



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

equitable and affordable Access To Medicines for all

Members: ADDvocate, Alzheimers New Zealand, Arthritis New Zealand, Asthma New Zealand, Balance, Breast Cancer Aotearoa Coalition, Cancer Society, Carers New Zealand, Continence Association, Cystic Fibrosis New Zealand, Diabetes New Zealand, Diabetes Youth, Epilepsy New Zealand, IDFNZ, Kidney Kids, LAM Trust, Leukaemia and Blood Foundation, Lysosomal Diseases New Zealand, Multiple Sclerosis Society of New Zealand, Myeloma Matters, New Zealand AIDS Foundation, New Zealand Organisation for Rare Disorders, Parkinsons New Zealand, Prader-Willi Syndrome, Prostate Cancer Foundation, Schizophrenia New Zealand.

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