearly two years to complete this 'review' and appears to have essentially ignored the advice from the two experts who recommended, for example:

- That PHARMAC be more explicit about the value judgements it makes.
- That PHARMAC be more explicit and transparent about its overarching approach to deciding which pharmaceuticals to fund. A four step approach for such a declaration was proposed.

[1] "Pharmac reviews high-cost drugs" page 11 The Dominion Post 24th November 2005.

- That PHARMAC consider 'tightening up' how it expresses its decision criteria and consult more fully with stakeholders as to what the criteria should be.
- That PHARMAC consider using more formal methods for determining the relative importance of its decision criteria rather than the intuitive approach currently used.
- The possible establishment of a committee to provide advice based on an ethical framework.
- Specified appeal mechanisms

3. PHARMAC's consultation on high cost medicines undermines the credibility of the New Zealand Medicines Strategy that is in development.

3.1 At the end of 2005 the development of a New Zealand Medicines Strategy was announced as part of United Future's Supply and Confidence agreement with Labour. Most people, including Hon Peter Dunne[2], expected that the issue of high cost medicines would be a key part of the strategy development. Surprisingly however, policy development in this important area has been left to PHARMAC.

3.2 The Ministry of Health's consultation document "Towards a New Zealand Medicines Strategy" was released on 12th December 2006. The document offers little discussion on the issue of high cost medicines (1 page out of 99). It did not seek any comment about making decisions on high cost medicines and simply referred[3] submitters to the PHARMAC consultation process that was at that time yet to be released.

3.3 The avoidance of any discussion on high cost medicines in the New Zealand Strategy consultation document undermines its credibility as a comprehensive policy review that will lead to appropriate and sustainable medicines policies for the future.

3.4 It is also inappropriate and unhelpful that PHARMAC had already formed its view prior to finally releasing the consultation paper "How should high cost medicines be funded?" on 18th December 2006 and stated its conclusion in the consultation documentation.

3.5 Prior experience has given the industry and other stakeholders little confidence in PHARMAC's ability or willingness to undertake meaningful consultation. For example, PHARMAC undertook consultation in 2005 on the third edition of its Operating Policy and Procedures document which sets out how PHARMAC carries out its role. The process started in April 2005 with a statement from PHARMAC that it "does not propose to make many changes..." but due to the level of response from

[2] Electorate brochure No 1 2006; Speech to the NZ Future Medicines Policy Summit, 29 May 2006; Speech to Self Medication Industry AGM, 27 February 2007

[3] "The Ministry of Health encourages you to read Pharmac's consultation paper and provide your thoughts on this complicated issue to Pharmac. The Ministry looks forward to Pharmac's consultation paper and Pharmac's report on the feedback it receives." New Zealand Medicines Strategy consultation document Page 57

all stakeholders, including District Health Boards, seeking a range of improvements to the system the 'consultation' continued through to the end of the year. Despite the active and constructive participation of many people and organizations, PHARMAC finally announced on 21st December 2005, that it would only make some minor changes in addition to the few amendments it had originally proposed. None of the substantive issues raised during the consultation process were acted on.

3.6 Given this typical experience with PHARMAC consultations, and the fact that PHARMAC has already formed and conveyed its views on this matter, raises questions about whether this is indeed genuine consultation and whether it meets with the elements of legal consultation as determined by the Court of Appeal[4] and Ministry of Health guidelines[5] that state that the party obliged to consult must keep an open mind.

3.7 Such issues impact negatively on stakeholder and public participation and confidence in the process. That the Ministry of Health relies entirely on PHARMAC's analysis and advice on this issue, further undermines the Strategy development process and the final outcome of this important policy review.

4. The wrong consultation question has been asked.

4.1 In his covering letter on the 18th December Matthew Brougham, PHARMAC Acting Chief Executive, invited submissions on the question of how should high cost medicines be funded and this question specifically to "Do 'high cost' medicines require a different approach to considering funding than other medicines?" The letter goes on to advise that PHARMAC has reached the conclusion that there are no persuasive arguments for treating the funding of high cost medicines differently from other medicines.

4.2 The view that high cost medicines should be treated the same way as other medicines is certainly arguable. All medicines should be scrutinized to ensure safety, quality and efficacy and the relative cost effectiveness of all medicines being considered for public funding need to be thoroughly evaluated. Furthermore, considerations of patient need, health priorities and funding priorities should apply to all medicines irrespective of whether they are low cost therapies or high cost therapies.

4.3 There is however a critical flaw in this argument when considered in the New Zealand context: it assumes that the systems that are in place for the funding of 'other' medicines are not only working well but are sufficiently robust to deal with the introduction of modern and innovative new therapies.

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[4] Wellington International Airport v Air New Zealand (1993) 1 NZLR 671,675.

[5] Consultation Guidelines for the Ministry of Health and District Health Boards relating to the provision of health and disability services, August 2002.

4.4 Clearly this is not the case in New Zealand. Investment in pharmaceuticals has been severely constrained over the last decade with expenditure growth held to less than 2% per annum on average. PHARMAC's ability to fund new medicines of any description is therefore greatly curtailed and we have seen an ever widening gap between the products that achieve funding in other developed counties and what is ultimately funded here.

4.5 The issue is therefore not about whether a different approach is required for high cost medicines but whether the current medicines funding system is working for medicines in general. Rather than question whether a different approach is required for high cost medicines the question must be "do we need a different approach to the funding of all medicines?" The answer to this question is a resounding "yes" and until we achieve good systems for the funding of medicines generally, we cannot have any confidence that PHARMAC has the ability to deal with high cost medicines.

5. Necessary reforms

5.1 In our view the key institutional problems with the current system of funding medicines are:

- The bundling of clinical assessment and procurement decisions—This is likely to create incentives to subordinate clinical judgement to budget imperative, and to understate the degree of rationing by claiming that unfunded medicines are not effective or cost-effective
- The bundling of decisions about therapeutic substitution and procurement—New Zealand appears to have adopted the most radical definition of therapeutic substitutability of any OECD country. As a result, the choice available to New Zealand consumers is severely restricted
- Poor quality of process—Existing decision-making processes have little credibility because they are non-transparent. More attention needs to be paid to openness, fairness, and high standards of consultation and review.

5.2 These weaknesses indicate that the public and the Government have little basis for confidence in the quality of decisions and outcomes. We have compared the existing institutional arrangements for access to pharmaceuticals in New Zealand with the international best practice, and with the practice in other areas of public policy in New Zealand. This comparison showed that the structures and processes involved in making the key decisions about the reimbursement of pharmaceuticals do not live up to the standards we expect of New Zealand government institutions.

5.3 To move from current practices to an improved model, we recommend:

- Separation of cost effectiveness decisions from funding decisions
- Separation of medical and scientific decisions from funding and procurement decisions
- Creation of reliable metrics and reporting requirements

– Improved decision-making processes.

5.4 Most importantly, funding decisions and rationing decisions need to be made openly, transparently and explicitly. Decisions as to the relative merit, including cost effectiveness, of medicines for which funding is sought must be made by an independent expert body so that an objective evaluation of the medicine, and what it can offer, is made. This independent body would also review and rank the medicines in terms of patient need, health priorities and funding priorities and determine the appropriate level of population access and any access restrictions.

5.5 The analysis of cost-effectiveness should essentially involve a process that is known internationally as "Health Technology Assessment" (HTA). This has been defined as:

> *A multidisciplinary activity that systematically examines the technical performance, safety, clinical efficacy and effectiveness, cost, cost-effectiveness, organisational implications, social consequences, and legal and ethical considerations of the application of a health technology.*[6]

HTA must be carried out as objectively as possible and should adequately cover all the issues in the definition above.

5.6 In summary, key recommendations for an improved decision-making model include an agreed set of standards for conducting assessments and ranking pharmaceuticals, peer-review, transparency of process, stakeholder involvement and a process for the review of decisions.

6. Pharmaceutical funding: investing in health

6.1 Because New Zealand's community pharmaceutical expenditure is capped, the fact that a medicine, high cost or otherwise, is evaluated as cost effective does not necessarily mean that it will be funded. As previously noted, growth in expenditure has been held to less than 2% per annum on average and after natural growth in the system (volume and mix) is accounted for, little is available for new investments. In the six years to May 2006 Australia subsidised 78 new innovative medicines. While 72 of the 78 were registered by Medsafe, only 20 of the 78 were subsidised in New Zealand[7].

6.2 While the industry accepts that rationing is inevitable, constraining expenditure to this degree means that the budget is simply unable to accommodate many cost effective medicines. Medicines that are higher in cost, in terms of net cost to the Schedule,

[6] EUR-ASSESS, Report from the EUR-ASSESS Project. Int J Technol Assess Health Care 1997;13(2):

[7] Access by patients in NZ to innovative new prescription-only medicines; how have they been faring in recent times in relation to their trans-Tasman counterparts. - Report by Michael Wonder, Senior Health Economist, Novartis Australia June 2006.

struggle to achieve funding and those that have a relatively high cost per patient or per QALY are even more unlikely to achieve funding.

6.3 Delays in listing[8] and restrictions on access are also used to help reduce expenditure. Timely and appropriate access to new medicines, and particularly higher cost medicines, is therefore significantly compromised.

6.4 The question of whether New Zealand's pharmaceutical management system is sufficiently robust to accommodate high cost medicines must therefore involve some discussion regarding the setting of the pharmaceutical budget. PHARMAC have not asked submitters for their views in this regard and the Ministry of Health's consultation on the Medicine Strategy simply proposes improved dialogue between PHARMAC and DHBs.

6.5 It is our view that budget setting should be transparent and involve a methodology that establishes the optimal level of investment in pharmaceuticals based on:

- cost- effectiveness (including benefits accrued across the health system)
- meeting patient needs and health priorities
- equity and social objectives
- affordability (to the taxpayer)

7. Conclusion

Sandra Coney, PHARMAC Consumer Advisory Committee Chairman, states, in commentary on the expert papers commissioned by PHARMAC, that "There is a strong case for making high-cost medicines more available." Unfortunately this will not occur without improved funding, supported by the institutional reforms we have proposed.

PHARMAC's "do nothing" conclusion is not a valid response and is clearly not an action supported by the two lead reports commissioned by PHARMAC and the nine peer reviews, all of which made various recommendations for improvement.

19 March 2007

[8] Medicines funded in New Zealand take on average 14 months longer to be listed on the Schedule compared to Australia.

The submission below has been transcribed from the handwritten original.

Pharmac
PO Box 10-254
Wellington

Dear Sir

I am aware that you have invited comment from the public on "How should high cost medicines be funded?"

Before GST insurers charged premiums at a level sufficient to pay claims comfortably.

After GST much the same situation applied with the difference being that premiums and [illegible] claims were both increased to take care of the GST content.

There was no reason to offer any further assistance to insurers such as under Section 20(3)(d) of the GST Act 1985

But amazingly section 20(3)(d) appears in the Act no doubt through the advocacy of insurers who took some part in 'helping" to ensure that a [illegible] result was achieved and in the process helped themselves to a refund to themselves from the Govt of all the GST content of all claims paid by insurers!

If section 20(3)(d) refunds had not been made during the 20 years since GST started on 1.10.86 Govt would have been better off by an estimated $3 to 4 billion dollars and would have been able to afford more money for medicine and other things and the profits of insurers and the dividends to their shareholders most of whom are domiciled overseas would have been less.

I have protested to Govt about the [illegible] of section 20(3)(d) and their response if any has been to infer that the section 20(3)(d) refunds are ok because they are in terms of the GST Act. Nicky Hager would perhaps be interested in this scandalous situation.

I enclose a photo copy of a letter dated 1.7.03 from IRD, Wanganui

Notes to be attached to the photocopy of a letter dated 1st July 2003 sent to me by the Inland Revenue Dept Wanganui.

The heading of the GST Act 1987 is "An Act to provide for the imposition and collection of Goods and Services Tax".

Presumably this means that all the GST imposed should be collected by Govt with no deductions.

Section 20(3)(d) of the Act is estimated to have resulted in refunds of GST to insurers since 1.10.87 of 3 to 4 billion dollars and it is considered that greater authorisation for this was required than its mention in a clause dealing with the calculation of the amount of the tax payable and that therefore section 20(3)(d) refunds to insurers are not legal.

Section 20(3)(d) as it appears in the Act seems to be calculated to confuse rather than to inform.

I think it likely that when the GST Bill was before the house there would have been much discussion upon whether or not the GST content of claims paid should be refunded to insurers. If common sense had prevailed the answer would have been that there should have been no refund. In other words the word "that" should have finished up in between the words "shall" and "the".

Perhaps the Act in its present form is a printers error which has benefited insurers and cost NZ taxpayers by 3 to 4 billion dollars so far. This should not be allowed to continue.

The first 4 paragraphs of my letter to Pharmac should be read again.

Yours faithfully

[ ]

Inland Revenue
Te Tari Taake

1 July 2003

Dear

IRD NUMBER:
OUR REF:

Thank you for your letter dated 26 May 2003. I apologise for the delay in replying.

A registered insurer may claim deductions for payments to policy holders when they are made (a tax invoice is not needed). This is confirmed by the Goods and Services Tax Act 1985, Section 20(3)(d) which reads as follows:

"……in calculating the amount of tax payable in respect of each taxable period, there shall be deducted from the amount of output tax of a registered person attributable to the taxable period-…… (d)An amount equal to the tax fraction of any payment made during the taxable period by that registered person to another person pursuant to any contact of insurance……".

The exception to this is life insurance which is exempt from Goods and Services Tax.

Please do not hesitate to contact the Department if you have any further queries regarding this matter.

Yours faithfully