

ATM Submission to the MOH on
Medicines Strategy Consultation Document

SUBMISSION ON

MOH CONSULTATION DOCUMENT:

TOWARDS A NEW ZEALAND
MEDICINES STRATEGY

Access to Medicines Coalition

April 2007

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FOREWORD

**To the Ministry of Health
The Minister of Health
The Associate Minister of Health**

It is vital that you appreciate how importantly this consultation is regarded by patients and support groups who advocate on their behalf. After many, many years of frustration and battling with ill health that could have been alleviated with an improved level of medicine access, or when dealing with the burden of paying personally for unsubsidised medicines, it is a great relief to know that the government has this formal consultation on the development of a National Medicines Strategy for New Zealand.

This is a unique opportunity, drawing attention to the needs of those whose access to essential medicines has been denied or restricted, and we (the ATM collation) trust that Ministers and the Ministry of Health fully understand the weight of feeling that is expressed in this document on behalf of those individuals whose hopes are riding on this process.

We believe the current system is fundamentally flawed. Although we understand there are limits to what can be provided in our health system and that priorities need to be set, we believe the current system does not adequately address the needs of New Zealand or New Zealanders.

The lack of funding for potentially life-saving medicines is an example that everyone is familiar with. Many patient groups have been very distressed by the fact that budget management has been almost the sole criteria guiding these decisions to date.

Another example is in the inequities in subsidies. People who currently have their medicines subsidised have had co-payments reduced to \$3 per item if they are in certain Primary Health Organisations and this will soon be extended to all patients in all PHOs. This investment of many millions of dollars seems very unfair to those large numbers of New Zealanders who still need to pay full cost themselves for their essential medicines. It is particularly unfair to those even larger numbers of people who can neither afford to pay nor get a subsidy on needed medications.

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This has certainly not helped reduce the health disparities for those we represent, and makes them part of a very vulnerable group in our society.

These are just two examples of many issues we hope will be addressed by setting a clear strategy for improved access to medicines for all New Zealanders.

It is important to note that we are concerned that investment in medicines might remain a heavily restricted item and that anxiety is high that this consultation process will not result in the changes that are needed. However, we hope that is not the case and this consultation will result in very close attention to the many problems that currently exist with access to medicines, so that a National Medicines Strategy can be developed to ensure better access to medicines for all New Zealanders.

Yours sincerely

The Access to Medicines Coalition

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1.0 Executive Summary

This submission represents the consensus view of the members of the ATM which consists of 26 organisations that collectively advocate for many tens of thousands of people in New Zealand affected by many diseases or conditions. The document was jointly written by a group of experts and consumer representatives.

Collective support exists for the development of an overarching National Medicines Strategy to achieve the following primary objective:

“Equal access to medicines for all people”

The MOH Consultation Document provides a good description of the sector structures and roles with regard to access to medicines. We acknowledge the existing structures and the need to build on the processes that work well, but there are also problems in structures and processes that need improvement.

We believe significant change to organisational structures, processes and resource levels will be needed to achieve our primary objective. We firmly believe that “fine tuning” the current system will result in continued failure to ensure access to medicines for those who need them.

To ensure equity in access to medicines we want to see our overarching goal of equal access for all to be backed up by the principle that:

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“Priority to be given to the most serious conditions and urgent cases”

To support the MOH develop a robust Medicines Strategy we have developed this submission based on the WHO guidelines on how to develop a National Medicines Policy. Our submission focuses on the following key areas:

1. Analysing the key problems with the current system:
 - Population health issues.
 - PHARMAC’s roles and how they are in conflict.
 - Strategic “fit” or alignment with the health sector as a whole and social and economic policy.
 - Case studies to provide examples that demonstrate how flawed the system is.

2. Exploring approaches on how best to make transparent and sound decisions on access to medicines:
 - Ethical frameworks for making decisions on access to medicines.
 - Legal frameworks within which the sector operates.
 - Consumer engagement.

3. Considering how best to set the total budget for pharmaceuticals.

4. Considering how to spend the pharmaceutical budget.

5. Considering how to decide access to high cost medicines and treatment for rare disorders.

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Our submission offers significant challenges to the status quo of medicines allocation in New Zealand:

- ATM offers a number of principles regarding access to medicines that we wish to see incorporated in the Medicines Strategy.
- We seek specific recognition of rights to health care contained in the International Covenant of Economic, Social and cultural Rights.
- We offer suggestions for restoring patient confidence in decision-making regarding medicines, by establishing greater transparency of decision-making, and we ask for a significant change of culture based on respectful partnerships with all stakeholders in the sector.
- We identify a number of ways in which the actions of DHBs and PHARMAC fail to comply with their statutory functions and objectives in developing and managing the pharmaceutical budget, as set out in the New Zealand Public Health and Disability Act.
- We argue for a tightening of the responsibilities, governance and oversight of DHBs and PHARMAC, in contrast to the relatively freer reign proposed by the Ministry's Consultation Document.

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- PHARMAC's approach to dealing with high-cost therapies is specifically challenged and we find that their analysis of this issue is inadequate and their conclusions wrong. They have failed to properly incorporate a specifically New Zealand set of values in their analysis of the ethical basis for dealing with this issue.

- ATM specifically addresses the conflict of roles that PHARMAC has, stressing the importance of this issue. These conflicts are contrary to proper public sector role separation and decision making, and set the scene for failure to comply with statutory functions. We identify how these conflicts lead to some failures to comply with certain statutory functions, and how some priorities become confused. We offer solutions to this through a clear separation of roles.

- We seek the establishment of an expert advisory group to work with the Ministry of Health to continue the development of the National Medicines Strategy for New Zealand.

We would welcome the opportunity to meet and discuss the issues raised in our submission with those involved in developing the strategy.

2.0 Recommendations

The ATM members collectively recommend that the MOH:

1. Develop a National Medicines Strategy with the following goals, objectives and values:
 - a) The overarching goal of ensuring

“Equal access to medicines for all people”

Backed up by the principle that

“Priority to be given to the most serious conditions and urgent cases”

- b) Underpinning values that provide demonstrable alignment with the ethical and social values of New Zealand, including a strong emphasis on fairness and the obligations set out in the Treaty of Waitangi, that require:
 - Rejecting PHARMAC’s proposal to treat all medicines the same in determining priority for funding, particularly medicines to treat rare disorders and high cost treatments.

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- Rejecting PHARMAC introducing a “cut off” point for access to high cost but effective medicines
- c) An objective to promote sustainable access to pharmaceuticals
- d) Continued use of a single purchaser to obtain the best price from pharmaceutical companies, for the wider benefit of patients and our health budgets but, importantly, within that objective:
 - Ensuring that negative consequences for our medical research structures are guarded against.
 - Ensuring that all the techniques used in price negotiation are analysed for possible negative consequences such as product withdrawal and supply problems, and these negative consequences specifically guarded against.
 - Ensuring close attention is paid to negative impacts on medicine use by patients and ensuring that systems are adjusted to avoid these negative consequences
- e) Includes broader principles of active and respectful partnerships between government, health officials, pharmaceutical industry and patient groups.

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2. Aligns the proposed National Medicines Strategy with broader government policy whereby it :
 - Actively promotes international collaborative research between the New Zealand health sector, our academic institutions and the pharmaceutical sector.
 - Implements regulatory processes that ensure domestic suppliers are treated fairly compared to those suppliers in Australia.
 - Reviews and modifies MEDSAFE's information requirements that are over and above those for other regulated markets (USA or Europe) and causing barriers to licensing that cannot be justified in terms of the additional costs or benefits, such as 12 months stability data at the time of dossier submission.
 - Proceeds with urgency to adopt the joint medicines regulation agency with Australia to avoid current delays with medicine registration and ensure improved medicines regulatory capacity for New Zealand.
3. Includes recognition of rights under the International Covenant of Economic, Social and Cultural Rights (ICESCR) to the highest attainable standard of health.
4. Follows a robust process to develop sound public policy that includes:

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- a) Public consultation early in the development of the Medicines Strategy to ensure meaningful participation of:
 - Maori
 - disadvantaged and high needs population groups
- b) Clear identification of the most significant problems in the current system with regard to access to medicines and development of objectives and strategies that will specifically address these problems.
- c) Undertaking a detailed situational analysis that includes defining roles and responsibilities, and sector structure to undertake all necessary steps in the processes to ensure agreed levels of access to medicines and that will enable the development of an effective accountability framework.
- d) Establishing an expert advisory group of key stakeholders to guide the policy development and implementation planning.
- e) Developing implementation plans to address inadequacies in providing access to medicines, and ensuring the plans are resource realistic, and provide appropriate incentives across the sector.
- f) Establishing meaningful accountability frameworks across the sector to ensure effective implementation of strategies to improve access to medicines.

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- g) Including in the National Medicines Strategy an objective of monitoring the implementation of the strategy and to measure an agreed set of desired outcomes put in place across the sector.
5. Considers how best to establish an appropriate national budget for medicines that takes into account and addresses the current conflict of roles held by PHARMAC and the current failure of the system to ensure that the people who could most benefit have access to available medicines.
6. Undertakes a review of the structures and decision making processes that are used to determine how best to allocate available resources to provide access to medicines in a manner that is consistent with the legal framework and commonly held values that underpin New Zealand society, that is transparent and builds consumer and professional confidence in the system. Important aspects of this review will be:
- Separating the conflicting roles of PHARMAC
 - Clarifying PHARMAC's role and statutory purpose
 - Tightening of PHARMAC governance and oversight
 - Building confidence in decision making processes
7. Request that the State Sector Development Branch of the State Services Commission undertake a review of the structures and processes currently in place to make decisions on access to medicines to address issues identified in this document including PHARMAC's conflicts of role and lack of alignment with statutory functions.

3.0 Background to Submission

3.1 Contributors

The ATM combines the voices of a large number of non-government organisations advocating for increased access to medicines in New Zealand. Members of the coalition are all disease-specific groups that provide support, information/education, health promotion or clinical services to their constituent groups.

Members of ATM

- [ADDvocate](#)
- [Alzheimers New Zealand](#)
- [Arthritis New Zealand](#)
- [Asthma New Zealand/The Lung Association](#)
- [Balance NZ – Bipolar and Depression Network](#)
- [Breast Cancer Aotearoa Coalition](#)
- [Cancer Society](#)
- [Carers New Zealand](#)
- [Continence Association](#)
- [Cystic Fibrosis Association New Zealand](#)
- [Diabetes New Zealand](#)
- [Diabetes Youth](#)
- [Epilepsy New Zealand](#)
- [IDFNZ - the Immune Deficiency Foundation](#)
- [Kidney Kids](#)
- [LAM trust](#)
- [Leukaemia and Blood Foundation of New Zealand](#)
- [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 Association](#)
- [Prostate Cancer Foundation](#)
- [Schizophrenia Fellowship New Zealand](#)

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Working Group

The ATM working group has overseen the development of this submission and is made up of the following members: John Forman (NZORD); Florence Leota (Schizophrenia Fellowship NZ); Sarah Perry (IDFNZ); Eamonn Smythe (NZ AIDS Foundation); Margaret Earle (Diabetes NZ); Roger Sowry (Arthritis NZ); Deirdre O'Sullivan (Parkinsons NZ); Secretary: Carolyn Macal tao (NZ AIDS Foundation).

Additional advice and input was received from Gerald Williams (Prader-Willi Syndrome Association); Pru Etcheverry (Leukaemia and Blood Foundation); Nola Rawson (Multiple Sclerosis Society of New Zealand); Alison Davies (Breast Cancer Aotearoa Coalition).

Expert Consultants

The ATM contracted expert advice from the following specialists to assist in developing this submission:

- Roger Palaret, Public Law specialist
- Maurice Ormsby, Ethicist and Public Policy Consultant
- Dr Lynne Lane, Public Health Physician

Roger and Maurice developed papers examining the ethical and legal issues that need to be considered in developing a National Medicines Strategy for New Zealand. Lynne considered the issues from a public health perspective and assisted in drafting the overall report.

They worked closely with the working group to develop papers that formed the draft submission that was confirmed by the working group. For further information on contributors please refer to the Appendix 3.

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Peer Review

Peer review has been sought on the draft submission from a number of sources and this feedback has been considered and incorporated. Expert peer review was sought, and input incorporated, from the following consultants

- Bruce Scoggins, previous CEO of the Health Research Council
- Jim Thornton, Ethicist

3.2 ATM Purpose

Our member NGOs aim to reduce the number of people affected by the conditions that the people we represent suffer from and/or to increase the health, wellbeing and quality of life of these individuals, their families and communities.

We believe the government of New Zealand has a responsibility to all New Zealanders to operate a pharmaceutical funding system that places health outcomes as its primary priority and recognises its role as fundamentally integrated with the overall health system.

Our Mission:

- To improve access to prescription medicines in New Zealand by increasing the efficiency of approval and distribution processes
- Ensure all New Zealanders have parity with regard to access to pharmaceutical treatments available in other OECD countries
- That health outcomes are maximised by efficient and coordinated use of all health sector services

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- Make sure that health practitioners are provided with adequate and appropriate resources and supported by an infrastructure that encourages best practice
 - Reduce the time and cost that has become inherent in listing new medications on the pharmaceutical schedule
 - Increase the number of new medicines listed on the pharmaceutical schedule so that there is parity with the numbers of medicines that other OECD countries make available to their populations
 - Develop a new focus on pharmaceuticals in New Zealand to include the consideration of new strategies. For example, adopting orphan drug* rules and creating a National Medicines Strategy for New Zealand.
- * *Special criteria for medicines for rare diseases where standard funding formulae are inappropriate.*

4.0 Support for Development of a National Medicines Strategy

The MOH has the ATM members' full support for the development of a Medicines Strategy. ATM brought the issue of a Medicines Strategy to public debate in 2005 and it was our lobbying of politicians prior to the election in that year that saw the development of a strategy included in the confidence and supply agreement that formed the government. We are pleased to contribute to its development.

We particularly, commend the objective proposed in the Consultation Document for the Medicines Strategy

“To support access to medicines that New Zealanders need regardless of an individual's ability to pay” (p vii)”

We offer a number of other principles about access among our recommendations.

Concern about the current level of access to medicines in New Zealand has been increasingly expressed by health professionals, the general public, patient groups, and the industry in the media and in published research articles.

There are limited data that systematically tracks access to medicines in New Zealand that enable accurate evaluation of how well the sector is achieving this goal. The published studies that provide information on access to medicines for some of the highest priority health problems indicate the sector is not performing well, as is discussed below.

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Information released by PHARMAC and the MOH stating how well the sector performs, with regard to access to medicines, is causing widespread confusion and mistrust of the bureaucracy and does not help to address the underlying problems.

Patient access to medicines is through a complex system of structures and processes. The detailed description of “who does what” in the MOH Consultation Document makes this point well. The available evidence confirms that there is a major systems failure, particularly for Maori, lower socioeconomic groups, and those groups of patients who need high cost treatments.

A careful systems analysis to determine why our health system is failing to provide an adequate level of access to medicines needs to be conducted. Such a task cannot be undertaken by the contributors to this submission with our limited resources. We do not believe that the MOH Consultation Document adequately identifies or addresses the underlying problems.

Significant change to organisational structures, processes and resource levels will be needed to achieve our collective goal. We firmly believe that “fine tuning” the current system will result in continued failure to ensure access to medicines for those who need them.

5.0 NATIONAL MEDICINES POLICY STRATEGIC DIRECTION

5.1 Proposed Aims of the National Medicines Strategy

The long term aims of the Medicines Strategy are set out in Appendix 2 (p79) of the Consultation Document. It states its aim is *“to ensure the best health and disability outcomes from medicines over the coming years.”*

The WHO medicines policy documents recommends a significantly different goal. The guidelines on how to develop and implement a national drug policy it states *“In its broadest sense a national drug policy should promote **equity and sustainability of the pharmaceutical sector.**”*

Equity

The universal logic of ethics requires us to treat equal cases equally, in accordance with our local values, whatever they may be. It is therefore recommended that the overarching objective be modified as follows:

“Equal access to medicines for all people”

Additional principles need to be included regarding access to ensure the principle is not too narrowly defined or interpreted. We offer:

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Equitable access

The strategy should state an aim of delivering access to medicines for New Zealanders that is comparable to similar OECD countries. Such an objective would give a suitable benchmark that is realistic as well as measurable.

Equitable access should also be stated as equitable between different groups of patients. This requires another key principle:

“Priority to be given to the most serious conditions and urgent cases”

Access regardless of ability to pay

The strategy should include the principle of universality that ensures patients are not disadvantaged by an inability to pay. To that end we strongly support the principle stated in the MOH Consultation Document “To support access to medicines that New Zealanders need regardless of an individual’s ability to pay”.

Sustainability of the Pharmaceutical Sector

For the strategy to succeed we believe it must also be consistent and align with the strategy direction of other sectors, such as the Ministry of Research Science and Technology and the Ministry of Economic Development. Again the discussion document refers to this requirement but does not provide any analysis or detail on how “strategic fit” will be achieved.

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Of particular interest to us, the Consultation Document includes proposals on:

- modifying how the Community Pharmaceuticals budget is set,
- increasing the transparency of PHARMAC's decision-making processes,
- waiting to see what PHARMAC's own analysis of decision-making about high-cost medicines produces.

We have made specific comment on these issues in regard to ethical and legal frameworks appropriate for New Zealand and from a practical perspective based on sector capacity.

5.2 Strategic Objectives of the National Medicines Strategy

We support the three objectives in the MOH Consultation Document and note they are entirely consistent with the WHO guidelines (WHO, 2000 and 2003).

1. Access to medicines
2. Quality of medicines
3. Rational use of medicines.

We are, however, concerned that the document states the strategy will focus on only three of the four "key planks" recommended in the WHO documents.

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The first objective recommended in the WHO documents, in addition to the three above, is to provide a policy framework that brings **all stakeholders** together to ensure a collective framework for action. The strategy should cover both the private and the public sector. The WHO specifically mentions the pharmaceutical industry and the need to ensure sustainable supply of medicines.

To achieve a good partnership with stakeholders will require a change of culture in PHARMAC and its Consumer Advisory Committee (CAC). Communications have been generally poor and competitive. The only formal communication ever received from the PHARMAC CAC was a discussion document that included the implication that support groups may be untrustworthy pawns of pharmaceutical companies. A significant change of attitude is required if there is any prospect of achieving active and respectful partnerships.

Australia

The WHO refers to the National Medicines Policy of Australia as an example of the first comprehensive national drug policy. The policy in Australia is based on ***active and respectful partnerships, taking into account elements of social and economic policy*** (Australian Government 2000).

The Australian policy also has a fourth specific objective that is missing in the Ministry's discussion document:

“Maintaining a responsible and viable medicines industry”

The MOH Consultation Document has taken a relatively narrow view of the system underpinning the pharmaceutical sector and how to improve access to medicines in comparison to the approach recommended by the WHO and adopted by Australia.

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It is therefore recommend that the MOH

- 1 Include in the National Medicines Strategy:
 - The objective of:
“Ensuring equal access to medicines for all people”
 - A key principle that:
“Priority must be given to the most serious conditions and urgent cases”
 - An objective to promote sustainable access to pharmaceuticals
 - Demonstrable alignment with social and economic policy
 - The broader principles of active and respectful partnerships

5.3 Alignment with Broader Government Policy

The WHO guidelines on developing National Medicines Strategy indicate the need to develop it within the strategic context of the sector as a whole. While the Consultation Document provides background information in this regard, there are a number of important challenges facing the New Zealand health sector that the Medicines Strategy goals and objectives will need to give due consideration to, and specifically address, as discussed earlier.

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Alignment with economic and social policy across other government sectors will also need to be demonstrated. The Consultation Document does not identify any specific issues arising from other sectors.

To follow is a brief analysis of some policies from outside the health sector that highlight examples of potential inconsistencies in policy objectives that the Government needs to address.

Proactively support international collaborative research on medicines

The Ministry of Research Science and Technology's (MORST) website sets out the Government's policy to support investment in science and research to promote the development of new products and services¹. MORST recognises the value to the economy of increasing investment, and international collaboration in this area generally. In the pharmaceutical sector international collaborations between the multinational pharmaceutical companies and academic institutions are becoming increasingly important for taking potential new products through clinical trials to commercialisation. The teaching hospitals are aware that their ability to retain senior clinicians is largely dependent on their ability to engage them in collaborative research.

The largely adversarial relationships between PHARMAC and the multinational pharmaceutical companies could put at risk their willingness to support collaborative research and development in New Zealand. This situation should be avoided at all cost.

¹ <http://morst.govt.nz/Documents/publications/policy/MoRST-Science-for-NZ.pdf>

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We recommend therefore that the National Medicines Strategy actively promotes international collaborative research between the New Zealand health sector, our academic institutions and the pharmaceutical sector.

Alignment of research and health policies

The Organisation for Economic Cooperation and Development (OECD) has published a report calling on governments to encourage pharmaceutical innovation by coordinating strategies for R&D and health policy.

It cites the example of the development of biopharmaceuticals, which are encouraged through R&D strategies but then face difficulties reaching the market as a result of health-care policies. Meanwhile, governments worldwide are increasingly introducing methods to assess the cost-effectiveness of drugs, in an attempt to reduce the strain on resource-stretched health systems (Royal Society newsletter May 2006).

Unfair advantage to suppliers in Australia

The Ministry of Economic Development set out key policy objectives on procurement of supplies. New Zealand's government procurement policy is non-discriminatory and based on the commercial principle of best value for money through competition, *including full and fair opportunity for domestic suppliers*². While the Ministry provides policy advice and has set some mandatory procedural rules, individual departments or agencies are responsible for their own purchasing decisions.

MEDSAFE approves medicines for import and distribution in New Zealand but does not provide a full and fair opportunity for domestic suppliers.

² http://www.med.govt.nz/templates/StandardSummary_____181.aspx

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The current “fast tracking” of evaluation for licensing product already licensed in Australia enables suppliers to achieve approval for New Zealand market in as little as a month. For suppliers wanting to distribute product only in New Zealand, MEDSAFE is unlikely to provide approval within 12 months. Given PHARMAC’s three year cycle of sole supply contracting, this situation can severely limit opportunities for dedicated New Zealand suppliers. We also note that the reciprocal arrangements for New Zealand suppliers to gain rapid approvals to import and distribute in New Zealand do not exist.

Reduce MEDSAFE’s regulatory barriers that delay access to medicines

Since August 2006, MEDSAFE requires suppliers to include a full 12 months stability data on three separate batches when submitting a medicine’s dossier for licensing. By comparison, regulators in the USA and Europe will accept dossiers containing an initial 3 or 6 months data and give provisional approval based on submission of the stability data for the balance of the required time as it becomes available. The requirements in New Zealand pose significant problems for multinational generics companies that are simultaneously preparing dossiers for multiple countries. Avoidable delays in licensing of lower cost medicines lead to PHARMAC paying higher costs for products than necessary. The National Medicines Strategy should therefore explicitly include strategies to remove barriers to gain regulatory approval to import and distribute medicines that cannot be readily justified.

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It is therefore recommend that the MOH:

2. Actively promotes through its Medicines policy, international collaborative research between the New Zealand health sector, our academic institutions and the pharmaceutical sector.
3. Implements regulatory processes that ensure domestic suppliers are treated fairly compared to those suppliers in Australia.
4. Reviews and modifies MEDSAFE's information requirements that are over and above those for other regulated markets (USA or Europe) and causing barriers to licensing that cannot be justified in terms of the additional costs or benefits, such as 12 months stability data at the time of dossier submission.
5. Proceeds with urgency to adopt the joint medicines regulation agency with Australia to avoid current delays with medicine regulation and ensure improved medicines regulatory capacity for New Zealand.

5.4 The Right Policy Process

For a National Medicines Strategy to be successful a robust process needs to be followed. The WHO provides a check list of the key elements of an effective medicines policy process (WHO 2003). There are three key elements of the process:

1. Steps in formulation
2. Implementation
3. Monitoring

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Formulation

During this phase the MOH needs to identify the key stakeholders and the key problems. A detailed situational analysis also needs to be conducted.

The MOH Consultation Document describes the current structures and roles of organisations in the sector. It does not however adequately set out the problems with the system. While some issues are identified there do not appear to be strategies proposed that will effectively address them.

Many key stakeholders will be excluded from the strategy development process at this early stage. At this time it is understood that there will be no public consultation processes. This step is essential to enable those population groups that would have difficulty developing written submissions, including those who have high health needs and or literacy problems, to participate in the process. It is inappropriate not to provide an opportunity for Maori to make verbal submissions at this early stage in the process of identifying problems with the system. The MOH will not have honoured its obligation under the Treaty if effective public consultation with Maori does not occur. Furthermore, it is likely that the groups that have not been able to effectively participate will lose confidence in the processes.

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1. Implementation Planning

The implementation of the Medicines Strategy will only be effective if clear priorities are set for the next 3-5 year. Agreement needs to be reached on what needs to be done, by when, who is responsible and how much resource will be needed.

The Consultation Document provides no indication of how these decisions will be made or by whom. Given the complexity and scale of the problems, an appropriate structure allowing expert advice from key stakeholders needs to be established. The purpose of this advisory group should be to facilitate evidence based, robust, transparent decision making. Input from all key stakeholder groups will need to be included, including consumer representation, to be successful.

2. Monitoring and Evaluation

The WHO recommended that for effective monitoring agreement needs to be reached on the relevant questions managers will need to answer. The data collected needs to be limited to data that is most likely to be used. Plans will be needed to establish reliable data systems that include initiatives to train staff and adequate resourcing.

The MOH Consultation Document does not have specific objectives to ensure the implementation of important components of the Medicines Strategy can be monitored. Without this information being systematically and readily available there can only be token accountability across the sector for the best use of limited resources. This objective is essential to support implementation and evaluation of the Medicines Strategy.

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It is therefore recommended that the MOH:

6. Undertake appropriate public consultation early in the development of the Medicines Strategy to ensure meaningful participation of (a) Maori and (b) other disadvantaged and high needs population groups.
7. Clearly identify the most important problems in the current system with regard to access to medicines and set goals and objectives that will specifically address these problems.
8. Undertake a detailed situational analysis that includes defining roles and responsibilities, and sector structure to undertake all necessary steps in the processes to ensure agreed levels of access to medicines and that will enable the development of an effective accountability framework.
9. Establish expert advisory group of key stakeholders to guide the policy development and implementation planning.
10. Develop implementation plans that address how poorly we are providing services, are resource realistic, and provide appropriate incentives across the sector.
11. Establish meaningful accountability frameworks across the sector to ensure effective implementation of strategies to improve access to medicines.
12. Include in the National Medicines Strategy an objective of monitoring the implementation of the strategy and to measure an agreed set of desired outcomes be put in place across the sector.

6.0 MEDICINES STRATEGY PRINCIPLES

ATM have agreed the following values and principles and would like to see them reflected in the Medicines Strategy:

Access to Medicines

The most important principle is equal access to medicines for all people.

Equitable access

The strategy should state an aim of delivering access to medicines for New Zealanders that is comparable to similar OECD countries. Such an objective would give a suitable benchmark that is realistic as well as measurable.

Equitable access should also be stated as equitable between different groups of patients. This requires that priority is given to the most serious conditions and urgent cases.

Access regardless of ability to pay

The strategy should include the principle of universality that ensures patients are not disadvantaged by an inability to pay. To that end we strongly support the principle stated in the strategy document "To support access to medicines that New Zealanders need regardless of an individual's ability to pay"

Recognition of rights under the International Covenant of Economic, Social and Cultural Rights (ICESCR)

ICESCR was adopted by the United Nations General Assembly in 1966 and ratified by New Zealand in 1978. The ICESCR is a binding legal instrument.

Including a reference to the ICESCR right to the highest attainable standard of health would underpin the basis for the Access objective that is proposed for the Medicines Strategy, and it would be a step towards defining the basic entitlement of New Zealanders to subsidised medicines.

Patient confidence in decision making processes

To achieve this will require greater transparency of decision making as well as separation of the conflicting roles currently vested in PHARMAC. This principle will need to be balanced with the ability of PHARMAC to undertake price negotiation with suppliers, but that interest should not deny consumers the opportunity to see whether the system is truly

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working for the best health outcomes, and reducing disparities in health status, by providing access to essential medicines. Significant work will be needed to restore an acceptable level of confidence.

Respectful partnerships

This principle requires a significant change of attitude by PHARMAC in its relationships with patient groups and with industry. Patient groups wish to have a positive working relationship with all stakeholders and build mutually beneficial relationships that enhance education, medicine access and health outcomes. Unfortunately there is currently a climate of suspicion, hostility and antagonism that prevents positive relationships.

Tightening of PHARMAC responsibilities, governance and oversight

The role of PHARMAC, how it makes its decisions on which medicines are subsidised, and how it should be held accountable are critical issues for the Medicines Strategy, and they are not analysed adequately in the Consultation Document.

PHARMAC's particular approach of maximising health outcomes across the whole population in a way that tends to discount the very serious health needs of relatively small groups is not mandated by the legislation governing PHARMAC. The Medicines Strategy is an opportunity to reiterate PHARMAC's statutory purposes and objectives.

The principles proposed in the Consultation Document for resolving difference in perspectives between PHARMAC and DHBs are inconsistent with the statutory purposes and objectives of the DHBs and PHARMAC, and would reinforce PHARMAC's practice of placing undue weight on minimising pharmaceutical costs.

The Minister should be exerting greater pressure on PHARMAC to follow its legislation and secure the best health outcomes reasonably achievable for people in need of pharmaceutical treatment. The proposal in the Consultation Document for the Medicines Strategy to reduce the accountability of PHARMAC to the Minister would be a backward step if it was accepted.

Separating the conflicting roles of PHARMAC

The Consultation Document should also have identified the conflict of roles between PHARMAC claiming that it does not have enough money to secure the best health outcomes reasonably achievable for people who need pharmaceutical treatment, at the same time as it is responsible for proposing the Community Pharmaceuticals budget to the Government. If the Community Pharmaceuticals budget is inadequate for PHARMAC to properly meet its statutory objectives, PHARMAC should be proposing and advocating in favour of an increase in the budget to meet the legitimate health needs of New Zealanders.

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To overcome this fundamental problem or role conflict, government should:

- Separate medical and scientific decisions from funding and procurement decisions.
- Create reliable metrics and reporting requirements.
- Improve decision-making processes across the wider health sector.

The RMI have developed similar values that we commend. We note they have independently arrived at similar conclusions to ATM across a wide range of topics under consideration in this consultation. This close correlation of a number of key points arrived at by independent processes by two major stakeholder groups, should be of some significance to the Ministry of Health in its assessment of submissions.

Problems with the Current System

To follow is a high level analysis of some of the problems faced by the sector that can be directly attributed to poor access to medicines and that lead to poor health outcomes.

7.0 POOR HEALTH OUTCOMES FOR MAORI

Life Expectancy Less for Maori

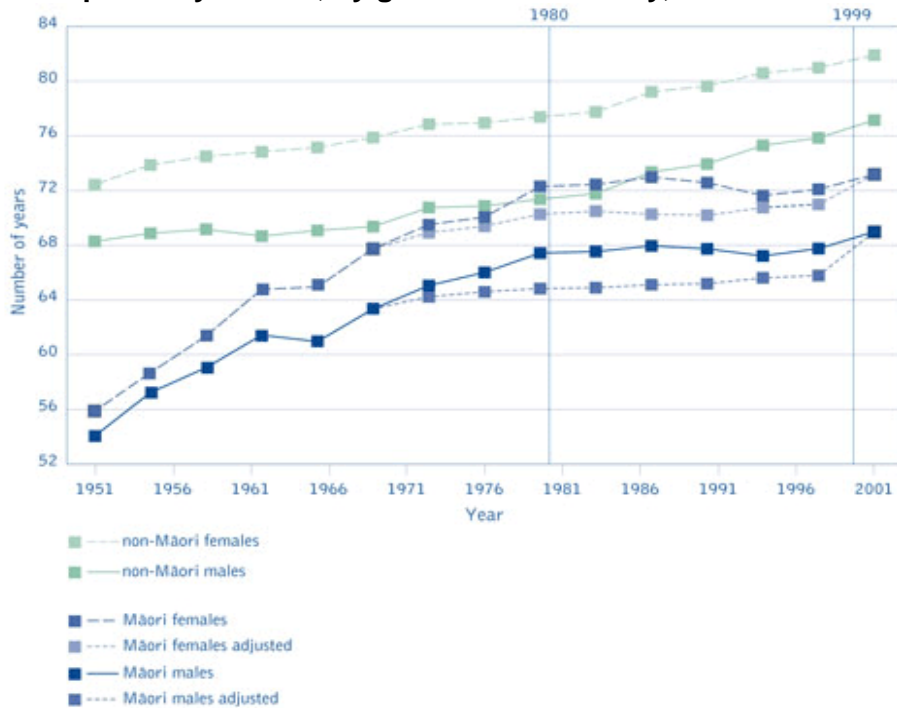
Overall, Maori life expectancy at birth was more than eight years less than non-Maori in 2001, for both genders. Over the 20 years from 1980 to 2000, life expectancy increased significantly for non Maori but was comparatively stable for Maori, resulting in an increased disparity in health outcomes.

Government has placed high priority on addressing this difference. In order to succeed we need to understand the major contributors to reduced life expectancy that can be addressed. The Medicines Strategy needs to clearly identify how it will contribute to addressing these factors.

The graph below charts trends in life expectancy from 1950 to 2001 for Maori and non-Maori males and females. It also shows adjusted life expectancy estimates for Maori from 1980 to 1999 using estimates from the New Zealand Census Mortality Study. The graph shows that in 2001, life expectancy at birth was 69 years for Maori males and 73 years for Maori females, while life expectancy at birth was 77 years for non-Maori males and 82 years for non-Maori females.

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Life expectancy at birth, by gender and ethnicity, 1951–2001



Note: Adjusted life expectancy estimates for Maori 1980-1999 use estimates from the New Zealand Census - Mortality Study graphed at the midpoint of each time period. Source: Ajwani et al 2003; Statistics New Zealand:

High Levels of Coronary Heart Disease in Maori

A major contributor to reduced life expectancy for Maori compared to non Maori is coronary heart disease. The data in the table below indicates that between 2000-2002, for people over 35 years, the overall death rate from CVD for Maori is 2.8 times the rate for non Maori. It is likely that the differences in rates between Maori and non-Maori could be reduced by improved access to medication.

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Between 2002-2004, Maori hospitalization rates for adults over 35 years with CVD were double the rate for non-Maori. These data are difficult to interpret as no account of private hospitalization is made, and these are known to be proportionally more common for non Maori.

Indicator	Maori			non-Maori		
	Males	Females	Total	Males	Females	Total
Total	691.4	459.8	569.4	267.9	149.3	204.5
cardiovascular disease mortality, 35+ years, 2000-02, rate per 100,000 ^{1,3*}	(656.9-727.4)	(434.3-486.4)	(548.2-591.2)	(263.6-272.3)	(147.1-151.7)	(202.2-206.8)
Total	4284.2	3402.2	3819.7	2478.1	1395.4	1913.3
cardiovascular disease hospitalisation, 35+ years, 2002-04, rate per 100,000 ^{1,3*}	(4198.7-4371.0)	(3330.7-3474.8)	(3764.3-3875.6)	(2462.4-2493.9)	(1385.4-1405.4)	(1904.2-1922.4)

High Maori Cancer Mortality Rates

Maori all-cancer mortality rates were more than twice the rate for non-Maori (RR 2.2, CI 2.1–2.3).

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Maori adults, however, had only slightly higher registration rates than non-Maori for all cancers (RR 1.2, CI 1.2–1.2) and there was no significant difference between the self-reported prevalence of cancer between Maori and non-Maori (RR 1.1, CI 0.8– 1.5).

The higher mortality for Maori associated with cancer is therefore likely to be associated with access to services i.e. diagnostic and treatment which includes medicines.

Table: Cancer Indicators

Indicator	Maori			non-Maori		
	Males	Females	Total	Males	Females	Total
All cancer registrations, 25+ years, 1999-2001, rate per 100,000 ^{1,3*}	493.2 (469.5-517.7)	537.0 (513.9-560.9)	512.5 (496.0-529.3)	457.2 (451.7-462.7)	412.4 (407.0-417.8)	430.4 (426.6-434.3)
All cancer mortality, 25+ years, 2000-02, rate per 100,000 ^{1,3*}	333.8 (314.3-354.2)	292.6 (275.7-310.3)	309.5 (296.7-322.7)	165.3 (162.2-168.4)	125.4 (122.9-128.0)	142.7 (140.8-144.6)
Cancer prevalence (self-reported), 25+ years, 2002/03, percent ^{1,2**}	2.1 (0.7-3.5)	7.0 (4.7-9.4)	4.7 (3.3-6.0)	3.3 (2.7-3.8)	4.9 (4.3-5.6)	4.1 (3.7-4.6)

Notes: ¹ Age-standardised to 2001 Census total Maori population.

² Prioritised Maori ethnic group - see [Methods and Data Sources section](#) for further information.

³ Ever-Maori ethnic group - see [Methods and Data Sources section](#) for further information.

Sources: ^{*} New Zealand Health Information Service

2002/03 New Zealand Survey

7.1 Unknown Levels of Access to Medicines

The MOH needs to agree a basis for determining desired levels of access to medicines for eligible people in New Zealand and indicators for evaluating progress towards achieving them.

Currently there is heated debate about how well or how poorly we are doing using information from a range of sources including:

- annual volumes of specific products over time
- numbers of new products added to the schedule
- range of products benchmarked against other countries
- expenditure as a percentage of GDP
- expenditure as a percentage of vote: Health
- etc.

The indicators being debated are relatively blunt tools and are difficult to interpret. Even these data are not readily available in a form that allows meaningful conclusions to be drawn about appropriate levels of access.

Levels of Access to New Medicines

PHARMAC state in their annual review that 14 new chemical entities were listed last year. However, we have no basis for determining whether this is an optimal number of new listings.

To assess how well we are doing with making new products available further information is required to undertake a meaningful analysis of the situation including answers to the following:

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- What new products are funded and used routinely in other countries that are not licensed in New Zealand?
- How many notifications do MEDSAFE receive to import and use these medicines?
- How long does it take for new products to be licensed by MEDSAFE compared to other countries?
- How many other new products are licensed in New Zealand that have not been listed?
- What proportion of unlisted new products (licensed or not) are considered to be clinically effective?
- How many people have applied for medicines under the exceptional circumstances scheme for treatments that are not funded, how many of them were given approval, how timely was this process, how many people opt to go to Australia for treatment etc.

7.2 Known Poor levels of Access to Medicines

To determine meaningful measures of access to medicines it would be useful to consider what proportion of people that meet clinical criteria as defined in appropriate treatment guidelines that are being treated according.

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Numerous clinical guidelines have been developed specifically for New Zealand for common conditions that are readily available on the New Zealand National Guidelines Group Website. The Medicines Strategy should consider how to ensure these guidelines are implemented and treatment regimes are adhered to.

The MOH has a myriad of strategies underway to develop better access to services (including medicines) and better clinical practice in primary care. Significant funds have been invested in these strategies primarily through the budget to implement the primary care strategy (in the order of \$200 million per annum) to establish and fund PHOs. However, the result of the Primary Care Policy has led to high needs patients being disadvantaged with reduced access to medicines if they are referred to specialist care. The cost of co-payment for medicines dispensed from a specialist's prescriptions is now significantly higher when compared to dispensing fees for medicines from the general practitioner with whom they are enrolled.

The published research that provides information on the level of access to medicines for conditions that are high priority for Government indicates that the current performance of the sector is well below what is desired. The MOH is literally spending billions of tax payers' money each year on health services and it would appear that the sector does not provide the most basic, cost effective services to the people who need them most. It is critical that the Medicines Strategy ensure this issue is addressed.

To follow are some examples that illustrate the low level of access to medicines based on agreed clinical guidelines:

Diabetes Control:

Improving diagnosis and management of diabetes, including prevention, is a high priority for Government. The Get Checked program has been underway for some six years and included funding the primary care sector to encourage better clinical management and information on health outcomes for people with diabetes. It is one of the few national

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health initiatives for which systematically collected health outcome data is available.

After a slow start, uptake of the 'Get Checked' programme is approaching 50% but much improvement is needed in making essential services available to all people with diabetes, including the more than 70,000 with Type 2 who remain undiagnosed.

The Diabetes Type 2 Report from PricewaterhouseCoopers, commissioned by Diabetes New Zealand in 2001 shows conclusively that optimal services including early diagnosis, regular monitoring and targeted treatment will result in reducing cost to the health service over a 20 year period. This is largely because the onset of expensive long term diabetes complications, such as renal failure, heart disease, blindness and limb amputations, can be delayed or prevented with adequate treatment. The figure estimated in the Diabetes New Zealand Type 2 Report was a saving of \$320 million a year in twenty years time. An update of this report is currently being prepared and will be released in May 2007.

For all people with diabetes, both Types 1 & 2, a critical part of optimal treatment is access to the best medicines available, including monitoring equipment and the best available means of delivering drugs (e.g. insulin pumps). It is particularly important for diabetes that a long term view be taken when determining access to medicines. Decisions about current funding should be seen as a contribution to a long term saving of \$320m if the best possible medicines are made available. If quality of life, family commitments, ability to work and other personal and socioeconomic factors are included the long term saving will be a lot more.

Diabetes New Zealand provides three examples of diabetes related treatments for which PHARMAC decided to restrict access despite good evidence of benefits associated with their wider use. In Australia and the UK there is better access to these products compared with New Zealand. Refer to appendix 2.

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Cardiac Risk Reduction:

Over the past two decades major improvements in mortality and morbidity associated with cardiovascular disease (“CVD”) have occurred globally based on interventions to reduce cardiac risk and treatments for those with CVD. Providing health services and in particular access to medicines to reduce cardiac risk, which include aspirin, statins and antihypertensive medications, are acknowledged to be a high priority for the New Zealand health sector.

New Zealand has led the world in the development of tools for health professionals to assess absolute cardiac risk and then clinical guidelines based on the level of CVD risk to optimize health outcomes (NZGG 2003,2004,2005). For many years, these guidelines and tools have been widely disseminated in the sector to facilitate access to best clinical practice. National initiatives to assist implementation of the guidelines have been funded by PHARMAC such as the “One Heart One Life campaign and PBAC initiatives. PBAC developed modules for continuing professional development of general practitioners based on best practice for clinical management of cardiac risk. The RNZCGP has accredited practice audit tools to assess and improve compliance with the guidelines.

PHARMAC report significant increases over recent years particularly in the use of statins. However, limited systematic data is available to determine the level of access to the appropriate medication, as per the guidelines, other than the volumes and costs of medicines consumed. The MOH has a project “Leading for Health Outcomes” underway to consider how best to collect systematic information to monitor performance in this area. Experts have been commissioned to write reports on the information systems needed.

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Despite these initiatives, health outcomes (morbidity and mortality) associated with heart disease continues to be worse in New Zealand than many other developed countries. Significantly higher rates of CVD in Maori are a major contributor to the difference in life expectancy as discussed above.

To more accurately determine levels of access to medicines a study was conducted looking at RNZCGP computerized patient records (Rafter N., 2005). The findings of this study are mentioned in the MOH Consultation Document, however their importance and implications are not discussed.

The study analyses records for 25,384 individual men aged at least 45 years and women at least 55 years, who consulted a doctor in 2000 to determine the extent to which they were being managed according to the CVD guidelines. The guidelines provide treatment recommendations based on a clinical assessment of the risk of CVD.

CVD Risk assessment: The first step requires all patients to be assessed for absolute risk for CVD. Patients should have their cholesterol levels and blood pressure measured. Only 25% of patients had them documented.

Lipid lowering and blood pressure lowering medications were used to assess the "treatment gap". This combination was prescribed to only 28% of those with documented cardiovascular disease. For the remainder without a history of disease and for whom 5-year absolute risk of cardiovascular disease could be estimated, prescription of combination therapy ranged from 8% in the lowest risk group (<5% 5-year risk) to 14-16% in the other risk categories.

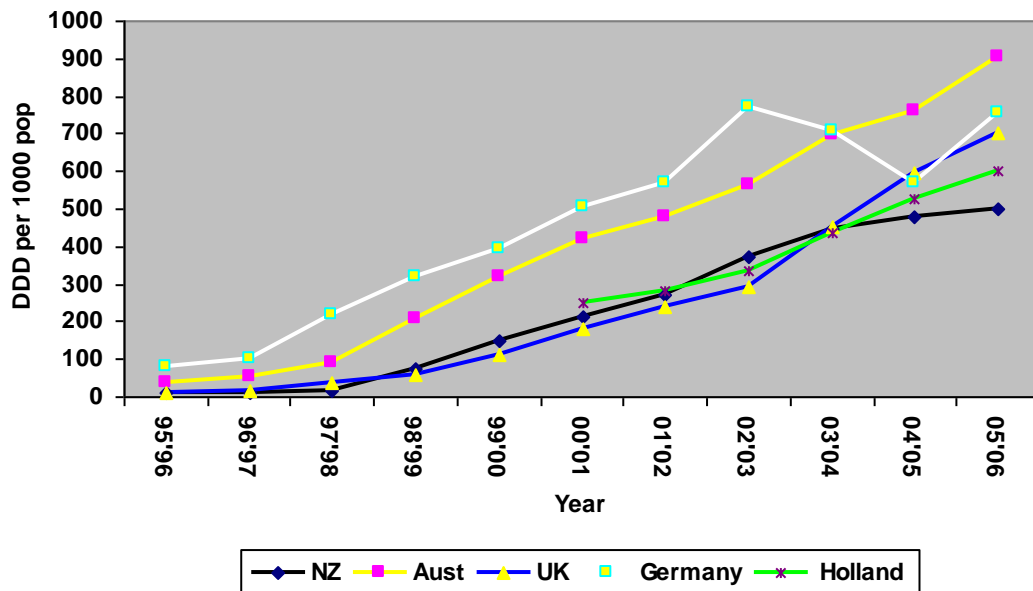
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In summary **more than two-thirds of people** with vascular disease were **not** receiving medications as recommended by the guidelines and there was little evidence of targeting by absolute risk for those without disease. While increased volumes of statins are now being used, we do not know if they are being prescribed appropriately, nor do we know if a substantial gap remains.

The RMI has produced comparisons of statin consumption based on equivalent potency confirming New Zealand's effective statin consumption is lower than other OECD countries.

Comparison is illustrated in Figure 1. Significantly, this comparison shows that, of the five countries studied, New Zealand had the lowest DDD rate of consumption of statins by 2005/2006.

Figure 1: Inter-country Comparison of Statin Consumption



Source: MIDAS database

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The comparison in Figure 1 also reveals that, while New Zealand may have equalled Australia in the number of statin prescriptions relative to population, New Zealand has never got close to Australia with regards to consumption of equivalent units of statins or indeed in ability to lower cholesterol. Furthermore, the gap between Australia and New Zealand is increasing.

7.3 No assessment of the impact of decisions not to fund effective medicines

There appears to be minimal effort to assess the real impact of a constrained pharmaceutical budget. There are a lot of individuals whose lives are profoundly adversely affected by decisions not to fund effective medicines or by delays in decisions to fund medicines. The MOH Consultation Document provides no objective data or qualitative information on these affected populations. This information should routinely be available to DHBs and the Minister at the time of setting the budget for pharmaceutical spending.

Case studies:

ATM has included some case studies to illustrate the negative impact decisions taken by PHARMAC have on individual's lives and on their families and care givers. These examples include poor access to treatments for people with diabetes, breast cancer and growth hormone therapy for children with Prader-Willi syndrome. Refer to Appendix 2 for more detail.

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The actual expenditure on community based medicines has increased at 2% per annum over the period 1993-2006. International comparisons indicate this result is well below the level of expenditure growth for medicines in other countries. There is a general assumption that this result is all good.

PHARMAC's strategy of sole supply contracting has certainly attracted the larger generic manufacturers into the New Zealand market. Given New Zealand's relatively small size internationally, this would not have otherwise been possible. Sole supply contracts also limit the need for investment in marketing. As a result very significant downward pressure has been put on pricing.

Significant expenditure savings due to aggressive contracting strategies leading to downward pressure on price, and better value for money, is highly commended by the DHBs which are under considerable budget pressures. Strong support for continued fiscal constraint may, however, have other negative impacts that have not been fully considered.

Delisting of Products

A direct result of sole supply contracting strategies is the delisting of products and a reduced choice of subsidized medicines. Over the past 12 years 1132 products have come off the schedule and are no longer subsidized. Many innovator products have been replaced by generic versions and can no longer be purchased (even privately) in New Zealand. For some patients there will have been adverse clinical effects, as was seen with the funding decision for statins. Other patients may have had to source product from overseas and purchase their medicines "out of pocket".

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Reclassification

Many medicines are being reclassified as their safety profile increases. The UK has an aggressive policy to reclassify as many products as possible to general sales or pharmacy/pharmacist only as rapidly as possible. Product that become available “over the counter” e.g. low dose aspirin, antihistamines, Noroxin etc will tend to be purchased at the full cost of the patient.

Cost shifting to patients

Another pricing strategy to constrain expenditure has been reference pricing, resulting in at times very significant co-payments being made by patients who are prescribed a particular medicine in preference to a cheaper product in the same category that is fully funded. The extent to which this trend is posing barriers to accessing medicines, particularly for low income people has not been assessed.

Poor Adherence

The pharmacy Guild has undertaken work to estimate adherence to prescriptions. A recent survey indicated a significant proportion of people did not collect their prescriptions, and the primary reason was they could not afford the co-payment.

Limited Number of New Medicines Listed on the schedule

The PHARMAC annual report indicates there are far more applications for new listings than can be fully assessed. Priority is given to new applications and they are processed accordingly. It is not known how this priority ranking is assessed or what the constraints are with regard to processing all applications in a timely manner.

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Delays in decisions to list new products are likely to result in savings against the pharmaceutical budget. This situation may provide a disincentive to processing applications more rapidly.

PHARMAC makes decisions not to fund medicines that are clinically effective because they are not affordable. As a result, patients will not benefit from the use of these products, even if it is the recommended treatment for their condition, unless they can pay for the medicine themselves. Implicit in this fact is that if there was more funding available these products could be purchased.

7.4 Lack of Confidence in Medicine Funding Decisions

In August 2005, a UMR survey of 750 adults has found 68% would back a review of PHARMAC. Half of those surveyed thought New Zealanders had worse access to medicines compared to Australia.

In November 2005, Pfizer commissioned another UMR Research to undertake a mail survey to determine doctors' views of PHARMAC's performance (Pfizer 2006). A mail survey was conducted of 1500 clinicians with a response rate of 33% (n=529). The key findings indicate a high level of concern by the majority of physicians relating to access to medicines that need to be addressed.

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Key findings

- An overwhelming majority of general practitioners and specialists believe **increased funding of medicines** should be a high priority for the Government.

- **71% rate as poor to very poor, PHARMAC's performance in ensuring New Zealander's access to new medicines is as good as countries like Australia**, compared with 7% who rate it good to excellent, while 22% think it is average (gave a mid-point rating).

- **57% rate as poor to very poor, PHARMAC's consultation with clinicians** over which medicines to subsidise, compared with 9% who give it a good to excellent assessment, and 31% who think it is average.

- **52% rated as poor to very poor**, PHARMAC's performance being held **accountable for decisions**, compared with 13% who rate it good to excellent, and 33% who assess it as average.

- **54% of clinicians consider PHARMAC's performance** with the setting of diagnostic thresholds for the **approval of special authority restrictions** (which deny access to funded medicines more freely available in other countries) is poor to very poor, compared with 15% who rate it well and 29% who consider it average.

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A review in the New Zealand Medical Journal has published a number of articles expressing concerns about access to statins. PHARMAC's funding decisions associated with statins provide examples of the basis for concerns expressed by clinicians in the UMR research (Ellis, 2006). The review findings are quoted from the abstract below.

The combined science and worldwide knowledge over the last 20 years has indicated that there is a need to deliver prolonged statin treatment, with substantial LDL cholesterol reductions, in all patients at high risk of any type of major vascular event.

PHARMAC's role in allowing New Zealand patients access to these important medicines has been truly awful. A review of their rationing methods clearly shows that the principle cost saving that they employ, is simply to deny and delay patients access to modern medicines. PHARMAC then supplement this strategy with a range of tactics, including misrepresentation of scientific data, the ability to ignore evidenced-based medicine when it suits them, major bureaucratic hurdles to the access of medicines, and frequent switching of funding of various drugs, with a significant resultant impact on patient trust and compliance with the use of their medicines.

Furthermore, PHARMAC have a continuous and clever public relations section, which assails the credibility and integrity of doctors, and have often personally and publicly attacked those who have attempted to present scientific evidence, and to discuss in a rational manner, issues of enormous importance to New Zealand patients and taxpayers.

Hence New Zealanders have now lost an environment in which the New Zealand Ministry of Health and the community can hold sensible and reasonable discussion, as to what medicines can, and truly cannot, be afforded.

The data in PHARMAC's annual reports is presented in a positive light. Statements and graphs about the level of savings made through

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PHARMAC's interventions are impressive but information on how these data were calculated is not provided. Industry has questioned the validity of these claims.

7.5 Lack of Accountability

We acknowledge that access to medicines is not the responsibility of any one agency. The MOH, however, is clearly responsible for developing strategy and monitoring health sector outcomes, for overseeing how vote health is spent, and for holding the organizations that use those resources accountable for their performance against agreed targets.

The MOH has recently undertaken work on how to develop information systems to monitor performance which can be found on the MOH website under Leading for Health Outcomes. This work is only at a preliminary stage so any information systems developments could be linked to monitoring implementation of the Medicines Strategy.

The roles and responsibilities of organizations concerned with ensuring access to medicines overlap in some key areas to the extent that no agency can be held accountable for any specific outcome. The following table in Appendix 4 attempts to describe the agency responsible for key activities and who is accountable for the outcomes.

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A comprehensive review of the structures and roles across the sector is required to clarify roles and responsibilities. Agreement needs to be reached about which organization is best equipped to undertake each specific activity, what performance targets should be achieved, how they will be monitored and the lines of accountability.

Urgent Need to Review PHARMAC's Role

It is inappropriate for PHARMAC to be responsible for multiple activities that are potentially in conflict. The table in Appendix 4 shows PHARMAC simultaneously has responsibility for the following

- input on setting the total budget for medicine
- ensuring expenditure is within the budget
- promoting medicines utilization
- manage the level and number of products subsidized
- determine new products to be listed
- assessing products for cost effectiveness
- assessing products value for money.

Initial analysis of PHARMAC's role would suggest it would be better for the organization to focus on the activities it undertakes best, that is supply side management. PHARMAC could be required to focus on managing the budget through contracting mechanisms to set prices to achieve value for money and to determine affordability of new products based on the available budget.

To facilitate more robust and transparent decision making with new treatments, and to avoid the problems seen with statins, clinical effectiveness would be better managed by a separate body as it is in Australia (PBAC). Decisions on clinical effectiveness could not then be confused with the affordability of a product.

DHBs to undertake Clinical Effectiveness Decisions

It would be more appropriate for DHBs to take responsibility for jointly

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making decisions on clinical effectiveness and appropriate guidelines for using new medicines. There would be a need to provide training to ensure clinicians are trained to undertake this work (National Advisory Health Committee, 2006). Having a larger pool of people skilled to undertake this form of decision making will reduce some of the delays in assessing new medicines and further enhance clinical service delivery. Separating decisions on clinical effectiveness and affordability will create more transparent decision making about the adequacy of the total budget and generate greater confidence in the sector.

7.6 Poor Access to New Cancer Treatments

In response to concerns raised about the limited number of new cancer treatments and the following information was published in a positively framed article by PHARMAC (Simpson 2005).

“For hospital-administered cancer treatments, PHARMAC currently assesses applications on behalf of district health boards (DHBs). Following that assessment, if national agreement is reached on funding, then PHARMAC will seek a contract with the supplier for the product, before consulting on a proposal and seeking the approval of the PHARMAC Board. PHARMAC also consults before declining applications.

PHARMAC receives about 30 applications for funding each year. The Pharmacology and Therapeutics Advisory Committee (PTAC) makes a recommendation about the relative priority of each application—when not referring applications to its expert subcommittees, or deferring pending further information.

- 20 applications for cancer drugs have moved through the process since 2002 (18 in the last two years).
- Of the six applications given a high priority, four have been funded.”

It is not clear why PHARMAC consider this result to be so positive. It seems that over 3 years there may have been 90 applications, and only

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4 had been funded. No benchmarking was provided regarding decisions to fund these medicines in other countries, for example in Australia.

The Breast Cancer Aotearoa Coalition case study in Appendix 2 provides clear examples of poor access to known effective cancer treatments for women with breast cancer. It is totally unethical for the Government to fund a breast screening program and then to fail to ensure access to medicines that will result in the best possible health outcomes for women diagnosed with the disease.

7.7 Lack of Capacity for Robust Decision Making by DHBs

Given the important role of DHBs in setting the budgets for community and hospital pharmaceuticals, it is important to consider their limited capacity to make good funding decisions and consider strategies to improve it.

In 2002, the National Advisory Committee on Health and Disability (“NHC”) produced a discussion paper on the processes used to make funding decisions for new technologies, including new medicines. In 2004 the NHC shifted its focus to consider the processes used by the 21 DHBs as the sector had moved away from centralised decision making to the majority of decisions on new technologies being devolved to DHBs.

In January 2006 the NHC published a discussion paper based on interviews with DHB decision makers that reviews the processes and associated issues in deciding whether to fund new interventions.

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The managers and clinicians felt that these decisions should primarily be made by clinical staff. Hospitals tend to use a mix of formal and informal decision making processes. Informal decision making was at risk of being driven by personalities or personal preferences, or be at odds with the DHBs priorities. Even where formal decision making processes have been established, they may not be very robust and can often be avoided. Decisions tend to be made within clinical departments and give little consideration to the extent the intervention will improve health outcomes, or whether using the funding elsewhere in the health service could result in greater benefits.

The criteria generally include clinical effectiveness and cost but seldom give consideration to issues of equity, Maori health and acceptability or the overall DHB priorities. Similarly there is little attempt to achieve consistency in decision making across the sector.

Decisions by the DHB funding teams to fund new interventions such as community based initiatives do take into account DHB priorities, but account for only a small proportion of the DHB's budget. Many DHBs are aiming to reduce deficits and any discretionary spend is under intense competition for allocating to initiatives that are identified as priorities for the DHBs. Better access to medicines is not a current priority for any DHB.

It is in this context that decisions to set the total pharmaceutical budget are set.

7.8 Lack of transparency in PHARMAC decision making

The ATM is concerned that greater transparency is needed in the pharmaceutical procurement and reimbursement process. At present, PHARMAC does not make a clear distinction between pharmaceuticals that are both clinically effective and economically cost-effective, and those which it selects to fund. Ideally, the cost-effectiveness assessment should be a distinct process that produces a “List of Need”—a list of cost-effective drugs that are approved as safe, that are needed by the community, and that New Zealanders should ideally have access to. PHARMAC could then, through a separate decision-making process, determine which of these drugs can be covered under its annual budget.

Without a clear indication of how many drugs the public is being denied access to because of limited funding, the Government cannot make informed decisions about funding needs, or about the efficiency of the procurement and reimbursement system in delivering good health outcomes. Rationing is a politically sensitive topic; however egalitarian the system that is used, there will always be particular groups that “miss out” or register protests. However, the public has a right to know how public finances are being allocated.

They also have a right to know if a given medicine is deemed cost-effective, but can’t be funded publicly — this not only creates space for open debate over the rationing process, but also creates a market for insuring cost-effective but non-subsidised pharmaceuticals. In the medium term, this will help to increase pharmaceutical access to New Zealanders, by giving them an option to cover pharmaceutical expenses outside the public health system.

In summary, to move from current practices to an improved model, we

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consider it will be necessary for Government to undertake significant changes in the funding of medicines to address the above issues. Our initial recommendations to Government include the need to:

- Separate medical and scientific decisions from funding and procurement decisions
- Create reliable metrics and reporting requirements
- Improve decision-making processes across the wider health sector.

8.0 TOTAL BUDGET FOR PHARMACEUTICALS: IS IT ENOUGH?

Currently the total budget for expenditure on medicines is agreed by DHBs with the MOH considering on advice from PHARMAC. There is no clarity about what information is used to determine optimal expenditure or what process is used. While the MOH and DHB managers and PHARMAC may consider the budget is set at an optimal level, the majority of the public and the health professionals do not agree with them.

To instil confidence in the sector, agreement needs to be reached on the budget setting process. The process will need to be transparent and reflect a number of issues including, but not limited to, the following:

- Quantified population health needs
- Clinical best treatment
- Trends in utilization
- Desirability of patients making out of pocket payments
- New product developments
- Pricing strategies

8.1 Industry View

Pfizer commissioned a review by Castalia Strategic Advisors of medicines funding in New Zealand compared to other countries. The review indicates the current drug funding regime in New Zealand severely restricts patient access to medicines for conditions such as heart disease and cancer (Sundakov, 2005). Report author Alex Sundakov says the poor health of many New Zealanders is because they don't have the same access to medicines as those in other countries.

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The Pfizer report also says New Zealand is lagging behind other developed countries in the level of government subsidisation for medicines. It says New Zealand spends about 8% of its total health budget on pharmaceuticals, while Australia spends more than 14%.

PHARMAC responded in the media to the concerns raised by the UMR research suggesting New Zealanders did not have as good access to medicines as Australians do that an independent review would find that New Zealanders do get value from what it spends on medicines. This view did not address the issues of greatest concern.

PHARMAC was openly sceptical about the motivation of industry and the kinds of questions asked in the Pfizer sponsored UMR survey. The CEO said that drug companies are always calling for more spending on medicines and it's unsurprising they are having another go before an election. He considered Pfizer and other drug companies just want to increase their own profits.

8.2 Public Perception

The UMR research of public opinion found 70% believe increased funding for PHARMAC should be a high priority for the Government, compared with just 7% who think it should be a low priority, and 22% seeing it as a moderate priority.

ATM holds the view that the total level of investment in medicines in New Zealand has not been subjected to a proper objective analysis, based on population health needs assessment, consultation, and appropriate budget setting.

We believe the artificial cap on expenditure since the early 1990s, with just marginal adjustments from time to time at a rate below inflation, gives no confidence at all in any suggestion of integrity in the budget setting process.

The failure to address this issue over a long period of time is inconsistent with the WHO guidance on investment in essential

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medicines. It should be apparent that a significant additional investment is needed in medicines if the objectives of DHBs and PHARMAC are to be met, regardless of how any of the other recommendations in our submission are acted upon.

These views are widely shared within our respective organisations memberships and constituencies. There is a substantial level of frustration at delays or denials of access by an agency charged with obtaining medicines for us. Statements by PHARMAC staff that “we manage the budget by creating waiting lists for medicines” (Stuart Bruce, personal communication at the launch of ATM Coalition, November 2005), and “PHARMAC’s role is to give DHBs options about where they spend their money” (Acting CEO Matthew Brougham, RMI Medicines Seminar, 7 March 2007), leave no confidence that our interests are being managed appropriately by PHARMAC.

The example in Appendix D demonstrates unacceptable delays by PHARMAC in making decisions about Enzyme Replacement Therapy for Gaucher disease, a Lysosomal storage disease. It appears to verify concerns among ATM member groups that PHARMAC deliberately uses significant delay in decision making as a device to assist it manage its budget, and clearly demonstrates the inadequacy of the budget provided.

Appendix E is a newsletter article from the New Zealand AIDS Foundation outlining significant delays with funding of anti-retroviral medication. Delays range from 2 to 4 years after the treatments were funded in Australia, before funding was eventually approved in New Zealand.

8.3 Decisions to deny access to effective medicines based on budgets

In September 2003 PHARMAC decided not to list celecoxib, rofecoxib and meloxicam on the Pharmaceutical Schedule. Chronic arthritis sufferers who could not tolerate the side effects of other non-steroidal anti-

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inflammatories were effectively denied the benefits of these products. This decision seemed most unfair particularly given Australia's decision to fund these products, presumably on the same information available to PHARMAC.

Following withdrawal of these products from the market, PHARMAC published an article justifying this decision based on efficacy, cost effectiveness and budgetary grounds stating:

“This decision meant that at least 18 other pharmaceuticals were able to be funded or have access extended, resulting in 437 ‘statistical lives’ saved per year, with net health gains, and savings for District Health Boards.” (Grocott, 2005).

The issue is not raised as to whether DHBs should have funded these 18 products irrespective of the decision to fund Cox-2 inhibitors.

The article also went on to make comparison with Australian access to this medication where these medicines had been available. The paper also estimates the excess morbidity and mortality associated with myocardial infarctions avoided in New Zealand as a result of their decision not to fund this product. The paper fails to specifically mention this information was unknown at the time of their decision but gained with hindsight.

9.0 LEGAL FRAMEWORK: PHARMAC DECISION-MAKING AND ACCOUNTABILITY

9.1 Summary

The role of PHARMAC, how it makes its decisions on which medicines are subsidised, and how it should be held accountable are critical issues for the Medicines Strategy. In this section Roger Palairret, a Public Law specialist, explores these issues in some depth as they are not analysed adequately in the MOH Consultation Document.

This part of the submission discusses PHARMAC's role and decision criteria, and some of the statements about PHARMAC in the Consultation Document and that PHARMAC has made about itself. It then measures this information against the legal framework that applies to PHARMAC. The conclusion is that PHARMAC's particular approach of maximising health outcomes across the whole population in a way that tends to discount the very serious health needs of relatively small groups is not mandated by the legislation governing PHARMAC. PHARMAC's primary objective under its legislation is to secure for people in need the best health outcomes reasonably achievable from pharmaceutical treatment from within the amount of funding provided. The Medicines Strategy is an opportunity to reiterate PHARMAC's statutory purposes and objectives.

Currently, PHARMAC's primary concerns are the cost-effectiveness of the spending on pharmaceuticals and staying within its budget. If PHARMAC followed its main statutory purpose more closely, it would put greater weight on securing the best health outcomes reasonably achievable for people who need pharmaceutical treatment. It would have to adjust the utility measurements it uses to decide which pharmaceuticals to subsidise, or not, and pay greater attention to the individual health needs of people who need subsidised medicines.

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The fact that PHARMAC is a Crown entity, and that it is part of the class of Crown entities that are subject to binding policy directions from their responsible Ministers, is highly relevant to the Medicines Strategy. PHARMAC is not an independent Crown entity; it is an instrument of government policy. The Medicines Strategy should provide for the Minister to issue a government policy statement that is legally binding on the board of PHARMAC.

One of the issues that should be resolved in a government policy statement is the confusion between PHARMAC's accountability to the Minister and to the DHBs. PHARMAC is primarily the agent of the Crown and the responsible Minister, but the Consultation Document describes PHARMAC as the agent of the District Health Boards (DHBs).

The Consultation Document refers to the tension between PHARMAC and the DHBs which is evident when they develop the Community Pharmaceuticals budget. This tension or difference in perspective should not exist because PHARMAC and the DHBs are supposed to be applying consistent statutory purposes and objectives from the same Act, and the same government policies and strategies. The Consultation Document suggests that the difference in perspective between PHARMAC and DHBs should be resolved by requiring PHARMAC and the DHBs to apply a consistent set of principles. The principles proposed in the Consultation Document are inconsistent with the statutory purposes and objectives of the DHBs and PHARMAC, and would reinforce PHARMAC's practice of placing undue weight on minimising pharmaceutical costs.

The suggestion in the Consultation Document that the Minister should no longer specifically approve the Community Pharmaceuticals budget proposed by PHARMAC and the DHBs would also reduce the capacity of the Minister to influence the Community Pharmaceuticals budget, which is inappropriate when PHARMAC and the DHBs are Crown agents.

The Minister should be exerting greater pressure on PHARMAC to

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follow its legislation and secure the best health outcomes reasonably achievable for people in need of pharmaceutical treatment. The proposal in the Consultation Document for the Medicines Strategy to reduce the accountability of PHARMAC to the Minister would be a backward step if it was accepted.

The Consultation Document should also have identified the conflict of roles between PHARMAC claiming that it does not have enough money to secure the best health outcomes reasonably achievable for people who need pharmaceutical treatment, at the same time as it is responsible for proposing the Community Pharmaceuticals budget to the Government. If the Community Pharmaceuticals budget is inadequate for PHARMAC to properly meet its statutory objectives, PHARMAC should be proposing and advocating in favour of an increase in the budget to meet the legitimate health needs of New Zealanders.

9.2 PHARMAC's Role and Decision Criteria

PHARMAC decides which medicines are subsidised and the level of the subsidies in New Zealand. The public subsidies are provided through PHARMAC putting the medicines on the Pharmaceutical Schedule.

Medicines on the Pharmaceutical Schedule are subsidised by the Crown through the DHBs. PHARMAC is often referred to as the Crown's drug funding agency, but that is not in fact accurate. PHARMAC itself does not fund or purchase the medicines on the Pharmaceutical Schedule, but it negotiates the prices and levels of subsidy for the medicines that the DHBs then purchase.

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The medicines are either Hospital Pharmaceuticals, dispensed through hospital pharmacies, or Community Pharmaceuticals, available in the community and dispensed through community pharmacies.

The budget for Community Pharmaceuticals is proposed by the DHBs and PHARMAC and approved by the Minister of Health. The Minister acts on the advice of the Ministry of Health. The budget includes an indicative three-year funding path, so PHARMAC and the DHBs can plan their pharmaceutical investments.

The allocation of the budget requires PHARMAC to make decisions about which pharmaceuticals will be subsidised and which will not, and PHARMAC has a set of decision criteria and processes to help make these decisions.

The decision criteria applied by PHARMAC are set out in its Operating Policies and Procedures. These decision criteria are not "legal" in the sense of being in an enactment, but PHARMAC has public law obligations to act within the statutory framework under which it operates, and to apply its policies consistently and rationally.

The decision criteria are important because the decision on whether or not to subsidise a pharmaceutical directly affects its availability and the ability of New Zealanders who might need the pharmaceutical to access it. PHARMAC's decision criteria are:

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- “(a) The health needs of all eligible people;
- (b) The particular health needs of Maori and Pacific peoples;
- (c) The availability and suitability of existing medicines, therapeutic medical devices and related products and related things;
- (d) The clinical benefits and risks of pharmaceuticals;
- (e) The cost-effectiveness of meeting health needs by funding pharmaceuticals rather than using other publicly funded health and disability support services;
- (f) The budgetary impact (in terms of the pharmaceutical budget and the Government's overall health budget) of any changes to the Schedule;
- (g) The direct cost to health service users;
- (h) The Government's priorities for health funding, as set out in the objectives notified by the Crown to PHARMAC, or in PHARMAC's Funding Agreement, or elsewhere; and
- (i) Such other criteria as PHARMAC thinks fit. PHARMAC will carry out appropriate consultation when it intends to take any such "other criteria" into account.”

The Operating Policies and Procedures (and the Consultation Document) say PHARMAC weighs each of the 9 criteria as it considers appropriate when it makes its funding decisions. How PHARMAC weighs the criteria is indicated in the Consultation Document, which says (at p. 24) the criteria require three key analyses:

- an assessment of the relative clinical effectiveness of the medicine
- an assessment of the cost-effectiveness of the medicine
- an assessment of the affordability of the medicine within the budget available.

These assessments are a synthesis of the decision criteria, but they emphasise clinical effectiveness and cost issues. They do not cover all the decision criteria.

For example, they do not include an assessment of the health needs being met, and the cost-effectiveness assessment appears to be an

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absolute assessment rather than a comparative assessment against other publicly funded health and disability support services.

PHARMAC's *Briefing to the Incoming Minister of Health (2005)* (BIM) also illustrates PHARMAC's tendency to focus narrowly on the clinical efficacy and cost-based elements of the decision criteria. The BIM says PHARMAC's decision criteria,

"direct it to assess and review:

- Cost effectiveness – are the health gains commensurate with added costs?
- Comparative effectiveness – does it do the job better than treatments that are already funded?
- Clinical information and research – does the scientific evidence support the health benefits claimed?
- Government health priorities, as outlined in government health strategies; and
- Cost – what is the impact on the wider health sector and the pharmaceutical budget?"

The BIM and other material produced by PHARMAC emphasises the cost-effectiveness element of the decision criteria, and the cost-utility analysis using Quality Adjusted Life Years (QALY) measurements. PHARMAC says that it gives weight to the other decision criteria apart from cost-effectiveness, such as patients' medical needs, the accessibility of suitable alternatives and the impact on the pharmaceutical budget (BIM p.22). However, it is not clear how much weight PHARMAC in fact attributes to the other decision criteria, or whether the cost-effectiveness analysis is the dominant decision criterion.

For example, PHARMAC also says that it is "charged with getting the best value (in terms of health gain) on pharmaceuticals when deciding which drugs should be subsidised, and at what levels" (BIM p.2).

The PHARMAC *Statement of Intent 2006/07* (SOI) says PHARMAC's first strategic priority is managing the Pharmaceutical Schedule to maximise health outcomes. The strategic priority is:

"Schedule management – promote efficient management

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of pharmaceutical expenditure. PHARMAC will ensure that the Community and Hospital Pharmaceutical Schedules are managed in a manner that ensures treatments are appropriately prioritised and listed, and *that maximises health outcomes from within the funding available* (including to use pricing and negotiation strategies to get the best possible outcomes for patients)." (*emphasis added*)

The strategic objective associated with the strategic priority is:

"Ongoing cost-utility assessment (including improvement over time as possible) of all major investments to achieve *maximisation of health outcomes.*" (*emphasis added*)

PHARMAC concedes that the cost-effectiveness approach and its cost-utility assessments are problematic for high-cost medicines, and for medicines for rare disorders. PHARMAC discussed this issue and how it is responding to it in the BIM as follows (p. 8):

"One of the most challenging areas of funding is for patients with diseases which are relatively uncommon and for which treatments are extremely costly. Examples of this include some conditions requiring enzyme replacement therapy, some types of cancer and some cardiac conditions. Treating these conditions with pharmaceuticals can cost hundreds of thousands of dollars per patient per year.

PHARMAC uses a number of mechanisms to ensure these very high cost medicines are targeted to patients who are most likely to benefit from the treatment. These include the use of expert panels of clinicians to assess applications, Special Authority criteria and direct supply to patients. PHARMAC also funds some high cost medicines through its Exceptional Circumstances scheme.

These types of treatment present a special challenge to PHARMAC, as the small number of patients, high cost and sometimes poor cost-effectiveness mean they may not compare favourably with other, less expensive treatments for much larger patient groups.

To add to this challenge, advances in technology suggest that there will be increasing numbers of "genetically targeted" medicines and other new medicines developed to treat small numbers of patients at extremely high cost.

In recognising this issue, PHARMAC has initiated a review of the way it considers funding of high cost

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medicines to look at whether these treatments should be assessed differently to other medicines."

9.3 High Cost Medicines

PHARMAC's consultation paper *How Should High Cost Medicines be Funded?* is part of the review PHARMAC has initiated. The consultation paper was released in December 2006, and it asks the question whether high-cost treatments should be assessed and funded differently to other medicines. The essential difficulty is that spending an amount of money to achieve a marginal health improvement for a large number of people tends to provide greater cost-effectiveness and utility than spending the same amount of money to achieve a dramatic health improvement for a small number of people. Applying a utilitarian formula to maximise health outcomes means that the relatively low numbers of people who need medicines for rare disorders tend to miss out. High-cost or low-volume medicines are less likely to be funded under the cost-effectiveness methodology PHARMAC applies, irrespective of how dire the needs of those who require the medicines might be.

The various papers and critiques attached to PHARMAC's consultation paper make it very clear that there is a philosophical and ethical element to this issue. The particular utilitarian analyses (and justifications) used by PHARMAC consistently value benefits to larger groups of people over benefits to smaller groups, and inherently undervalue the interests of people with rare disorders. The utilitarian approach is fundamentally rational, but there is room to adjust the utility measurements in a sophisticated way to better capture the real weight of the needs of people with rare disorders, or who need medicines that PHARMAC has elected not to subsidise.

9.4 Exceptional Circumstances Schemes

The fact that the Exceptional Circumstances schemes exist at all could

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be taken to be an implicit acceptance by PHARMAC that a different mechanism for funding high-cost medicines is required, and that decision-making based on PHARMAC's cost-utility analysis does not always lead to a satisfactory outcome. However the Exceptional Circumstances schemes do not bear this out.

There are three Exceptional Circumstances schemes operated by PHARMAC:

- Community Exceptional Circumstances
- Hospital Exceptional Circumstances
- Cancer Exceptional Circumstances

The Hospital and Cancer Exceptional Circumstances schemes apply if the patient is being treated in a public hospital, and the DHBs meet the costs of providing the treatment.

The Community Exceptional Circumstances scheme is funded by PHARMAC from the rebate income it receives from pharmaceutical companies, and pharmaceuticals under the scheme are available to patients who are not being treated in public hospitals. The Community Exceptional Circumstances budget is approximately \$2.5 million per annum, which is 0.35% of the Community Pharmaceuticals budget in 2006 (excluding rebates). The Community Exceptional Circumstances scheme therefore does very little to mitigate the hardship caused by PHARMAC refusing to subsidise particular pharmaceuticals.

Part of the reason the Community Exceptional Circumstances scheme is so small is that the eligibility criteria are so restrictive. The scheme only applies to rare conditions, or cases where there is an unusual reaction to alternative (funded) treatments, or an unusual combination of clinical circumstances. A "rare" condition is defined as being one that less than 10 people have.

The other problem with the Community Exceptional Circumstances scheme is that the standard PHARMAC cost utility analysis is applied if the cost of the treatment is greater than \$30,000 per annum. The

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Community Exceptional Circumstances scheme is therefore configured towards rare and unusual conditions that do not require high-cost treatment. Although PHARMAC says it funds some high-cost medicines through the Community Exceptional Circumstances scheme, the scheme is not designed to achieve that outcome and the amount of money available is not significant enough to make a material difference.

9.5 Legal Framework

There is a legal aspect to these issues because PHARMAC is a statutory entity, operating under a legal framework. The legal question is whether the statutory framework under which PHARMAC has been established and operates either allows or requires PHARMAC to make funding decisions that are influenced by a particular view of maximising health outcomes across the whole population, and which discounts the very serious health needs of relatively small groups.

PHARMAC is a statutory entity established under the New Zealand Public Health and Disability Act 2000 (NZPHD Act). It is also subject to the Crown Entities Act 2004, which sets out the generic governance framework for statutory entities. PHARMAC therefore has a public law obligation to operate within its statutory framework, including its statutory objectives and functions.

The high-level purpose and objectives of the NZPHD Act are set out in section 3, and the "new publicly-owned health and disability organisations" referred to in section 3 include PHARMAC. Section 3 says:

“3 Purpose

(1) The purpose of this Act is to provide for the public funding and provision of personal health services, public health services, and disability support services, and to establish new publicly-owned health and disability organisations, in order to pursue the following objectives:

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- (a) to achieve for New Zealanders –
 - (i) the improvement, promotion, and protection of their health:
 - (ii) the promotion of the inclusion and participation in society and independence of people with disabilities:
 - (iii) the best care or support for those in need of services:
 - (b) to reduce health disparities by improving the health outcomes of Maori and other population groups:
 - (c) to provide a community voice in matters relating to personal health services, public health services, and disability support services ...
 - (d) to facilitate access to, and the dissemination of information to deliver, appropriate, effective, and timely health services, public health services and programmes, both for the protection and promotion of public health, and disability support services.
- (2) The objectives stated in subsection (1) to be pursued to the extent that they are reasonably achievable within the funding provided."

The qualification in subsection (2) reflects that the potential demand and cost of health services will always tend to exceed the amount of funding provided, and that there are limits to what can be achieved within the resources available. However section 3(1) suggests that people who need high-cost medicines, or who have rare disorders, should not be disadvantaged by the blunt utilitarian methodology applied by PHARMAC. In particular PHARMAC's decision-making methodology does not meet the purposes and objectives in section 3 if it does not:

- achieve the best care or support for those in need of services;
- reduce health disparities between different population groups;
- and
- facilitate access to appropriate, effective and timely health services.

PHARMAC claims that it is charged with "getting the best value in terms of health gain on pharmaceuticals", and its SOI refers to maximising health outcomes from within the funding available, but those objectives do not necessarily meet the purposes and objectives in section 3. People who need drugs that are not subsidised do not get the best care or support, their disparities as ill or disabled people are not reduced, and they are denied access to appropriate, effective and timely health services.

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The specific objectives and functions of PHARMAC are set out in section 47 and 48 of the NZPHD Act. The primary objective of PHARMAC is,

“s.47(a) 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;”

This language is clearly consistent with section 3. The objective includes references to some of PHARMAC's most difficult issues:

- It applies to eligible people (effectively New Zealanders) who "need" pharmaceuticals. The level of need is relative; some patients need a drug to avert an acute crisis; others need a drug to control a chronic illness that may not be curable. Other patients need preventative medicines. In all but the most trivial cases, it would be difficult to decide that a patient does not "need" a medicine.
- The objective is to secure "the best health outcomes that are reasonably achievable from pharmaceutical treatment." This involves an assessment of the clinical effectiveness of a medicine; in some cases pharmaceutical treatment may not be able to achieve an improved health outcome. The use of the drug might be experimental, and it may not be reasonable to seek to achieve an improved health outcome from pharmaceutical treatment in such a case. The "best" health outcome may not be a "good" health outcome, especially in cases of chronic or terminal illnesses. PHARMAC has to assess how to prioritise a health outcome that may be the best reasonably achievable, but that may still not be good.

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- The PHARMAC's decisions must all be made within the constraint of the amount of funding provided. This seems to be the dominant objective as far as PHARMAC is concerned, but as a matter of context and interpretation, meeting health needs and achieving the best health outcomes should be given a higher priority.

The functions of PHARMAC are set out in section 48 of the NZPHD Act. The functions complement the objectives, and are also subject to the governance mechanisms provided in the Crown Entities Act. The NZPHD Act provides:

“48. Functions of PHARMAC

The functions of PHARMAC are to perform the following within the amount of funding provided to it and in accordance with its statements of intent (including the statement of forecast service performance) and (subject to section 65) any directions given under the Crown Entities Act 2004:

- (a) to maintain and manage a pharmaceutical schedule that applies consistently throughout New Zealand, including determining eligibility and criteria for the provision of subsidies:
- (b) to manage incidental matters arising out of paragraph (a), including an exceptional circumstances providing for subsidies for the supply of pharmaceuticals not on the pharmaceutical schedule:
- (c) to engage as it sees fit, but within its operational budget, and research to meet the objectives set out in section 47(a):
- (d) to promote the responsible use of pharmaceuticals:
- (e) any other functions that it is for the time being given by or under any enactment, or authorised to perform both the Minister by written notice to the board of PHARMAC after consultation with it."

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Section 48 expressly provides for PHARMAC to operate within the amount of funding it receives. This is consistent with sections 3 and 47. The need for PHARMAC to prioritise and make decisions to allocate limited resources is also implicit in the functions of determining eligibility and criteria for the provision of subsidies, and in the function of providing for exceptional circumstances. Section 48 is silent on *how* PHARMAC should perform its functions, except that it must perform them in accordance with its SOI, which is one of the governance mechanisms in the Crown Entities Act. In particular, PHARMAC is not directed under the NZPHD Act to apply a particular utilitarian decision-making process that inherently values marginal health improvements for large numbers of people above dramatic health improvements for small groups of people who need pharmaceutical treatment.

Therefore the decision criteria developed by PHARMAC, and the administrative processes it has developed to weigh different decision criteria as it considers appropriate, are not mandated by the legislation under which PHARMAC is established.

The particular utilitarian approach developed by PHARMAC, which emphasises cost-effectiveness and clinical effectiveness rather than the needs of people who require pharmaceutical treatment, is one way of allocating limited resources, but it does not necessarily meet the statutory objectives of PHARMAC.

The Medicines Strategy is an opportunity for the Government to reiterate PHARMAC's statutory objectives in section 47 of the NZPHD Act. PHARMAC would have to change its current utilitarian-based approach of maximising health outcomes across the board, and pay greater attention to individual health needs if the Medicines Strategy reflected the wording of PHARMAC's objectives in section 47.

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The Medicines Strategy should explicitly say that the Government's policy is to secure the best health outcomes reasonably achievable from pharmaceutical treatment for people in need of pharmaceuticals (within the amount of funding provided).

PHARMAC's own decision criteria say it is required to take into account the Government's priorities for health funding, although it is not clear how much weight PHARMAC attributes to that criterion. The Government also has the opportunity to influence PHARMAC's decision-making through its funding agreement and SOI. The current SOI uses the language of PHARMAC's self-defined objective of maximising health outcomes from within the funding available, rather than the statutory language of securing the best health outcomes reasonably achievable for people in need of pharmaceuticals.

If this change was made, hard decisions would still need to be taken, and a certain number of people who need high-cost medicines or treatment for rare disorders would still inevitably miss out on subsidised treatment. However more of these people could be helped if PHARMAC was required to pay closer regard to its statutory objectives.

9.6 PHARMAC as a Crown Entity

PHARMAC is a relatively small Crown entity with responsibility for managing the Pharmaceutical Schedule, as well as various other functions such as promoting the responsible use of medicines.

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The Consultation Document says that PHARMAC in practice operates as an agent of the DHBs.³ PHARMAC is the agent of the DHBs in the sense that it negotiates with the pharmaceutical companies on behalf of the DHBs that purchase the medicines. However, technically, as a Crown entity, PHARMAC is primarily the agent of its responsible Minister, who is the Minister of Health.

Crown entities are legally separate from the Crown, and they are usually governed by a board. There are different categories of Crown entities under the Crown Entities Act 2004, and the distinctions between them depend on the degree of control or influence over them by their responsible Ministers.

The role of the responsible Ministers is to oversee and manage the Crown's interest in Crown entities, and to set and monitor the Crown entities' strategic direction (Crown Entities Act 2004 section 27). This is achieved through mechanisms such as the Statement of Intent (SOI) and output agreement, and PHARMAC is subject to both these mechanisms. The board members of PHARMAC and other Crown entities have a legal duty to ensure their entity acts in a manner consistent with its objectives, functions, current SOI and output agreement (section 49).

The Crown entities that are closest to the Crown are Crown agents, and they tend to be responsible for the delivery of government programmes. PHARMAC and the DHBs are Crown agents.

The added feature that only applies to those Crown entities that are Crown agents is that the responsible Minister can direct the entity to give effect to a government policy that relates to the functions and objectives of the Crown entity (section 103), and the board must comply with that direction (section 114).

³ *Towards a New Zealand Medicines Strategy: Consultation Document* p. 21

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The Minister's power to issue directions to PHARMAC is limited by section 65(3) of the NZPHD Act. Section 65(3) prevents the Minister from issuing directions to PHARMAC for it to purchase pharmaceuticals from a particular source or at a particular price, or to provide any pharmaceutical or subsidy to a named individual.⁴ Section 65(3) therefore preserves the operational independence of PHARMAC, but the Minister has a high degree of potential control over the policies that PHARMAC is bound to apply.

This is relevant to the Medicines Strategy, because the Minister has the opportunity to give effect to all or part of the Medicines Strategy by issuing a government policy statement that would be binding on PHARMAC. This would enhance the standing and effectiveness of the Medicines Strategy.

PHARMAC is primarily responsible and accountable to the Minister, but its function of acting as the agent for the DHBs which are also Crown agents also creates the potential for its accountabilities to become very confused. If the DHBs and PHARMAC had similar perspectives and were giving effect to the same strategies and similar legislative objectives then the accountability issues might not be serious. However the Consultation Document makes the point that the DHBs and PHARMAC have different perspectives on drug funding and budgeting.⁵

The Consultation Document characterises the differences between the DHBs and PHARMAC as follows:

- DHBs, in managing their budgets, consider how best to allocate their funding to achieve their strategic priorities, which are based on an assessment of the health needs of their populations. These decisions involve determining the correct balance of

⁴ Section 65(3) of the NZPHD Act seems to assume that PHARMAC in fact purchases pharmaceuticals, when that is not actually the case.

⁵ Consultation Document p.45

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expenditure on pharmaceuticals versus expenditure on other services to achieve their strategic priorities.

- DHBs are funded according to the characteristics of their populations using the population-based funding formula. This is adjusted annually by an amount sufficient to fund price and technology growth. DHBs also receive adjustments for demographic changes in their population. Any increases in pharmaceutical expenditure need to be balanced against investment in other service priorities.
- PHARMAC is expert in managing expenditure on pharmaceuticals, including forecasting growth in demand, likely savings and potential new investments.⁶

It is interesting that the Consultation Document attributes a health-needs perspective to the DHBs, and a more technical and financial perspective to PHARMAC. Clearly the DHBs do have a health-needs perspective under the NZPHD Act. The function of DHBs under section 23(1) of the NZPHD Act is "to ensure the provision of services for its resident population." Their objectives include:

- to improve, promote, and protect the health of people and communities (section 22(1)(a));
- to promote the integration of health services, especially primary and secondary health services (section 22(1)(b));
- to promote effective care or support for those in need of personal health services or disability support services (section 22(1)(c)).

DHBs are also required to uphold the ethical and quality standards commonly expected of the providers of services and of public sector organisations (section 22(1)(i)). Specifically requiring DHBs to consider

⁶ *Op cit*

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the ethical context of the decisions they make has an obvious application to their decisions in relation to funding pharmaceuticals.

The DHBs are responsible for spending their Community Pharmaceutical budgets, as well as their Hospital Pharmaceutical budgets, to give effect to these objectives and functions. All of the activities of DHBs, including their relationship with PHARMAC and the decisions regarding the funding of pharmaceuticals, will be influenced by the statutory objectives and functions of the DHBs under the NZPHD Act.

The statutory objectives and functions of PHARMAC are narrower than those of the DHBs, because PHARMAC only deals with pharmaceuticals. However the objectives of PHARMAC still have a health-needs perspective. Section 47(a) of the NZPHD Act says the objectives of PHARMAC are:

- (a) 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;

The reference to the amount of funding provided introduces the fact that PHARMAC's task includes prioritising the availability of subsidies for pharmaceuticals, but the primary objective is securing the best health outcomes that are reasonably achievable for eligible people in need of pharmaceuticals. Interestingly, the funding provided comes from the DHBs, primarily through the Community and Hospital Pharmaceutical budgets.

The tension and difference in perspectives between the DHBs and PHARMAC referred to in the Consultation Document is presumably real, but in terms of the legislation establishing PHARMAC and the DHBs there should not be such a fundamental difference in perspective. The board of PHARMAC has a legal duty to ensure PHARMAC acts consistently with its statutory objectives and functions, and the board members are accountable to the Minister to ensure they perform that

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duty.

The fact that there seems to be a difference in perspective is particularly important in the context of the Community Pharmaceuticals budget, which is developed by PHARMAC and the DHBs in consultation together, and proposed to the Minister of Health. One of the proposals in the Consultation Document is that the process for determining the Community Pharmaceuticals budget should be revised and improved.

The main improvement to the process for determining the Community Pharmaceuticals budget suggested in the Consultation Document is that the DHBs and PHARMAC should apply a consistent set of principles when they determine the budget they recommend to the Minister.

The argument is that the prioritisation decisions inherent in setting the Community Pharmaceuticals budget will be more transparent, and the decision-making will be better, if the different perspectives of the DHBs and PHARMAC are resolved, and a more consistent set of principles is applied.

The fundamental problem with the proposal suggested in the Consultation Document is that the "consistent set of principles" that is proposed reflects PHARMAC's technical and financial perspective on pharmaceutical funding, and would require the DHBs to de-emphasise their current health-needs perspective. The principles the Consultation Document proposes focus on "value for money" and "affordability", and the Consultation Document describes the principles in these terms,

Value for money -- including taking into account:

- forecasts of potential volume growth
- the potential for new investments
- government health priorities
- opportunities for disinvestment
- maximising the benefits of pharmaceutical spending relative to spending on other health-related services (i.e. how effective are spending money on medicines in improving health status compared to

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other expenditure?)

Affordability -- this means ensuring that DHBs are able to remain within their overall funding parameters: the budget must be sustainable, in terms of increased access to medicines, the effects of government priorities (e.g. PHOs), and the fiscal impact on DHBs.⁷

These principles would narrow the perspective of DHBs, and limit the ability of DHBs to focus on their obligations under section 22 of the NZPHD Act. The principles do not explicitly refer to the health needs of the communities served by DHBs, or to any of the ethical elements of pharmaceutical decisions.

The principles proposed in the Consultation Document are narrower than the principles PHARMAC should properly be applying under its own statutory objectives and functions. They are not consistent with PHARMAC's own primary objective of securing the best health outcomes that are reasonably achievable for people in need of pharmaceutical treatment.

The other element of the proposals concerning the Community Pharmaceuticals budget that should be resisted is the suggestion that the Minister would no longer have to approve the budget if it was set by the DHBs and PHARMAC on a more principled basis. Quite apart from the issue of what the appropriate principles should be, from a governance and accountability perspective it is appropriate for the Minister to have an influence over the Community Pharmaceuticals budget. PHARMAC as a Crown agent is supposed to be highly accountable to the Minister. There is already an issue with PHARMAC distorting its statutory objectives and functions and over-emphasising the financial aspect of its mandate, and the change discussed in the Consultation Document would remove another opportunity for the Minister to hold PHARMAC to account. It would also remove the opportunity for the Minister to support the DHBs if they put pressure on

⁷ *Ibid* p.48

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PHARMAC to take a more holistic and health-needs focused approach to setting the Community Pharmaceuticals budget.

It is likely that the Minister (no doubt acting on the advice of the Ministry of Health) has not taken advantage of this accountability lever as well as he or she might have since the DHBs were established in 2000, but that is not a good reason for the Minister to surrender the lever.

PHARMAC's conflict of roles in relation to the Community Pharmaceutical budget setting process is another aspect which should have been referred to in the Consultation Document, but which is not. PHARMAC's legislation and the material it produces refer to the fact that PHARMAC's role includes making prioritisation decisions about the availability of subsidised pharmaceuticals from within the amount of the funding provided. When PHARMAC decides not to subsidise a high-cost pharmaceutical, or a pharmaceutical for a rare disorder, it cites the cost and the fact that it does not have an unlimited budget.

The fact that PHARMAC has a key role in determining the budget which it claims is a constraint is not so transparent. If the Community Pharmaceutical budget is inadequate to provide effective care and support for eligible people with legitimate health needs, PHARMAC should be proposing and advocating for an increase in the budget to meet that need.

The PHARMAC Annual Report to 30 June 2006 reports to the Government on PHARMAC's purchase objectives, including the purchase objective of reviewing the pharmaceutical expenditure targets quarterly and midway through the year, and recommending any adjustments to be Minister. The Annual Report says no changes were made to the expenditure targets, and that PHARMAC did not recommend any changes.⁸

In fact the reason PHARMAC would not have recommended any

⁸ PHARMAC Annual Report, 30 June 2006 p.30

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increase in the Community Pharmaceutical budget for 2005-06 is that the Community Pharmaceutical budget was under spent by \$19.41 million in the year to 30 June 2006.⁹

The Consultation Document should have discussed how it is possible for PHARMAC to refuse to meet the legitimate health needs of eligible people because it has to operate within a financial constraint when PHARMAC proposes the Community Pharmaceuticals budget itself anyway. The Consultation Document should also have discussed whether it is appropriate for \$19.41 million of the Community Pharmaceuticals budget to have been unspent in the year to 30 June 2006, at the same time as PHARMAC was refusing to subsidise some pharmaceuticals that would have met the health needs of people who were unwell.

Finally, the Consultation Document should have discussed whether the mechanisms by which PHARMAC is accountable for its performance and for carrying out its statutory objectives are either adequate or being used most effectively. It should not be proposing to reduce PHARMAC's accountability to the Minister by removing the Minister from the process of approving the Community Pharmaceuticals budget.

9.7 Access to Medicines and International Human Rights Norms

Enhancing access to medicines is one of the objectives that the Consultation Document proposes for the Medicines Strategy. While the Consultation Document discusses increasing access to medicines as a desirable objective, it does not say anything about whether the Government might have an obligation to provide access to medicines for all New Zealanders, or whether New Zealanders might have a right to access to subsidised medicines or health services generally.

⁹ *Ibid* p.16

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Patients in New Zealand have no direct statutory right to access medical services, including subsidised pharmaceuticals. The New Zealand Government has deliberately avoided creating such rights. For example, the New Zealand Bill of Rights Act 1990 confers civil and political rights based largely on the International Covenant on Civil and Political Rights, but it does not confer any economic, social or cultural rights such as a right to medical care.

The Code of Health and Disability Service Consumers' Rights also illustrates this point. The Code includes consumer rights such as the right to have services provided in a manner consistent with consumers' needs (Right 4(3)), and that minimise the potential harm and optimise the quality of life of the consumer (Right 4(4)). However, the jurisdiction of the Health and Disability Commissioner only extends to quality of care, and does not cover issues of funding or entitlement to a service. Therefore the Code of Consumers' Rights expressly excludes any right or entitlement to health services.

Nevertheless, there is an expectation in New Zealand that the Government will deliver acceptable standards of healthcare, as well as education and other social services. These expectations are political expectations, and Governments that fail to meet the political expectations of voters face the political consequences. However, there is no underlying legal right to healthcare against which a Government could be held accountable.

The Medicines Strategy will be incomplete if it does not say anything about the fundamental issue of what level of entitlement New Zealanders either have, or should have, to subsidised medicines when they need them.

International human rights law provides a possible basis for referring to a basic level of entitlement to access to pharmaceuticals in the Medicines Strategy. The starting point for modern international human rights law is usually taken to be the Universal Declaration of Human

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Rights (UDHR), adopted by the United Nations General Assembly in 1946.¹⁰ The UDHR is not a binding legal document, but it has formed the basis for many subsequent instruments that are binding on national governments. The aspirational rights in the UDHR include Article 25.1, which says:

“Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including ... medical care and necessary social services, and the right to security in the event [of] ... sickness, disability, or other lack of livelihood in circumstances beyond his control.”

The International Covenant of Economic, Social and Cultural Rights (ICESCR) was adopted by the United Nations General Assembly in 1966 and ratified by New Zealand in 1978.

The ICESCR is a binding legal instrument, although it does not include an effective enforcement mechanism. The rights protected include “the right of everyone to the highest attainable standard of physical and mental health” (Article 12.1). Article 12.2 provides that, to realise these rights, steps must be taken by the state to reduce infant mortality, to improve hygiene, to prevent, treat and control diseases and assure all medical service and medical attention in the event of sickness.

It would be appropriate for the Medicines Strategy to refer to the rights to the highest attainable physical and mental health and to medical service and attention that are included in the ICESCR. The ICESCR itself qualifies the rights it confers by referring to the maximum extent of available resources, which is similar to in intent to the language used in the New Zealand Public Health and Disability Act 2000. Similar qualifications could be included in the Medicines Strategy. However, including a reference to the ICESCR rights would underpin the basis for the Access objective that is proposed for the Medicines Strategy, and it

¹⁰ Butler and Butler *New Zealand Bill of Rights Act – A Commentary* p.63

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would be a step towards defining the basic entitlement of New Zealanders to subsidised medicines.

10.0 THE ETHICS OF SUBSIDISING MEDICINES

The ethics of subsidising medicines has been explored in some depth by Maurice Ormsby. To follow is a summary of his conclusions, which are fully supported by the ATM working group. His full paper is attached in Appendix 1 for your information and reference.

This paper sets out what ethics or moral considerations should inform any government funded national medicines policy in New Zealand. It is a long paper because it deals with a large number of ethical arguments developed over eighteen months to two years by government through its organisations, PHARMAC and the Ministry of Health. Some of these arguments are mistaken and lead to erroneous conclusions. It is therefore important to correct them.

However the argument of the paper, leading to a more robust and acceptable moral vision than that currently in evidence, is relatively simple. This summary is presented as a roadmap through the paper so that readers will not lose their way in the unfortunately necessary detailed exposition.

The paper accepts the government argument that there are many values in the world, many theories of justice as well, none of which command universal support. This is not a problem, however, since we need to develop ethical policy only for New Zealand. Furthermore, while values are diverse, the logic of ethics is not. The logic of ethics is universal, just as is the logic of mathematics. It is the same for all people, at all times and in all cultures. There is growing understanding of how that logic works. From the universal logic of morals operating on entrenched New Zealand values we are able to make a rational judgement about the ethics that should inform a national Medicines Strategy.

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New Zealand public policy values lie behind the ethics of the Treaty of Waitangi, and are manifested in our institutions, such as the Accident Compensation Commission, and public policy documents such as the Treaty itself and more recently the report of the 2000 Royal Commission on Genetic Modification. These values are based on Bentham's principle of utilitarianism, as developed by J S Mill.

PHARMAC uses Cost Utility Analysis and other criteria essentially to develop a utilitarian policy that, given limited financial resources, the ethically right distribution of funds for subsidising expensive medicines should be founded on whatever is conducive to maximising the greatest benefit to the greatest number, regarding the needs of every individual as deserving equal consideration.

This in PHARMAC's view necessarily involves fixing a cut off point above which the funding of expensive medicines for some would necessarily involve an unfair reduction in the funding of medicines for others. This means some will be left to perish but that cannot be avoided if a just distribution of limited funds is to be maintained.

This view is mistaken, not because it is based on the principle of utilitarianism, but because PHARMAC's understanding of that principle is hopelessly crude. The correct view involves ranking medical conditions on the basis of their urgency and seriousness of need. Funds can be allocated among different patients with roughly the same level of urgency and seriousness, based on a CUA analysis, or something like it. Some urgent life saving treatments, at say level one, will be relatively cheap to treat through using say blood clotting medicines, or preventive measures to prevent the condition arising in the first place. Others will involve expensive treatments for chronic serious conditions. Yet others may not be worth treating at all because the patient has a poor prognosis. These are all medical issues to be decided by physicians and their patients.

At the next level down, similar considerations will apply, until at the

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lowest level where conditions are not serious or life threatening, we may run out of insurance funds and patients will have to look out for themselves.

The value that urgent and serious cases take priority is what we learn from the so-called “rule of rescue”, which has not been properly understood in any of the government papers, at least not within the New Zealand context. The rule of rescue reflects the high value placed on life itself in this country, and is manifest when many people will drop everything and spare no effort to rescue, say, a pod of stranded whales, much more so a trapped adult or child. Less effort will be made to help someone with a sprained ankle. It is therefore morally justified to deprive less serious and less urgent cases to fund more serious and urgent cases.

Furthermore there may be occasions when a departure from any formula for the distribution of funds designed to reflect the utilitarian principle is, paradoxically, consistent with utilitarianism properly understood. This is because a society where such urgent rescue actions are regarded as ethically justified, even where less urgent but equally serious cases are deprived as a consequence, is one likely to be more conducive to the well being of its members *in the long run*. This is because even a sophisticated utilitarian analysis will not invariably or infallibly produce the morally correct outcome, just because we humans are fallible in all our endeavours including our ethical decisions.

Finally, it is suggested that the reason PHARMAC has wandered so far from New Zealand ethical norms found in, for example, the Accident Compensation Corporation, is that it has been given three roles which conflict with one another. These are the roles of negotiating supply and price arrangements with the pharmaceutical companies, recommending the overall size of the medicines budget to government and then managing that budget.

Separating these roles offers a practical way in which the institutions of

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government would be able to comprehend a more profound understanding of how the utilitarian principle should be implemented. How these roles might best be separated out in the pursuit of the common interest in comprehensive affordable medicines is a governance question, beyond the scope of this ethics paper. But that it can and should be done is shown by the way in which the roles of police, defence, judge, jury and prosecution have been separated out over the years better to achieve the common interest of justice.

11.0 HIGH COST TREATMENTS

In December 2006, PHARMAC released a consultation paper on how best to make funding decisions on high cost treatments. The PHARMAC paper includes views from a range of experts including ethicists, economists, clinicians, lawyers and consumers.

Our submission wishes to debate two of the key findings as summarised by PHARMAC in their consultation document.

- i) The acceptance of the need to make difficult tradeoffs within a limited budget, in the context of how the overall budget is set, and subsequent level of tradeoffs (if any) that would be needed.
- ii) The finding “there is little justification for assessing high cost medicines differently to other medicines” without detailed consideration of the legal and ethical frameworks that underpin New Zealand society.

11.1 ATM Submission to PHARMAC on High Cost Therapies

To follow is the Access to Medicines Coalition submission to PHARMAC on their consultation paper on high cost pharmaceuticals. It briefly touches on many of the points made in more detail in the body this submission on developing a national Medicines Strategy.

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High Cost Medicines Review

PHARMAC

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 focused 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

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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 focused 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

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of the purposes of the New Zealand 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

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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

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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 focusing 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.

John Forman
Spokesperson, Access to Medicines Coalition

11.2 European Policy on Access to Medicines for Rare Disorders

Ultra-orphan drugs are medicines used to treat exceptionally rare diseases that are chronically debilitating or life-threatening. The European Union (EU) regulations promote the development of such drugs however there is no prospect of a pan-European agency on drug prioritization.

Health service funding of ultra-orphan drugs, which varies across the EU and within the UK, has led to geographical inequities in patients' access to treatment. Conflicting views have been expressed on the optimal process for making decisions on funding such drugs. In some instances, support for these drugs would appear to have been approved on the basis that diseases that are rare and severe are a special case (Hughes 2005).

Hughes explores how a policy on the use of these drugs in the NHS, which aims to maximize population health while aspiring to the values of the EU directive might be developed. He considers policy that could be a compromise between a utilitarian view and a non-abandonment approach, drawing on an open debate on whether utilities are to be weighted according to prevalence, or whether a dedicated fund should be top-sliced. Risk-sharing schemes (with industry) might offset some of the high costs, while giving manufacturers incentives to produce more robust evidence on clinical effectiveness. A complete restriction on the funding of ultra-orphan drugs is not considered a practical or realistic solution.

These options for making funding decisions are considered to provide explicit criteria on whether or not funding should be available for ultra-orphan drugs that are more equitable, rights based and would address the "rule of rescue".

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Opposing views have been put forward and debated in the published literature. McCabe concludes that the NHS should apply the same criteria to make decisions on medicines for rare diseases as for low cost treatments for common diseases based on simplistic theoretical utilitarian arguments (McCabe 2005).

Conclusions drawn by McCabe include:

- The costs of production and the value of innovation cannot justify special treatment for orphan drugs
- Arguments about the measurement and valuation of health outcomes apply equally to orphan drugs and drugs for more common conditions
- The cost effectiveness of orphan drugs should be treated in the same way as for other technologies.

In response, a letter to the editor raises the issue that patients want to be treated fairly and decisions that consider cost effectiveness alone will not enable this value to be upheld (Sheehan 2005). Fairness and the need to treat all people with the same needs equally is a central theme in New Zealand policy. It would therefore be inappropriate based on the legal and ethical frameworks that underpin such decisions in the New Zealand context, to support a crude utilitarian approach as proposed by McCabe.

11.3 International Genetic Alliance Policy Statement

The International Genetic Alliance (“IGA”) recognizes that rapidly expanding genetic knowledge and technological advances are greatly improving our ability to intervene in a very wide range of health conditions, including rare diseases.

In order for this potential to be realized it is essential that rare diseases are the subject of a particular focus in health policy and in service delivery if the needs of those affected or at risk are not to be overlooked.

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In March 2006 the IGA agreed a policy statement on the need for improved information, diagnosis, clinical care and treatment for rare diseases (IGA, 2006). It includes a set of principles are provided to guide the policy of their members' Governments.

PHARMAC processes that result in decisions not to fund treatments for people with rare disorders, based primarily on cost and budget implications, and the lack of dialogue with concerned parties, are inconsistent with some of the principles in the IGA policy statement. The following principles in the IGA statement are relevant to this discussion:

1. Rare diseases are a significant public health issue. They affect around 8% of the population and when the immediate family is factored in, rare diseases impact on nearly 25% of the population.

In many countries 8% is equivalent to the size of significant minority populations. Just as leaving the health needs of such a population unmet would be unacceptable and discriminatory, so is the neglect of equivalent populations affected by rare diseases.

2. Health care and treatment for rare diseases is a human rights issue. Non-discrimination, justice and equity of access to health care, all require that specific policies are put in place to address the needs of people affected by rare diseases.

Responses such as prioritisation and the need to ration resources, as reasons for lesser attention to rare diseases in health research, planning and service delivery, are not ethically sustainable arguments.

3. A comprehensive approach to rare diseases is needed, including education, research, prevention, diagnosis, care and treatment.

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Services and support for patients and families need to be holistic and integrated to provide for the many health, disability and social issues often associated with them.

Furthermore, the IGA offers guidance to governments on suitable action plans to implement these principles in health planning and service delivery. These are relevant to the development of Medicines Strategy:

1. Governments should recognise the impact of rare diseases as a significant public health problem, and require their health systems to adopt action plans to deal with them.
2. Governments should adopt policies that aim to achieve equitable allocation of resources towards all aspects of rare diseases, including research, clinical care, information resources and development of treatments. Targeted budgets for orphan drugs and rare disease research, the development of specialist services, and information services for professionals and the public, are just some ways this can be achieved.
3. Governments and health systems should recognise that priority setting towards common diseases with high impact in total costs and in numbers of people affected, will create disparities in health status for populations affected by rare diseases, unless specific counterbalancing policies are put in place to meet their needs.
4. Governments should recognise the human rights issues inherent in rare disease care and treatment. They should adopt the principle that the frequently higher unit costs for rare diseases should not be grounds for denying access to services or

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therapies, and that specific programmes and policies will be needed to protect those rights.

5. Health economics criteria should take account of the personal, social and economic benefits of treating diseases, even where the unit cost of treatment may be more expensive. Recognising these wider factors will improve the cost effectiveness assessment for many higher cost interventions that also have significant benefits in clinical effectiveness.

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12.0 ATM RESPONSES TO THE MINISTRY'S CONSULTATION QUESTIONS

12.1 Medicines: Current Systems, Structures and Processes

Q1. Does this description reflect your understanding of medicines systems, structures and processes? Are there any elements that have not been included that you consider should be?

ATM considers this section does not have a sufficiently robust analysis of the present situation. Though it describes systems accurately, it does not give a detailed analysis of sector performance by providing any suitable measures of outcomes associated with access to medicines, nor detailed comparative data with other countries, by which these systems might be compared.

The document fails to identify and explore problems with access to medicines. It is overly optimistic, therefore, in its assessment of the system as evidenced by the list of frequently asked questions and the MOH's conclusion that New Zealanders do have good access to medicines. We have identified a number of areas where that optimistic view of access is clearly not correct and provided detailed case studies to illustrate them as per Appendix 2.

The overview of the current structure has not provided an adequate analysis of the structural problems. We believe our submission provides a more rigorous analysis of the problems in those structures - in particular the dilemmas with PHARMAC's conflict of roles.

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The description of processes is light on how and why those processes lead to difficulties, including issues related to significant delays, low level of new medicines listed, tense relationships within the sector, and many other issues which lead to the current crisis of confidence that many support groups have in PHARMAC.

12.2 A New Strategic Direction for Medicines in New Zealand

- Q2. *Do you agree with the overarching objectives of the proposed Medicines Strategy? If not, why not?*
- Q3. *Are any objectives missing? If so, what are they and why should they be included?*

The three overarching principles of (1) quality, safety and efficacy, (2) access regardless of ability to pay, and (3) optimal use, are sound objectives but qualification is needed to the second of these.

Access regardless of ability to pay is important to avoid cost being a barrier, but at present there is preferential access for those whose medicine is listed on the schedule, compared to those whose medicine is not, and who are thus restricted in their access and burdened as to cost. In addition the level of subsidy is reduced for patients who have their medicines dispensed from a specialist's prescriptions compared to the General Practitioner with whom they are enrolled.

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Our submission expands on this point and offers some additional principles to guide equity of access and priority for allocation of subsidy, and we specifically suggest recognition of the rights under ICESCR.

- Q4. *Do you agree with the proposed principles to guide decision-making? If not, why not?*
- Q5. *Are any principles missing? If so, what are they and why should they be included?*

The principle of *value for money* needs clear description to distinguish the approach generally adopted by PHARMAC in its decision making process, and to include the important principle of prioritisation that ATM has identified in its submission, as a key principle in the decision making process.

- Q6. *Do you agree with the key elements of implementation? Are there others you would like to add? Please explain your reasons.*

ATM supports the principle of cross sector involvement to progress the development of a medicines strategy but we qualify this with emphasis on the need for significant review and change to structural issues, as outlined in our submission, before such work could be done in a meaningful way. Tweaking the existing system could not be a meaningful start to the process needed for a good medicines strategy for New Zealand.

12.3 Getting Started

- Q7. *Are there other issues that you consider should be addressed as a matter of priority to improve the quality, safety and efficacy of medicines?*

Urgent attention should be given to reviewing and addressing the conflicting roles of PHARMAC and the lack of accountability across the sector to ensuring adequate access to medicines,

ATM has identified the urgency of progressing the joint trans-Tasman medicines regulatory agency as an important step.

- Q8. *Do you agree that the current budget-setting process for community pharmaceuticals is generally working well, in practice, but could be improved by having Pharmac and DHBs use a set of agreed principles to make a joint recommendation to the Minister of Health on the level of the budget? If not, why not?*

We do not agree, ATM consider this process as confused, contradictory and a poor standard or system of public sector decision making that prevents PHARMAC and DHBs from giving full effect to their mandate under the Act. We recommend significant structural change to avoid the conflict of roles.

- Q9. *Do you consider value for money/cost-effectiveness and affordability are useful principles for Pharmac and DHBs to apply in making a recommendation to the Minister on the proposed community pharmaceutical budget? Are there other principles you consider should also be applied? If so,*

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what are these and why should they be considered?

We challenge these principles as being far too limited. In particular the context in which they are included in the document appears to leave out all consideration of ethics, equity, access and affordability for patients, at this critical decision making point. The inclusion of these items in the overarching objectives and guiding principles would be of very limited value unless they remain a clear and direct guidance at the time the budget is set.

Q10. Is a three-year funding path helpful? If not, why not? What improvements do you suggest?

No comment.

Q11. Do you have any other comments on the proposed process for setting the community pharmaceutical budget?

In our submission we detail reasons that this process needs to be more transparent and also that it needs to be separated from other functions in the medicines budget management and medicines procurement system.

Q12. What are your views on the options proposed to increase the understanding of decision-making?

A more transparent decision making system is required that includes meaningful consumer input and makes available to the public medicines that have been approved for import and distribution by MEDSAFE and are pending decisions on funding. Information should also be available to the public on medicines that have been recommended as

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effective and consistent with international clinical practice but that have not been approved for listing on the schedule by PHARMAC.

Q13. *Do you have any further suggestions about the provision of free and frank advice to the decision-making process?*

Decisions on the clinical effectiveness of new medicines and their affordability should be undertaken by separate entities. Delays in this process should be quantified and strategies to address them put in place. Training for more clinicians to participate in robust decision making on the clinical effectiveness of new medicines is clearly needed.

Q14. *What, if any, experience have you had of the public summary documents produced in Australia? Do you think the public summary documents assist people to better understand the decision-making process?*

As in Australia, information on the volumes of all medicines subsidized should be readily available to the NZ public.

Q15. *Are there any other options you consider would be useful to pursue? Please describe these and explain how they would increase understanding of decision-making.*

ATM's response to this group of questions is covered in our submission with recommendations for the separation of roles, so that decisions about clinical matters are separated from budget management and from procurement decisions.

Q16. *Do you agree that decision-making about vaccines should be more transparent? If not, why not?*

Q17. *Do you agree that consideration should be given to the*

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best arrangements for supporting the Immunisation Technical Working Group process? If not, why not?

Q18. *Do you agree that options for the ongoing funding of vaccines should be explored? If not, why not?*

Q19. *Do you agree that options for vaccine procurement should be explored? If not, why not?*

ATM has not considered the issue of vaccines and PHARMAC's possible role in their procurement, in great detail but we urge caution about the decisions that are contemplated. Past experience has shown some serious shortcomings by PHARMAC in procuring vaccines.

In addition the scale of funding involved and weight of decisions needed about MenZB vaccine procurement, and more recently decisions about cervical cancer vaccine, probably put the questions about vaccine procurement into a category that is simply not compatible with consideration within a pharmaceutical budget setting process. The decisions are often far more strategic, long term public health prevention focused, than the more operational "treatment" decisions that DHBs and PHARMAC are used to working on.

We note that in the case of MenZB and Cervical cancer vaccines, decisions are being made at a Cabinet level, demonstrating perhaps that the political and funding dimensions of these vaccine decisions put them outside of the realm in which DHBs and PHARMAC could comfortably work, and indicating also that other key medicine funding issues need political input that is not apparent at present.

Q20. *Are there any other issues you consider are missing and should be addressed as a matter of priority to improve access to*

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medicines?

The ATM submission spells out a number of areas that need attention. These include performance criteria, measurement of outcomes, respectful partnerships, qualifications to the single purchaser approach, alignment with broader government policy, separation of conflicting roles and tighter governance of the roles currently performed by PHARMAC and DHBs.

Implicit also is the need for a boost to total medicine funding. It has been artificially constrained for far too long.

- Q21. *Where do you think the greatest gains in the optimal use of medicines are to be made?*
- Q22. *Which areas of the optimal use of medicines do you think will have the greatest impact in reducing inequalities in health outcomes between different population groups?*
- Q23. *What other optimal-use initiatives do you consider should be pursued? Why?*
- Q24. *Do you have any suggestions about how to improve co-ordination and communication between agencies involved in optimal-use activities in the sector?*
- Q25. *Do you have any suggestions about how the use of evidence-based guidelines in clinical practice can be better supported?*

No specific comments on optimal use.

- Q26. *Are there any issues missing from the 'Getting Started' list on page 40? If so, what are they?*

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Implicit in much of the ATM commentary on this strategy consultation document, and specifically mentioned in places, is significant concern at the relationships within the sector. It will not be possible to make significant progress in improving the system with relationships so tense and adversarial.

Part of the solution to sector problems must be by improved transparency. ATM believes structural changes needed to achieve the separation of conflicting roles will help considerably with this process.

Another area needing change is PHARMAC's consumer advisory committee. This is not a criticism of the people on it, but an acknowledgement that confidence has been sorely dented by a committee that has no effective engagement with medicine consumers and has produced only one public discussion document that was hostile to consumer groups. Its role as non-accountable to consumers and fully funded and controlled by PHARMAC needs careful evaluation and change.

APPENDICES

APPENDIX 1:

THE ETHICS OF SUBSIDISING MEDICINES

Summary

This paper sets out what ethics or moral considerations should inform any government funded national medicines policy in New Zealand. It is a long paper because it deals with a large number of ethical arguments developed over eighteen months to two years by government through its organisations, Pharmac and the Ministry of Health. Some of these arguments are mistaken and lead to erroneous conclusions. It is therefore important to correct them.

However, the argument of the paper, leading to a more robust and acceptable moral vision than that currently in evidence, is relatively simple. This summary is presented as a roadmap through the paper so that readers will not lose their way in the unfortunately necessary detailed exposition.

The paper accepts the government argument that there are many values in the world, many theories of justice as well, none of which command universal support. This is not a problem, however, since we need to develop ethical policy only for New Zealand. Furthermore, while values are diverse, the logic of ethics is not. The logic of ethics is universal, just as is the logic of mathematics. It is the same for all people, at all times and in all cultures. There is growing understanding of how that logic works. From the universal logic of morals operating on entrenched New Zealand values we are able to make a rational judgment about the ethics that should inform a national medicines strategy.

New Zealand public policy values lie behind the ethics of the Treaty of Waitangi, and are manifested in our institutions, such as the Accident Compensation Commission, and public policy

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documents such as the Treaty itself and more recently the report of the 2000 Royal Commission on Genetic Modification. These values are based on Bentham's principle of utilitarianism, as developed by J S Mill.

Pharmac uses Cost Utility Analysis and other criteria essentially to develop a utilitarian policy that, given limited financial resources, the ethically right distribution of funds for subsidising expensive medicines should be founded on whatever is conducive to maximising the greatest benefit to the greatest number, regarding the needs of every individual as deserving equal consideration.

This in Pharmac's view necessarily involves fixing a cut off point above which the funding of expensive medicines for some would necessarily involve an unfair reduction in the funding of medicines for others. This means some may be left to perish but that cannot be avoided if a just distribution of limited funds is to be maintained.

This view is mistaken, not because it is based on the principle of utilitarianism, but because Pharmac's understanding of that principle is hopelessly crude. The correct view involves ranking medical conditions on the basis of their urgency and seriousness of need. Funds can be allocated among different patients with roughly the same level of urgency and seriousness, based on a CUA analysis, or something like it. Some urgent life saving treatments, at say level one, will be relatively cheap to treat through using say blood clotting medicines, or preventive measures to prevent the condition arising in the first place.

Others will involve expensive treatments for chronic serious conditions. Yet others may not be treated at all because the patient has such a poor prognosis and palliative care is the appropriate course of treatment. These are all medical issues to be decided by physicians and their patients.

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At the next level down, similar considerations will apply, until at the lowest level where conditions are not serious or life threatening, we may run out of insurance funds and patients will have to look out for themselves.

The value that urgent and serious cases take priority is what we learn from the so-called “rule of rescue”, which has not been properly understood in any of the government papers, at least not within the New Zealand context. The rule of rescue reflects the high value placed on life itself in this country, and is manifest when many people will drop everything and spare no effort to rescue, say, a pod of stranded whales, much more so a trapped adult or child. Less effort will be made to help someone with a sprained ankle. It is therefore morally justified to deprive less serious and less urgent cases to fund more serious and urgent cases.

Furthermore, there may be occasions when a departure from any formula for the distribution of funds designed to reflect the utilitarian principle is, paradoxically, consistent with utilitarianism properly understood. This is because a society where such urgent rescue actions are regarded as ethically justified, even where less urgent but equally serious cases are deprived as a consequence, is one likely to be more conducive to the well being of its members *in the long run*. This is because even a sophisticated utilitarian analysis will not invariably or infallibly produce the morally correct outcome, just because we humans are fallible in all our endeavours including our ethical decisions.

Finally, it is suggested that the reason Pharmac has wandered so far from New Zealand ethical norms found in, for example, the Accident Compensation Corporation, is that it has been given three roles which conflict with one another. These are the roles of negotiating supply and price arrangements with the pharmaceutical companies, recommending the overall size of the medicines budget to government and then managing that budget.

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Separating these roles offers a practical way in which the institutions of government would be able to comprehend a more profound understanding of how the utilitarian principle should be implemented. How these roles might best be separated out in the pursuit of the common interest in comprehensive affordable medicines is a governance question, beyond the scope of this ethics paper. But that it can and should be done is shown by the way in which the roles of police, defence, judge, jury and prosecution have been separated out over the years better to achieve the common interest of justice.

Introduction

New Zealand has a population of about four million people. There are always people in this population who need medical treatment and seek it. Government currently provides a nationwide insurance function, subsidising a selection of effective medicines. These are available to all eligible people in the country. This paper discusses the ethics of government subsidising high cost medicines. It is intended as a contribution to the development by government of an integrated state medicines policy for New Zealand.

Medicines are regarded by the government as high cost if they are extremely expensive on a per capita basis, even if the condition is rare and only a few people are involved, or if the medicines are less expensive per treatment but in aggregate become extremely expensive because the conditions they treat are more commonplace and cheaper less effective alternatives are available. For discussion purposes call these expensive in the first sense and expensive in the second sense.

No specific figures have been given, but the Ministry of Health discussion document mentioned medicines of up to \$180,000 per

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Qaly being subsidised in certain circumstances, although the normal cut off point is much less. It is understood to be about \$20,000 a Qaly, although Pharmac will not reveal the actual level. In Australia it is about \$40,000 and in the UK about \$80,000.

One ethical problem is that under current arrangements there is a cost cut off point such that there are some people with rare conditions who, on the ground of expense (in the first sense), may receive no effective subsidised medicine for their condition and who may therefore perish prematurely. Is this morally right?

There are many more people whose condition would be better alleviated by improved medicines which are not currently subsidised on the ground of expense. They must either accept less effective medicines and suffer, or meet the whole cost of the better medicines themselves. Against the background of nationwide state insurance, is this fair?

Background

The New Zealand Government through its agencies Pharmac and the Ministry of Health is developing a national medicines strategy with the aim of improving the health of New Zealanders. One question raised is "...whether it is appropriate to fund high cost medicines for a few people (assuming funding is available) at the expense of lower cost medicines that benefit many more people."

¹ The question has been starkly phrased to invite the obvious response that it would not be ethical to save or treat the few at the expense of the many. The Government currently adopts this policy and has enlisted the support of international expertise to support it. The public has been offered an opportunity to comment.

Two central reports have been commissioned by Pharmac and published, one on ethical issues by medical ethicist, Professor

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Raanon Gillon, Imperial College London, and the other by welfare economist, Professor Paul Hansen, Otago University. Nine reviews of these two lead reports have also been commissioned. The Ministry of Health has also prepared a paper on the proposed overall medicines strategy. The pile of primary reading for this consultation stands over 60 mm high.

The paper must assume that readers are thoroughly familiar with the relevant ethical arguments in this pile of primary reading. For reasons of space, it is clearly not possible to restate the government's arguments in any detail, in order to make the essay an entirely self contained or stand-alone piece of work. In its work to give a blow by blow rebuttal of the government arguments, the paper is quite long enough as it is. Furthermore, this paper deals only with the ethical issues raised by Pharmac and the Ministry of Health, since both papers raise the same issues. The ethical conclusions are offered as a contribution to the overall medicines strategy, which will also include legal, medical, governance and public policy components beyond the scope of an essay on ethics. One would hope, however, that a sound ethical outlook would inform conclusions drawn in these other areas.

Both Gillon and Hansen agree that there are a wide variety of ethical theories and moral values no single set of which has universal acceptance. They have also made a number of suggestions about how Pharmac could improve its process of decision making by being much clearer about what values it actually takes into account in reaching its various decisions and the weighting it actually gives on each occasion to the many factors it takes into account in reaching decisions. However, apart from improvements in these processes, they have offered no argument for changing the basic thrust of Pharmac policy or reorganising its governance.

Economics

Hansen's paper admirably illustrates both the strengths and weaknesses of economic analysis for determining social policy. He is fully aware of them and acknowledges them in his paper. Professor Gillon is also attracted by the clarity and simplicity of the mathematical model used by Hansen to illustrate several different distributional theories of ethics, but writes "...

I doubt that this sort of mathematics is **always** the morally relevant approach to moral judgment about conflicting values, even though it may **sometimes** be. Furthermore, I also distrust it because I know that large numbers of conscientious moral thinkers also distrust it." ²

One might add that another reason for distrusting it is that we can and often do get the mathematics wrong by adding up the wrong things. This will be seen when we come to discuss Gillon's example of Jim and Pedro.

One weakness of this approach, as Hansen acknowledges, is that mathematics requires simplification of the variables measured and the allocation to them of numerical values which might not accurately reflect reality. Values and how strongly people feel about things are hard to measure. However, economic theory can represent some social realities exactly. For example, prices and budgets are easily measured, which is why economic theory is such a useful tool for working out a just allocation of resources by a government providing nationwide subsidised medical care including medicines that most people could not otherwise afford.

This is a form of national insurance in which each person is levied what they can afford through the taxation system and ill people are provided for out of the sum collected in proportion to their needs, unless that need is either very expensive or more expensive than the sums allocated to everyone else with a similar condition. (That is expensive in the second sense.)

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On the positive side, economics is improving its scientific status fast. Economic theory cannot be tested in the traditional scientific manner, by setting up carefully controlled and repeatable experiments designed to falsify the theory. While this does not invalidate economics as a science any more than it invalidates scientific efforts to explain earthquakes or the weather, it does make it harder.

But the collection by governments around the world of huge, reliable statistical databases, which economists can analyse using mathematical techniques, and the advent of computers, which can tackle huge tasks such as regression analyses, make economics the most advanced of the social sciences.³ Regression analysis does not show causal direction, but it is able to pick out correlated data with often surprising and controversial results.

Economics is an invaluable tool which carefully used can lead to improvements in social policy. A recent important example has been the ability of governments to control inflation by using central banks to control the money supply. Inflation has caused enormous suffering worldwide over the last 100 years. It propelled the awful events leading to World War II and lay behind much of the social disruption, revolution, famine and premature deaths that characterised the 20th century. In its contribution to the relief of human suffering, this victory of the social science of economics could fairly be compared to the discovery of penicillin.

A further advantage of economic analyses is that they help to clarify the concepts involved, and one of the primary functions of philosophers is to help clarify our thinking. For example, Professor Hansen sets up a simple allocation model to demonstrate the inevitability of value judgments in making allocations, even when maximum economic efficiency has been reached.

In Hansen's model we are to suppose that we must choose from a

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fixed budget an ethical allocation, ie a fair or just allocation, of medicines between two groups of people, one group which has greater needs than the other.

One value that can probably be taken as read in New Zealand is that that there should be no waste. This would imply, for example, that the medicines budget should so far as possible be fully allocated to medicine. (Sadly, there are countries where some of it might make a contribution to Ministers' Swiss bank accounts, and others where public servants responding to perverse incentives under spend the medicines budget, thereby neglecting health needs that could in fact be met within budget.)

Assuming therefore that there is no leakage from the budget, a curve can be drawn representing all the points at which the entire budget is spent on the two medicines, ranging from one group receiving everything to the other group receiving everything.

Health is measured in QALYS, which are "quality adjusted life years" a concept that incorporates both life expectancy and health related quality of life. For the purposes of this paper we must assume that the QALY is a well-formed concept, i.e. that it is the best measure of benefit received from a medicine.

(However, the two values of life length and life quality will need to be separated out for some decisions, which we shall do later in the paper.)

The points on the graph represent all the points at which no one can achieve a QALY gain without someone else losing. (Such no loss gains could be made if the budget was under spent, or some misappropriated funds retrieved from a Swiss bank account. In these cases the budget would not be operating at Pareto efficiency. There is one other way in which no loss gains could be made which we shall discuss further in the essay.) All the points on the curve therefore represent an economically efficient use of

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funds. But this curve, which represents all the points at which the budget is Pareto efficient, gives us no indication as to how resources should be allocated as between the two groups. Hansen demonstrates in diagrammatic form that while achieving Pareto efficiency, different values will place the allocation as between the two groups at different points on the Pareto curve.

On Hansen's model the point at which the total number of QALYS are maximised indicates a bias of spending in favour of the healthiest patients. Moving from that point to favour increasingly the more needy leads us to a point at which, whatever their starting need, each patient group receives the same improvement in health. When expenditure is shifted to give each patient group health care in proportion to their need the bias in favour of the needy increases further.

If expenditure is shifted to give everyone the same number of quality adjusted life years, whatever their initial health, expenditure shifts to favour the worst off the most. This might be seen as a sort of levelling up process.

Hansen's range of distribution possibilities probably spans all the acceptable ones. For example, no one has seriously suggested that health expenditure should be shifted to give the worst off more quality adjusted life years than those whose health is better. Such an allocation is probably not within the gift of medical science anyway, at least not without a social policy of actively harming the healthy. H. G. Wells once wrote a short story making fun of the saying that in a land of the blind the one eyed man is king. In Wells's plot the sighted man is blinded. Something along these lines might be attractive to some New Zealanders, since Wells felt under appreciated by his contemporaries and would have sympathised with those in our country who complain of our tall poppy syndrome. There are also those difficult cases in the field of medical ethics in which profoundly deaf couples wish to have a profoundly deaf child and seek medical intervention to

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achieve that result.

Nor has anyone since the Nazis seriously suggested trying to speed up evolution by focusing all expenditure on the best off, leaving the worst off to perish. However, this policy has been a very successful New Zealand agriculture practice. As a result we now have among the healthiest domestic cattle in the world. So much so in fact that the European Community once floated the idea that our meat should be banned on the basis that we gave no birth assistance to our animals and thus through cruelty kept our prices artificially low. The response was that our farm animals do not require birth assistance since our animal husbandry practices have long since culled out all the defective mothers.

Hansen has clearly set out how different allocation practices can be based on different views as to what in the same circumstances would be the right thing to do. But there are limitations to the mathematical approach. Hansen writes that there are an infinite number of points on the Pareto curve at which expenditure is economically efficient.

What is required is a value judgment as to which particular economically efficient distribution is the morally just one. He writes "...an infinite number of such value judgments is possible in theory---one for each and every point on the health possibilities (efficiency) frontier!"⁴ This frontier is another term for the Pareto curve.

This is a mistake. There are an infinite number of mathematical points on any line, however short. But mathematics is an abstraction from reality. In the real world the number of dots on a page representing actual values is quite small, they never lie cleanly on a smooth line and they can be enumerated easily. For example, the New Zealand population is some 4 million, not all of whom need Pharmaceuticals. Each citizen has an expectation of say 70 QALYS. The maximum number of QALYS to be

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considered therefore, will be a number less than 280 million, assuming that some of us stay healthy unaided. There will be a large number of possible distribution patterns from these distributions, but only a small number of them will be Pareto efficient. Once we take into account such logical rules as Professor Gillon's quote from Aristotle that like cases must be treated alike, the patients will fall into groups of like cases, so that the numbers we must deal with in reality will be smaller still.

In short, the numbers involved, even in a worst case scenario, are relatively small and with the aid of modern computers, easily surveyable. However, Hansen's model does show clearly that once Pareto efficiency has been reached, there is still a decision to be made about which one of the relatively small number of possible economically efficient distributions would be morally right for New Zealand.

Economic theory, although the most reliable and advanced of the social sciences, has the danger of giving an impression that there is more exactness in the results than is possible given the nature of the material being worked on. Economics has helped us to cope well with inflation, but not to eliminate it.

What is exciting about Hansen's analysis is that it offers the possibility of a rational approach to decision making, whatever ethical assumptions are brought into play. His further suggestion of, as I understand it, a decision grid based on a points system would be a further move in the direction of sound and rational decision making. (Decision grids work very well in making complex choices among a large number of candidates. For example, if one were looking to buy a house, a decision grid would list all the likely addresses along one side with all the characteristics sought along the top. A number between say one and five can be awarded for the desirable characteristic, so that after viewing 20 possible houses the search can be narrowed or concluded by a simple addition. The same process can be used

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in awarding scholarships or grants, and the results kept in the event of a legal challenge.

The grids would reveal the whole judgment process and provide evidence that it was reasonable and fair. Hansen's system seems to be a good deal more sophisticated than my back of the envelope example, although even such a simple decision grid as this is a remarkably powerful tool.)

An interim conclusion of this paper is that it would be ethically desirable to carry out further work on these mechanical techniques. They will make our moral judgments more rational and consistent. Whether they are more fair or just, however, will depend on other things.

The Logic of Ethics

Professor Gillon states at the outset of his paper that there is a wide variety of substantive ethical theories and principles of distributive justice with no one theory commanding wide, much less universal acceptance. Some of these theories have already been mentioned above and others discussed by Gillon will lead to similar results as those enumerated by Hansen, that is, a certain distribution that can be represented at a point on the Pareto curve.

While explaining the wide variety of theories of justice, Gillon points out that many of them "...could conform to the Aristotelian principle that equals should be treated equally and unequals, unequally in proportion to the relevant inequalities."⁵ Gillon describes this principle as a formal principle of justice. It is the only example he offers as a candidate for a rule of the logic of ethics. There are other simpler formal rules, such as that like cases should be treated alike if justice is to be done, which we shall come to presently.

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It is a remarkable fact that different ethical theories often produce the same practical result in real life. This is a fortunate result, because it allows people from different cultures, or people from the same culture but with different ethical views, to discuss their differences rationally, reach compromise and muddle along together. It is for this reason that tolerant democracies work.⁶

For example, Kant's ethical views, sophisticated utilitarianism, virtue theories, and various religious theories would all come up with the view that roughly the same sorts of killings are wrong. There will be disagreement only at the margins (abortion and euthanasia). In the medicines area both Marxist theories and Libertarian theories, which on the surface seem to lie at opposite extremes, might produce the same result. The New Zealand taxation system, as we have seen is based on the Marxist principle (according to Gillon) of "to each according to his need, from each according to his ability"⁷ and Libertarians might regard the New Zealand Health system as a form of national health insurance into which they have voluntarily contracted; voluntarily because New Zealand is easy enough to leave.

While particular values are far from universal, the logic of ethics, like the logic of mathematics, is universal. In order to reach rational decisions about what we ought to do, we need to understand something about the logic of ethics, as well as its appropriate content. Different branches of mathematics seem quite different, but are all compatible with one another.

Before the invention (or discovery, depending on your philosophical views on the nature of mathematics) of calculus, Galileo was forced to represent his theory of motion using the diagrams of Euclidean geometry, which made his reasoning difficult to follow. Today the average sixth form science student can understand them using simple algebra or calculus. Calculus is ideally suited to much of science. Geometry is more useful for measuring land areas than for expressing the laws of motion, and

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arithmetic better for doing the grocery bill.

As we learn to understand the logic of ethics better, there is hope that the different approaches to ethics enumerated by Gillon will be seen in time to be compatible. For example, Kant's views on ethics have been shown to be compatible with sophisticated utilitarianism.⁸ We can also say that some ethical theories are more suitable for some purposes than others, just as geometry is better for measuring space and arithmetic for doing bills. For example, focusing on the injunctions of mainstream religions, or as Aristotle did, on the virtues, is of more use in bringing up children and leading a good personal life than in arguing for social reforms, such as the elimination of slavery or homosexual law reform. As Bertrand Russell pointed out, the virtues are designed to preserve the status quo.⁹

Utilitarianism is used in deciding public policy, because it gives equal weight to equal interests of everyone impartially. However, Gillon, Hansen and Pharmac's current allocation policy, demonstrate the pitfalls that attend crude Utilitarianism. For example, arguing simply for the greatest happiness of the greatest number leaves out those who might prefer a simple life of suffering, fasting and prayer. (What the Scottish philosopher David Hume called the monkish virtues, which to his *bon vivant* nature were no virtues at all.¹⁰)

Utilitarianism is not, on the whole, a suitable doctrine for personal morality, since the tendency to give ones own interests overwhelming weight is almost impossible for fallible humans to resist. An individual would often find it almost impossible to make the utilitarian calculation impartially.

This is supported by the enormous amount of evidence found in court records of conflict of interest cases. It follows therefore that in personal and professional life, the best outcome all in all will more likely be achieved through relying on established principles,

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codes of professional ethics and in difficult cases seeking the advice of friends or moral specialists. This is a utilitarian argument for not relying on utilitarianism for standard decisions in ordinary life.¹¹

Logic has to do with the way our ideas fit together. If ideas do not fit together they are said to be ill formed or contradictory or inconsistent. In mathematics, ill formed ideas lead to contradictions and there are formal procedures for demonstrating this. Aristotle probably founded the study of logic and Gillon quotes a version of Aristotle's important principle that in ethics like cases must be treated alike. Another expression of this rule of logic is that our ethical statements must be consistent with one another, or we shall end up prescribing contradictory ethical judgments.

Since Aristotle, Immanuel Kant (1724-1804) has made the greatest contribution to our understanding of the logic of ethics. He was looking for certainty in ethics, just as he looked for certainty in our knowledge of the external world.

He was aware that the world of the a priori, the world of mathematics and logic, gave a level of certainty denied to the world of emotion, sentiment, belief, observation and experience. These latter give rise to merely temporary, inaccurate and unreliable beliefs.

Kant distinguished between on the one hand the logic of ethics, which was a priori (independent of experience), and therefore a secure basis on which to ground ethical beliefs, and on the other hand the study of what people actually did, which was empirical, belonged to anthropology rather than ethics, and was therefore not an adequate basis for providing a ground for moral belief.

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In modern terms we might rephrase this as the view that in order to reach rational decisions about what we ought to do, we need to understand something about the logic of ethics, as well as its appropriate content.

Ethical claims, which Kant couched in the language of unqualified duties, are universalisable prescriptions, which command us through our own autonomous consciences and reason. Kant's view is that in our dealings with others we should issue our moral prescriptions only if we are prepared to see them as universal laws. We bind ourselves in uttering such moral prescriptions. Kant wrote that we should never treat other people merely as means to our own ends, but also as ends in themselves. The reason is "For, the ends of a subject who is an end in itself must as far as possible be also my ends, if that representation is to have its full effect in me." ¹² In other words to decide ethically we must be able to put ourselves in the shoes of others.

To be ethical we should treat what other people want just as seriously as we treat our own wishes or preferences. This means, for example, that if we believe it right to have a cost cut-off point after which people may be allowed to perish, we are logically committed to prescribing that policy for whoever is affected by it, including ourselves and our own families. This rule might be called the logic of ethical reciprocity.

Another important feature of the logic of ethics, which Kant did not emphasise, but which the utilitarians did, is that ethical rules have to do with what is important to us as people, objectives such as happiness. It has been argued against the Kantian view that a universal rule that one ought to clasp and unclasp ones hands several times a day would not normally qualify as a duty, other things equal. The reason is that such a rule does not bear on anything in which anyone has an interest, and therefore no one

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would normally want to issue it as an ethical imperative.¹³

In fact Kant wrote that the "...natural end which all people have is their own happiness"¹⁴ but he also made the astute observation that "...it is a misfortune that the concept of happiness is such an indeterminate concept that, although every human being wishes to attain this, he can still never say determinately and consistently with himself what he really wishes and wills."¹⁵

Although he made the distinction, Kant did not fully appreciate the difference between the universal laws of ethical logic and the variety of values that might provide its content. His life experience was limited and he lived all his life in provincial Germany.

His was a monocultural world. Kant concentrated on the formal or logical properties of ethical rules with great success. His substantive values, on the other hand, were rigoristic and conventional and often mistaken; for example an absolute prohibition on lying (even to save a life) and absolute sexual prohibitions. They were the values of a German Lutheran, born and brought up in Konisberg, a centre of pietism where he lived all his life.

There is another feature of the logic of ethics that can be seen by what many theories have in common. First there is the Kantian view just discussed. Second there is the Christian view, apparently shared by many other religions, that we should do unto others as we would wish should be done to us. Third there is Rawls theory (discussed by both Gillon and Hansen) that we should do what is required by the principles which a group of rational and self interested people would accept for a future society if they did not know in advance what position they would have in it. (Rawls feels this would lead to adopting the maxmin principle to ensure that the worst off should be as well off as

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possible, but there is great dispute about this because it overlooks the wild rover who might prefer the opportunity to be very well off even at the risk of missing out altogether, and the dynamic society with opportunities for all to rise limitlessly, offset by equally dramatic falls.)

All these and probably many of the other views mentioned by Gillon have in common the idea of impartial or disinterested rules that operate independently of any special pleading. In other words, ethical rules must be impartial if they are to qualify as ethical.

These insights into the logic of ethics explain part of the basic framework we employ when we argue about how we should conduct our lives. Universalisability teaches us, for example, that if certain activities are wrong, then they are wrong for all irrespective of race, gender, age, religious confession or class position. If some activities are permitted, then they are permissible for anyone in similar circumstances.

New Zealand Values

We have both diverse values and many kinds of values. Not all values can be rationally debated, such as for example food preferences. Hence, the adage *de gustibus non disputandum*. As well as moral values there are architectural values, literary values, standards of physical beauty, rules of etiquette, rules of fair chairmanship, sartorial values, religious and spiritual values, fashion, tradition and so on indefinitely. The logic of ethics enables us to distinguish those values that are ethical, because they are issued as universal dispassionate prescriptions, from those that are merely local, such as Ponsonby table manners.

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One needs to be careful in making these distinctions, however, because it could quite reasonably be argued that morally one ought to adopt local table customs, out of consideration for one's hosts. Similarly, while the rule to drive on the left is not universal, there might be a moral requirement to adopt some conventions in order to diminish harm and danger and increase freedom of movement.

The logic of ethics helps, but does not take us a lot further down the track of what set of values should determine our position on the Pareto health curve, that is, what is a just distribution of subsidies for medicines among various groups. We can of course discount the Wellsian values at one end of the scale and the cattle breeding values at the other, although not all cultures at all times necessarily would.

Fortunately we do not have to recommend policy for all cultures over all times. We need to recommend policy only for four million New Zealanders now. We also, fortunately, have a well developed set of local New Zealand values. These are the values we must use because they are our own and we can all be expected to sign up for them.

On the occasion of his special appointment to the Order of New Zealand, on Waitangi Day 2007, Sir Owen Woodhouse spoke about his designing New Zealand's no-fault accident compensation scheme. He said "New Zealanders like to think that they are good practical people, as they are, though they are also a caring community, though they don't always say much about that. The scheme I tried to put together pulls these two qualities together."¹⁶

The logic of ethics requires that New Zealand's medicines policy should be consistent in its moral content with ACC and other such institutions. One morally relevant aspect is that the scheme is inclusive. That is, no one is left out.

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The Treaty of Waitangi also exemplifies a set of local New Zealand values, which are broadly accepted, increasingly enshrined in legislation and openly supported by past governments of different political views. The logic of ethical reciprocity ensures that these values, if applied, must be applied to all equally. This requirement will keep the Treaty relevant for the foreseeable future, and for all races here in New Zealand.

The Treaty of Waitangi

Before discussing the Treaty, it is important to make a distinction between the values manifested in the Treaty, its ethical whakapapa, and the current set of claims for compensation for misappropriated property. Compensation for misappropriated property is not based on need. Even if Maori were in the top ten percent of wealthy New Zealanders, justice would require compensation for misappropriated property. Indeed some individually wealthy Maori have benefited from settlements, although none of the settlements have come close to the real value of what has been misappropriated in the past.

What we are going to examine is the ethical background to the Treaty of Waitangi, which would be what it is even if there had been no breach of its undertakings. For the purposes of this paper, therefore, the ethical implications of breaches of the Treaty can be set aside.

The Treaty of Waitangi established nationwide governance in New Zealand for the first time. It was also New Zealand's first important public policy document. The Treaty recognized the moral equality of Maori and guaranteed them the Queen of England's protection and "...all the Rights and Privileges of British Subjects." It is important to recall just how radical this move was in 1840. At the time, for example, slavery was still a legal institution in the Southern States of the USA, and would continue to remain so for

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another twenty years.

Immanuel Kant, whose 1795 essay “Towards perpetual peace” (a wry pun on a tombstone inscription) foreshadowed the formation of the United Nations, wrote in 1797 that we should repudiate the taking of land by force or deception from its original inhabitants. No one took the slightest notice of his views at the time. He mentions with disapproval the forceful subjugation of “the American Indians, the Hottentots and the inhabitants of New Holland”¹⁷.

Just 43 years after Kant wrote this, the Treaty of Waitangi recognized the rights of original inhabitants, one of the earliest public documents to do so in human history. It is hardly surprising that subsequently in New Zealand there were lapses from the egalitarian ideal, most notably with the treatment of Maori interests and women’s interests, but also the treatment of ethnic minorities such as Chinese immigrants early last century and Polynesian immigrants later that century. What is a cause for celebration is that the founding ideals have not yet been lost from sight. Institutions such as the Ministry of Women’s Affairs, the Waitangi Tribunal, the Human Rights Commission and the Race relations Conciliator have been set up to promote the ideal of equality of all people in the advancement and protection of their interests.

The Treaty of Waitangi is an agreement between peoples. It expresses an early attempt to recognise the moral equality of an indigenous people, to include them in the moral community. The Treaty has powerful ethical implications. It influences public policy. Within New Zealand the laws have been changed, and will undoubtedly be changed again, to bring the legal system into greater conformity with the moral prescriptions seen to derive from the Treaty of Waitangi. Why is this?

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In her book on the Treaty, Claudia Orange has remarked that treaties with indigenous people were not unusual in British History. Most of these she writes are now forgotten and many people are puzzled that the Treaty of Waitangi remains a central issue in New Zealand.¹⁸ Michael King also accepts this view in his Penguin History of New Zealand. Although Hobson was instructed to negotiate a willing transfer of sovereignty from Maori to the Crown, King writes, Hobson was given no draft document prepared by the colonial office. Hobson cobbled together his own draft with the help of his secretary, James Freeman, and the British resident James Busby.¹⁹

These historical remarks completely overlook the distinguished whakapapa of the Treaty. They give a misleading impression that there was something off hand about it. In fact The Treaty is an expression of the most sophisticated ethical thinking of its time. This is one reason it continues to flourish.

In the mid nineteenth century, Britain had a classical liberal government with a tradition back into the great reforming Whig administrations of the past.

The cabinet ministers who succeeded one another as secretary of state in 1839 (Gleneg, Normanby and Russell) and the Colonial Office public servant who developed policy for them, James Stephen, shared enlightened views on the property rights of indigenous people and equality. They had been part of the movement that had led to the abolition of slavery in the British colonies.

These men were responsible for developing the policy that led to the Treaty of Waitangi. Sir James Stephen, for many years colonial under-secretary, had a hand in drafting the instructions that Lord Normanby and his successor, Lord John Russell, delivered to Hobson. Stephen was Virginia Woolf's grandfather.

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Lord John Russell (1792-1878) was Colonial Secretary from 1839 to 1841 and later Prime Minister of Britain. He was also Bertrand Russell's grandfather. The philosopher and mathematician, who was orphaned at three, grew up in Lord John's household and in due course inherited his title.

In his dispatch to Governor Hobson transmitting letters patent for the administration of the government of New Zealand as a separate colony, Russell set out in section IV the principles that should guide the Governor's dealings with Maori.

Russell ruled out any toleration of serious tribal warfare, leading one tribe to drive away or "almost exterminate another". He instructed Hobson that in such cases the Queen's sovereignty must be vindicated and the Governor exercising his authority must demonstrate the benefits of the whole community being protected.

However Russell suggested that in governing Maori it might be necessary to make some adaptations to English law. He wrote that Maori were "...a people among whom the arts of government had made some progress; who have established by their own customs a division and appropriation of the soil; who are not without some measure of agricultural skill, and a certain subordination of ranks; with usages having the character and authority of law."

Russell instructed Hobson to develop positive declaratory law authorizing the executive to tolerate local customs, since 'the analogies of the laws of England, as administered among Englishmen, whether at home or abroad, will, in many respects, be found to fail.' As with serious tribal warfare, not all customs were to be tolerated.

He wrote 'Amongst native customs, there are some which it will be

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the duty of the Government not to tolerate. Of these, the chief are cannibalism, human sacrifice, and infanticide. With such violations of the eternal and universal laws of morality no compromise can be made, under whatever pretext of religious or superstitious opinion they may have grown up.’²⁰(Russell J, 1840, p. 151.)

Russell went on to distinguish two other kinds of value; namely those which should be overcome gradually by the benign influence of ‘example, instruction and encouragement rather than legal penalties’ and finally those ‘which, being rather absurd and impolitic, than directly injurious, may be borne with, until they shall be voluntarily laid aside by a more enlightened generation.’

Today we would recognise this threefold distinction as separating public morality, private morality and manners, (in the sense of etiquette, as opposed to ethics). Furthermore, in Russell’s tripartite division of Maori values we can discern the beginnings of a genuine sense of cultural pluralism. Intrinsic to that pluralism is the important principle of toleration.

Russell’s instructions to Hobson were written against the background of the gradual extension in the 19th century of civic rights in education and politics to dissenters; Catholics, Jews, Wesleyans. The process is still going on in accord with the inexorable logic of the universality of ethical rules, demanding accommodation of the equal interests of all equally.

John Stuart Mill

At the same time development of economic theory was proceeding apace in Britain under the guidance of such men as Bentham, Ricardo and John Stuart Mill. Many of these classical

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liberals were also arguing for such social ideas as reform in prisons and factories, and political improvements such as extension of the vote to women and workingmen and the removal of political discrimination against Catholics and Jews. These two streams of rational economic and social thinking met most prominently in the economic and philosophical work of J S Mill.

His book, "Principles of Political Economy, with some of their applications to social philosophy", first published in 1848, replaced Adam Smith's "Wealth of Nations" as the dominant text in British Universities for the next forty years. Mill espoused the cause of workingmen and was elected a Member of Parliament for Westminster in 1865. He achieved a majority of several hundred over his Conservative rival.²¹ In that year he published "On Liberty" and "Political Economy" in cheap editions, such was the demand for them from working people.²²

Although he developed and changed his philosophical opinions over the years, Mill was too unbending to be a successful politician. He refused to put any of his personal assets into his election expenses, on the basis that it would be equivalent to buying a seat.²³ To others this just looked mean spirited.²⁴ He lost at the following election in 1868.

Something of his character is revealed from a remark he made in reply to Lord John Russell's courteous congratulations. Russell, although a liberal in the Whig tradition, was not wholly in agreement with all of Mill's views.²⁵ A week after Mill's success in the 1865 election, at lunch with his daughter-in-law Kate, Mill himself and Mill's step-daughter Helen, Lord Russell told Mill how glad he was that he had got in. Mill replied rather sourly "It remains to be seen if it is of any advantage to myself or anyone else."²⁶ (Russell, 1937, Vol 1, p 401) The relationship between the families was sufficiently close for Kate Amberly and her

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husband to ask Mill and his daughter to serve as secular godparents to the infant Bertrand Russell. Russell took lifelong pride in their acceptance of this role.

Mill was the first MP elected who had openly advocated votes for women. This success launched the long campaign, which eventually resulted in enfranchising women, first in New Zealand (1893) and subsequently in other democracies. He was a Member during the passage of the 1867 Reform Bill, which extended the vote to householders, mostly workingmen. He also argued for proportional representation because he felt that all electors should have their views represented.

In spite of his awkward personality and rigoristic ideals, he was the most famous British philosopher and economist of his time. Educated migrants leaving for New Zealand were often familiar with his ideas. He had a personal letter read into the New Zealand parliamentary record in 1868 by premier, William Stafford. A staunch defender of free trade, Mill argued against the use of tariffs to protect local infant industries, and went on in his letter to Stafford to suggest an economically less damaging method of moving beyond New Zealand's agricultural base through paying a temporary subsidy on manufactures.²⁷

Sir George Grey, Governor from 1845 to 1853 and again from 1861 to 1867, and Premier from 1877 to 1879, met Mill in London during a visit in 1868 and returned to New Zealand enthusiastic about Mill's views on land taxation. (Rogers, 1963, p157) Sir Robert Stout, Premier from 1884 to 1887 was also an enthusiast for Mill's ideas. Stout was said to speak in parliament, often with Mill's works piled "three feet high in front of him".²⁸

Mills economic research led him to the view that famine in Ireland had been caused by the cottier tenancy system, which gave the farmer no incentive to create a surplus. Mill's ideas on land

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reform and the superiority of “peasant proprietorship” led Liberal premier John Ballance, to establish the family owned farm as the normal form of land holding in New Zealand. Ballance, whose father had been a tenant farmer in Ireland, had a strong personal interest in improved forms of land tenure.²⁹

Ethics and public policy in New Zealand

It is clear therefore from even a casual glance at our history that public policy in New Zealand has been utilitarian from the first formation of nationwide governance. The Treaty of Waitangi itself is the first example. A recent significant example of pragmatic public policy typical of New Zealand is the report of the Royal Commission on Genetic Modification (RCGM). At the most general level the Royal Commission concluded that New Zealand should keep its options open. It expressed the view that the human race has ever been on the cusp of innovation, and that currently biotechnology is the new frontier. The detailed recommendations were formulated with the objective of permitting research to go forward with care, a sensible pragmatic outcome which carefully took into account the many views expressed during the hearings.³⁰ Another example mentioned earlier is the Accident Compensation Commission.

Public policy has been based on seeking policies which government expects will lead to the best outcome, all in all, for society as a whole. New Zealand has been in pursuit of an egalitarian society because the experience of the British settlers prior to their coming to New Zealand gave them good reason to believe that such a society would, on the whole, give greater opportunity for everyone to achieve their objectives. Policies have been designed to advance the equal interests of all equally. No one has been excluded.

Utilitarianism is suitable for making decisions in a pluralistic

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society because no assumption is made about what any person's particular preferences might be. Utilitarianism merely recommends the policy mix within which every person's values are recognized and their interests advanced to the maximum.³¹

Public consultation is now a common policy tool in New Zealand. Consultation has three important functions in the utilitarian calculus. First, it allows governments to gauge the range and weight of interests and the room for trade offs. Second, it provides an opportunity to reconcile apparently conflicting values. Third and perhaps most important, it gives people an opportunity to develop and modify their views in the face of new knowledge.

Objections to Utilitarianism

There are problems with getting the Utilitarian calculus right. It seems easy to devise farfetched cases which cast doubt on the theory. Gillon cites the famous case of Jim and Pedro, devised by the late Bernard Williams. Jim, a botanist travelling in South America, arrives in a small town market square, as Pedro is about to shoot 20 indigenous Indians to deter them from political activities. Pedro offers Jim, as an honoured visitor, the privilege of shooting one of the Indians and freeing the other 19. If Jim declines then Pedro will simply pursue his original plan and shoot all 20. Williams argues that it would clearly be morally wrong to shoot one of the Indians in cold blood. We are to conclude, therefore, that utilitarianism is wrong.

Utilitarianism is an unsuitable standpoint for personal morality, because of the difficulty of being impartial about one's own interests. Virtue ethics is a better system in which to raise one's children, for example, and good utilitarian reasons were given for this. So what would a virtuous person do in these highly unusual circumstances? One possibility is that being well brought up, he

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would refuse the offer and so condemn all 20 to death. If he were sensible, Pedro would then shoot Jim in case he gave evidence to a subsequent war crimes commission.

This does not seem to be the right course of action either and the difficulty of deciding demonstrates how one's moral intuitions can let one down in unusual or unforeseen circumstances. It is not only in cases of serious temptation that it is difficult to do the right thing. In this sort of case it is extremely difficult even to know what one ought to do.

To tackle a moral dilemma for which we have not been equipped by childhood training and upbringing or by commonly accepted rules that do not fit the case, it is necessary to do some difficult ethical analysis. A good start might be to put the case into an appropriate moral framework by comparing it with cases which might have illuminating similarities.

This is what we are trying to do with the moral dilemma of allocating medicines expenditure. The case of Jim and Pedro is instructive for this very reason and we shall pursue it further. First, we need to look at a range of other realistic cases sufficiently similar in their moral qualities to give guidance in the case of Jim and Pedro.

One realistic case discussed by moral philosophers before the development of synthetic fibres is the situation in which there is a climbing accident in which the lower climbers are left hanging from a sisal rope, which is fraying against the rocks. If the penultimate climber cuts the rope, thus saving all the rest, it would not be murder.

If the portly last climber cuts herself free thus plunging to her death, it would not be suicide, but an act of great moral heroism.

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Conservative Christian Thomist moral philosophers accept this result. It shows that not all taking of innocent life is wrong.

A second set of more difficult cases centers on 19th century shipwreck survivors stranded in lifeboats. In one famous case in which the lifeboat was overloaded and taking in water, the Captain ordered the two oldest people to leave.

As it happened the couple agreed that they had had a good life, and that the younger people and those with the skill to navigate the boat to safety should remain. In fact a passing ship rescued the survivors the next morning. The captain received a short gaol sentence for acting before absolutely necessary. What he did would in extreme circumstances have been morally right, but he acted prematurely.

Other cases are more difficult. There are historical accounts of shipwrecked New England whalers drawing lots to eat one another. In one case on which the novel "Moby Dick" is said to have been loosely based, the captain acted impartially and agreed when the time came, that his young nephew should be eaten. The story has a special irony in that the sailors could have reached Tonga on their existing supplies, but decided to travel directly to New England because of their belief that the Tongans were cannibals. On their return it was accepted that necessity had made what they did right, but the rest of the community in the township of New Bedford shunned the survivors ever after.

I have heard of only one case where sailors were hanged for murder after surviving such an ordeal. In that case lots were not drawn. These hard men ate the cabin boy, who was young and plump.

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There is no need to think up far-fetched and silly examples to test utilitarian theory. In real life lived in extreme conditions there are many difficult cases which are made more difficult because most of us have no experience of dealing with them. In such circumstances most people would stay with the moral intuitions and instincts that they have as a result of their early upbringing. So they should.

The results would be calamitous if every person were able to revise their moral code in difficult circumstances, especially if things were going against them, as things do for all of us from time to time.

Against this background we may look again at the case of Jim and Pedro. If we accept Kant's analysis of autonomy and give equal weight to the ends of others (that is in modern language, the objectives, interests or preferences of all concerned) we should in the absence of a standard rule of behaviour, imaginatively put ourselves in the position of each person in turn, so treating them as ends and never merely as means alone. In the case of the twenty peasants we could imagine asking Pedro to tell them to choose among themselves the one person who has the least to lose by death, perhaps the oldest man with many descendants who has lost his capacity to enjoy life. He might even choose himself and volunteer for the job.

While this is going on, one might buy more time to make ones Kantian calculation by borrowing Pedro's gun, to sight it in and familiarize oneself with its operation. Putting oneself in the position of the peasants, assuming they are not just bandits, one would see the aims they were fighting for and understand how they felt suffering under a vile and tyrannous dictatorship, represented by Pedro. What they want is freedom, justice and a reasonable life. They may also enjoy the excitement of revolution

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and war for its own sake. In the case of Pedro one could see that he believed that unless the peasants were ruled with a firm hand his country would be constantly subject to war, strikes and rebellion. Progress out of the third world would remain an elusive dream and disease, famine and underdevelopment would continue to stalk the land.

Jim must also consider what he would will himself, for his interests also count. He has been brought up to be revolted at the thought of killing another. He also believed that he should exercise the Aristotelian virtue of courage, midway between cowardice and rashness. He was not acting precipitately or rashly, neither was he in an abject funk, refusing to deal with the problem. On Kant's analysis he was putting himself in the position of each person in turn.

He felt he understood what each person wanted and how intensely. He accepted that often doing the right thing is very difficult and takes great courage. Furthermore, the old man who in the interim has volunteered for death is now pleading with him to get it over with. Jim who in his schooldays would often wait outside the headmaster's office for a caning, knew very well that waiting was worse than the event itself. He had complete empathy with the old man and decided on the spot to get it over with. He made his decision and acted.

What decision did he make? For us to decide on a Kantian basis what Jim ought to do we in turn have to put ourselves imaginatively in his shoes, make his ends our ends. Few of us know how we would behave in such extreme circumstances. When I lived in a war zone, and on another occasion spent time with insurgents and armed soldiers, I often felt very frightened. Sometimes we cannot live up to our own expectations of ourselves. That is just human and why living a moral life is so

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difficult. But if the case of Jim and Pedro is to be taken seriously, against the background of the similar cases discussed above, it is quite clear to me what one ought to do if one were Jim.

The morally correct thing to do after rational reflection and sighting in the gun would be to shoot Pedro. After apologising to the old man for making his life pretty miserable for half an hour or so, one might give serious consideration to joining the revolution.

Of course Williams, who like many academic philosophers seems to have preferred arguing for the fun of it rather than making a serious contribution to real life ethical problems, would argue that the act would have been futile, since both Jim and the peasants would likely be all killed by Pedro's soldiers. Williams was hostile to a Kantian analysis of the sort outlined above.

But we cannot be confident that Jim's act was futile. The soldiers, recognizing an ethical act of leadership and courage might also join the revolution. Even if the militia does kill Jim and all the peasants, some soldiers may think about events later in life and contritely change their attitudes. These stories can and do get about in the real world, and the revolution might be greatly heartened by it. Finally, even if all die, no soldier subsequently feels contrite, and the revolution ultimately fails, Jim and the peasants will at least all die in better spirits knowing that the right thing had been done.

Because these likely outcomes are the best, taking everything into account without breaching the logic of ethics, the morally correct outcome can also be said to be utilitarian. What is interesting to us about Williams's case is that it also has a cross-cultural component. Jim, being a gentle English scholar, did not share the taste for violence indulged by Pedro and the peasants.

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Pedro and the peasants both wanted the economic development of their country, but Jim the botanist had a stronger interest in preserving the endangered plant species he had discovered. Nevertheless, in spite of these differences and conflicts, it was possible to make the morally right choice.

We have spent a lot of time on the Jim and Pedro case because it is absolutely typical of simplistic objections to utilitarianism. All these examples trade on a lack of sufficient ethically relevant detail to show that only one course of action is required by utilitarian theory, and that course is clearly wrong. If someone were clever enough to detail such a case, then the answer might well be that the intuitively wrong course of action was in fact morally right. But we still await the production of such a case.

Unfortunately, the utilitarian calculus can and often is done carelessly, especially when it is not governed by the logic of ethical language. Crude utilitarianism is extremely dangerous and has been justly blamed for such appalling public policies as the Vietnam War. But in New Zealand, crude rights based policy has fared no better. For example, the US places great emphasis on rights, and correctly understood they are important tools in defending our liberties. But legal and ethical rights are often confused.

Some argue, for example, that citizens have a right to bear arms. They argue that even if society were better off without hand guns, that is too bad, because the right to bear arms is more important and must not be infringed.

In New Zealand there are people who argue that, even if some are killed by their mentally ill living companions, or swindled by their dishonest business partners, the right to privacy trumps the social benefits of being able to learn all you might need to know

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about those you live with. Here moral rights are being confused with legal rights. Utilitarianism would give different answers.

During the reforms of the 1980s much harm was done by the careless introduction of rights based thinking, probably by American analysts in Treasury and New Zealand economists and lawyers trained in the US. For example, the policy reforms allowed military style firearms and dangerous dogs such as pit bull terriers into the country. But few New Zealanders are persuaded by rights based arguments that citizens should be free to own dangerous dogs or weapons. If such items, all in all, leave the community worse off, then it is best to do without them. New Zealanders would regard this as plain common sense.

The strongest objection to utilitarianism is the difficulty of getting the calculation right. Kant was rightly suspicious of the concept of happiness because of its vagueness. Aristotle's concept of happiness was that it came from the successful pursuit of one's most important goals and objectives and much modern management jargon and advice on personal living derives from this definition.

The injunction to set goals, solve problems and get results, to avoid conflicting objectives and be sure that what you think you want is what you really do want (because you will probably end up getting it) is Aristotle's ethics in modern jargon.

So in spite of Kant's reservations about it, happiness, at least in this sense, is fairly close to the mark as an appropriate goal of public policy.

Another objection we have already covered is the difficulty of remaining impartial about one's own interests in making the

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calculation, which is why in personal life one must rely on the ethical virtues that one has (hopefully) learned growing up.

Governments unfortunately face similar difficulties in formulating utilitarian public policy, as do individuals. Furthermore, governments face the daunting and complicated problem of trying to assess what millions of their citizens really want, a process fortunately sharpened by the prospect of losing elections. In addition, governments must have an eye to the medium term at least, because many actions that seem reasonable to the individual (driving home after a bottle of wine, for example) will if adopted on a large scale do great harm. Few of us felt morally wrong driving our cars this morning, but perhaps we were. Millions of people driving their cars every day are changing the climate, bringing death and destruction on a horrendous scale. A large number of insignificant harms can add up to a very great harm indeed. The nation of Tuvalu, for example, may be completely submerged in the next fifty years, or sooner.

Finally, it has never been claimed by utilitarians that following that theory will make us morally infallible. Mistakes can and will be made. But in difficult moral dilemmas where there is no clear cut broadly accepted answer, a careful utilitarian calculation is most likely, most of the time, to come up with the most morally acceptable judgement.

Funding Medicines

Pharmac posed the stark question whether it is appropriate to fund high cost medicines for a few people at the expense of lower cost medicines that benefit many more people. There are also expensive medicines that are better for some people than the lower cost ones currently subsidized. Pharmac has also written "The cost of these medicines can be so high that the health gain,

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even if relatively large, is swamped by the cost of the medicine and so becomes....poor value for money.” (p.1)

As a result of these considerations, some people above the cut off point for funding may perish. Many more suffer greatly because they are unable to access better but more expensive medicines.

The whole point of a national insurance function is to fund medicines that are beyond the reach of average incomes. For this reason, the question of expense is not in itself relevant except in so far as the insurance fund cannot meet it. Morally, those covered by the insurance ought to get support.

Our values, described by Sir Owen Woodhouse, of being a practical caring people would lead to the view that something practical should be done to solve the problem of the inadequacy of the insurance fund. In an earlier section of the paper discussing Hansen’s economic model we saw that maximum economic efficiency was reached at the point at which no group could make a gain without others losing out.

We saw that the Pareto curve tracked those points and showed how inside the curve no loss gains could be made by, for example, squeezing corruption or bureaucratic inefficiency out of the system. Another possibility would be to review the entire schedule from time to time searching for medicines funded historically rather than because of their effectiveness, and removing them.

Pharmac’s Conflicting Roles

However, we also claimed that there was one other way in which

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a no loss gain could be made, for example for those suffering from rare and expensive diseases. (para 2, p.4) This result could be simply and practically achieved, of course, by increasing the budget. Pharmac is charged with managing the existing budget and recommending its total size. Both these roles serve the interest of providing New Zealanders with affordable medicines, but the two roles conflict.

The concept of conflicting roles is an important one that has only recently been recognised in public policy making. It is illustrated by the different roles played by police, defence and prosecution lawyers, judge and jury in the justice system. All these players have the same interest, namely the delivery of justice, but long experience has shown that the common interest is better achieved if all these roles are separated out.

In its role of both recommending the total budget and managing it Pharmac cannot help but see those who require expensive medicines as getting them at the expense of others, because Pharmac operates (we hope) at Pareto efficiency. This is one of the many illuminating conclusions that can be drawn from Hansen's model.

Another consideration is the harsh trade off offered between the some and the many. This is not a realistic trade off. It may be more realistic to save the few at the expense of free entry to Te Papa, or funding for a new frigate, or toll free highways, or by shaving a dollar off all welfare benefits for the physically fit, or innumerable other ways of reorganising the public purse. Such trade offs are not within the gift of Pharmac and provide a further reason that the funding recommendations and the fund management roles should be separated. Making life and death policy decisions of this sort is the proper job of politicians who are immediately answerable to the electorate.

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Cabinet must make budget trade offs, especially those affecting life and death decisions. These decisions must be made on the basis of impartial information, rather than on the basis of the views of budget managers charged with negotiating best value for money.

Another example of a life and death decision which society must make is a decision about whether or not to go to war, or to offer troops to another country at war. These decisions are not delegated to the armed forces. Nor should critical decisions on funding medicines be delegated to Pharmac, or indeed any other group of public servants.

The Treaty of Waitangi promised Maori continued possession of their lands forests fisheries and taonga. Taonga has been given a suitably wide interpretation to cover cultural and linguistic possessions. The logic of ethical reciprocity requires the state to extend such protection equally to all New Zealanders. Hobson expressed the point of the Treaty on the day, to reassure Maori that in the moral and political sense, that we are one people. That is, we are equals in the eyes of the crown. It was of course assumed that the Crown would secure the British settlers in their possessions, but that Maori needed an undertaking that their property would be safeguarded.

For pakeha New Zealanders, as well as Maori, high among the most treasured possessions must rank good health and life, so to the extent that the government is prepared to seek these for one, it is morally obligated to seek them for all equally. Even in the artificial situation of fixed funding there are many ways of allocating resources that might be fairer than current practice, and more in keeping with New Zealand values.

The Treaty of Waitangi would imply that the most serious cases should receive priority. These cases will include cheap

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preventative therapy for cases such as diabetes, which if left untreated will quickly lead to more serious conditions. But it will also include rare and expensive diseases. It follows from this that, it is not obviously right that cheap medicines for mild conditions affecting many people should be weighed on the same balance as expensive medicines for rare and serious conditions affecting a few people.

A major defect of the current use of the concept of a QALY is that it appears to do just that. Another defect is that it conflates two different values, length of life and quality of life. Some people who have had a full life and who have largely discharged their family responsibilities might choose a shorter more enjoyable life, pumped up on palliative drugs. Others concerned about their children, or finishing an important project such as a book, might choose a much longer life wracked by torment and suffering.

The concept of a QALY could be used to assess medicines and treatments for cases of equal seriousness, but not for allocating resources among different levels of seriousness.

The rule of rescue

Gillon and others discussed the so called “rule of rescue” at length. Gillon quotes the “rule of rescue” as ‘the powerful human proclivity to rescue endangered life’.

One might add that in New Zealand and no doubt other places this proclivity also extends to saving the lives of animals and plants, especially but not only those belonging to endangered species. The rule of rescue is also described as the urge to rescue identifiable individuals facing avoidable death, without giving much thought to the opportunity cost of doing so.

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Gillon describes several variants of the rule, including the tendency to fly children at great expense with non life threatening conditions from developing countries to receive surgery in developed countries for their disfigurement. There are many cases where publicity, especially on television, generates an apparently disproportionate public response. The moral dilemma is that the money might be spent more efficiently saving many more lives.

Gillon writes “It would be nice to be able to answer questions about how to deal with conflicting moral values or principles, and how to deal with moral dilemmas, with moral certainty or even with moral confidence, but alas I can’t”³² Indeed.

There are good reasons for reinforcing and supporting the rule of rescue in everyday life. A society in which the community turns out to rescue a pod of whales stranded on a beach, or in which people pull out all stops to rescue trapped miners no matter the cost, is more likely to be the sort of society in which we will take care to advance everyone’s legitimate interest whenever we reasonably can. Thus, we raise funds to send off promising musicians for further training or promising young sports people and give awards for valour to those who have contributed heroically to the interests of others.

Gillon has also totally missed the moral significance of making disproportionate efforts in the face of imminent, life threatening harm. The point is that were any one of us in that situation we would want to be helped similarly. We do not feel the same way about someone with a sprained ankle, although we might sympathise. Furthermore, financial cost is not the basis on which we act. If someone trapped under a motor vehicle were haemorrhaging to death, most people would immediately, and

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indifferently, press a cheap towel or an expensive Irish linen table cloth, or anything to hand, against the wound to stem the blood flow until help arrived.

The rule of rescue has many splendid examples in New Zealand and is recognised across cultures. For example, in March 1884 Wetere Te Rerenga rescued two English surveyors whose boat had capsized on the Mokau river bar. He was awarded the medal of the Royal Humane Society of Australasia for the rescue.³³ What is remarkable about this case is that in 1869 Wetere had led an attack on a British military redoubt that threatened his lands in Mokau and killed everyone in it. In New Zealand, in extreme circumstances, the rule of rescue also applies to one's enemies.

It should be noted that giving high priority to urgent life threatening situations is not a universal value. Why is this an important value to both pakeha and Maori New Zealanders? It might possibly have something to do with what Kant felt belonged to anthropology rather than ethics. We might surmise that people in overpopulated countries tend to be less concerned about death because there is no shortage of people.

By contrast Maori arriving in this country a mere thirty generations ago, found themselves in a land empty of human life. The Ngaiterangi whakatauki, "Kei hea te komako e ki nei? Hei aha te mea nui o te ao? Maku ka ki atu, he tangata, he tangata." quoted by commentator Matiu Dickson³⁴, is completely intelligible against that background. In some other traditions we put it more bluntly, "He aha te mea nui, he tangata, he tangata, he tangata".

Early pakeha settlers arriving five or six generations ago found themselves in a land which looked empty, from the point of view of the England they had left behind. This, combined with their Christian sensitivity to the sanctity of life might explain their

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concern. Whether concern for the sanctity of life survives burgeoning population growth and the diminishment of Christian ethics remains to be seen.

What is morally significant about the rule of rescue is that we in New Zealand give urgent priority to cases of greater need. The issue of cost is morally secondary. From the logic of ethics requiring us to treat like cases alike, it follows that all cases of urgent need should receive the same consideration. This is yet another argument for separating policy development on budget size from responsibility for managing the budget decided on, and to separate both from responsibility for negotiating price and supply with the pharmaceutical companies.

Prioritising Medicines

How should resources be prioritised within a fixed budget? The instinctive response of most New Zealanders would be to give priority to the most serious cases. This suggests that the most serious cases head the queue, with the less serious cases following. The cut off point, where we run out of funds, would then lie somewhere further down the scale of seriousness. Here it might turn out that most medicines were within the reach of most citizens. This would be a case of offering national insurance for the most serious cases only, which is the normal insurance function. This already happens in a muddled sort of way, since no one seriously argues that the government should subsidise medicines for the most trivial of situations.

The problem with prioritizing medicines based on the seriousness of the conditions they treat effectively is that, although ethical, the political consequences might not be predictable. It is difficult to discuss such an allocation system in the absence of information about the costs involved. The Ministry of Health should undertake

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the analysis to see what such an allocation would look like.

Under present policy there is a cut off point for expensive medicines after which subsidy is much less likely to be available. Putting oneself imaginatively in the position of these people, as Kant said we must, is not a pleasant exercise. It probably feels like being thrown out of the lifeboat, without volunteering and without even having drawn the short straw.

Two possible policies suggest themselves. For those better but more expensive medicines treating relatively common conditions, the same level of subsidy should be available as for the subsidised but cheaper medicine. The extra cost would then be borne by the patient. This is not ideal because it focuses on price and not on the level of suffering. But the cost to the community would be the same. In other words, the sum provided is the same, but the patient and physician are free to choose any medicine to which to apply it, the patient then making up any difference between the subsidy level and the price.

For the high cost per capita medicines well beyond the cut off point, the obvious, practical and caring solution is to pool the resources available to all the patients at the cut off point, and run a ballot for those who will receive the medicine. It is better that one person lives and nine die than that all ten die. This is morally analogous to the lifeboat cases discussed above. It is in keeping with our values. New Zealand used to ballot Lands and Survey farms so that young qualified farmers could be settled on the land. These farmers received great benefits from the community, but no one felt that was unfair, anymore than they think it unfair that some win lotto and others do not.

Furthermore, a ballot system would bring home to the community the reality of the decisions that government is making on our

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behalf. It would provide an opportunity for altruistic people to drop out of the ballot to enhance the chances of younger patients or close relatives or just because they felt others might benefit more from treatment. It would keep hope alive. In time as prosperity rises and medicines costs fall it may become unnecessary. Balloting would strengthen and enhance the moral community. These are additional reasons for introducing it.

The idea of a cut-off point after which there is little hope is totally contrary to New Zealand values and quite unethical. It also encourages an apparatchik approach to public policy, dulling moral sensibilities and causing socially disruptive anger and resentment.

Knock on Effects

While we have discussed the primary ethical considerations for the patients who may benefit from expensive medicines, we also need to give thought to the knock on effects of rationing medicines. Just as sound ethical action leads to desirable developments, so do unethical actions and unethical policy settings lead to further downstream evil.

The good effects of robust and successful efforts to buy effective medicines more cheaply are that drug prices are kept at reasonable levels, more people can be treated effectively and the Pharmaceutical budget stretches further.

On the other hand, doctors who are unable to prescribe suitable drugs for their patients will, if the situation becomes too drastic, lose morale and find themselves practicing their skills at less than optimum level. They may even find their skills slipping. They may, and apparently do, leave New Zealand to practice medicine elsewhere.

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Patients will lose confidence in the health system. There is worse to come. Apart from prescription charges there is no health insurance available in New Zealand for medicines. Some will be able to afford expensive private treatments, again giving rise to socially unhealthy envy and resentment. The very wealthy will be able to afford the best treatment in the world, in the United States or in Switzerland.

Making some care available through balloting it, on the other hand, will help keep medical knowledge growing here in New Zealand, and provide some small hope for doctors that at least some of their patients can be treated until affordable alternatives are discovered.

Conclusion

The paper began by noting that under current arrangements there is a cost cut off point such that there are some people with rare conditions who, on the ground of cost alone, may receive no effective subsidized medicine and therefore perish prematurely. The question was whether that was ethically acceptable.

The answer we have reached is that it is certainly not. Such a policy falls away from the national insurance function of medicines policy. The logic of ethics requires us to treat the equal interests of everyone equally, and therefore give equal priority to cases of equal seriousness, whether a life threatening haemorrhage cheaply treatable, or a life threatening rare and extremely expensive condition.

Non life threatening conditions causing great discomfort would come next on the scale and would all have to be treated equally,

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at least to the extent that patients felt equally strongly about them.

Several suggestions were made about how this moral obligation might be met consistent with our own values; increasing the budget through Cabinet taking responsibility for the trade offs involved, shifting funding from less serious conditions and balloting. Probably some appropriate mix would be the most ethical compromise. To achieve this result, the role of budget setting must be separated from the role of budget management, and both roles separated from negotiating price and supply arrangements.

The second point with which we began was that there are many more people with conditions that would be alleviated by medicines that are not currently subsidized on the ground of expense. They must either suffer or meet the whole cost themselves. The question is whether this is fair.

The answer we have reached is that it is not fair, but the situation is less serious than the first set of cases. A fair interim solution would be to offer a set level of subsidy which the patient and physician could apply as they saw fit.

Pharmac's crude utilitarian analyses give insufficient weight to the severity of illnesses and too much negative weight to the costs of medicines for them. This does not reflect New Zealand values.

There is a serious conflict of roles with Pharmac having responsibility for setting the medicines budget, managing the budget finally decided on and also negotiating prices and supply arrangements with the pharmaceutical companies.

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It is hopelessly immoral to use the lives of unwell New Zealanders as bargaining chips in the otherwise laudable effort to drive down the price of pharmaceuticals. Furthermore, to use the lives of seriously ill people in need of very expensive medicines as bargaining chips in an effort to bring down prices of other drugs to treat large numbers of people with less expensive conditions would not be treating cases of equal seriousness equally. It would be using the very ill people as means only, in breach of their moral autonomy (in the Kantian sense) and would be proportionately evil.

Finally, further work should be undertaken on developing a points system and on using decision grid type techniques such as Hansen's computer programme to make allocation decisions more consistent, fair and transparent, in the effort to treat cases of equal urgency and seriousness equally. Further work will also be required to rank four or five levels of seriousness in order to facilitate a fair allocation of resources among the different levels. The techniques, such as Cost Utility Analysis, already exist to spread resources within a given level of seriousness.

Acknowledgements

This paper has benefited from discussions with colleagues John Forman, Lynne Lane and Roger Palairt and members of the Access to Medicines Coalition. Reflections on the ethical background to the Treaty of Waitangi stemmed from a long conversation with Richard Carlyon. I am grateful to him. Lawyers John Kennedy Good and Richman Wee made helpful comments on the relationship between Kant and the Utilitarians. Historian Louise Ormsby provided historical guidance, in particular drawing my attention to the article by Frank Rogers.

The paper was peer reviewed by philosopher Jim Thornton and

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health research specialist, Bruce Scoggins. I have endeavored to take their perceptive comments into account.

I am responsible for remaining shortcomings and mistakes.

M J ORMSBY

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APPENDIX 2:

CASE STUDIES ON 'PEOPLE WHO MISS OUT'

- A) Diabetes Treatments**
- B) Breast Cancer Treatments**
- C) Growth Hormone for Children with Prader-Willi Syndrome**
- D) Enzyme Replacement Therapy for Gaucher disease**
- E) Delays in funding medicines for HIV/Aids**

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A) Poor Access to Diabetes Treatments in New Zealand

This information was supplied by Diabetes New Zealand on consequences of denied subsidies and restricted access to medicines - March 2007

Summary

Medicines for all diabetes patients contribute to current quality of life, but also have a critical role in preventing life threatening long term complications. Three examples are presented of diabetes related treatments for which PHARMAC decided to restrict access despite good evidence of benefits associated with their wider use. In Australia and the UK there is better access to these products compared with New Zealand.

It is important to understand that increased access to these products would not only lead to better health outcomes, but the increased costs in the short term would be offset by longer term improvement in health outcomes and savings in other health services e.g. kidney dialysis (40% of patients with renal failure in New Zealand have diabetes), surgery and prostheses for amputations. A report commissioned in 2001 by Diabetes New Zealand, reviewed policies which would result in better outcomes and ultimate cost reductions in dealing with the Type 2 diabetes epidemic. One of their recommendations was that PHARMAC “be encouraged to take a 10–20 year perspective”. They also calculated that cost savings from an optimal services approach to diabetes could be as high as \$320 million a year in 20 years time. (PriceWaterhouseCooper, Diabetes New Zealand, Type 2 Diabetes, Managing for Better Health Outcomes 2001, p96).

1. DIABETES TYPE 1: INSULIN GLARGINE

1.1 Action and Benefits

This is long acting insulin which provides relatively constant action with no pronounced peak over 24 hours. It closely mimics the background insulin production of the pancreas. This action substantially reduces the chances of hypoglycaemia, an acute complication resulting from too much insulin or too little food lowering the blood glucose level. Use of insulin glargine enables the patient to gain greater control over blood glucose levels and this in turn is a critical step towards reducing long term, expensive complications (kidney failure, blindness, cardiovascular disease etc.). For children with Type 1 diabetes the benefits are especially likely in avoiding stressful and disruptive 'hypos' and in reducing the long term damage caused by extended blood glucose variability.

1.2 Pharmaceutical Schedule

After a lengthy delay, insulin glargine has been listed on the Pharmaceutical Schedule, but with strict limitations for prescribing. It can only be prescribed by a relevant specialist for 1 year for Type 1 patients with certain severe hypoglaecemic reactions or allergic reactions to other insulins. Renewal is also subject to limitations and patients with Type 2 diabetes who are on insulin are not eligible at all. Diabetes Youth New Zealand has reports of refusals of applications for insulin glargine and of inconsistencies in prescribing.

In Australia and UK, Insulin glargine is fully funded.

2. DIABETES TYPE 1: BLOOD KETONE TESTING STRIPS

2.1 Action and Benefits

Diabetic Ketoacidosis (DKA) can be a life threatening condition for Type 1 diabetes patients. An insulin deficit means that glucose cannot enter the body cells, giving rise to a 'starvation' response and production of ketones which form when cells do not have enough energy. A build up of ketones causes the blood to become acidic and, untreated, can result in coma and death. It is very important to measure ketone levels as part of the management of Type 1. Children with Type 1 may have a high rate of eating disorders and may manipulate insulin doses to encourage fat burning ketones.

Urine testing has been the traditional method and test strips are partially funded. They are inconvenient for obvious reasons but, most important, give a delayed, outdated reading.

Since 2001 quantitative, real time testing has been possible with blood testing strips. These can be used with available subsidised meters and provide immediate and accurate measures of the ketone levels in the blood.

2.2 Pharmaceutical Schedule

Application has been made by Diabetes Youth New Zealand for listing of blood ketone strips, without success.

In Australia **only** blood ketone strips are available, having replaced the urine strips.

3. DIABETES TYPE 2: BLOOD GLUCOSE TESTING STRIPS

3.1 Action and Benefits

Many Type 2 patients are able to control their blood glucose (BG) with diet and exercise and others with the addition of oral medication. In many of these cases there is little or no likelihood of a hypoglycaemic reaction (very low blood glucose). However, it is critical for all patients to attain control over BG levels to help prevent long term, costly complications – i.e. to use self management. Regular daily testing with a blood glucose meter, using blood glucose testing strips, gives feedback for patient and GP on the success of the diet, activity levels and medication. Frequent, testing (3-4 times a day) is of most importance for a period after first diagnosis, during changes in treatment, for children and adolescents, during illness, and when medication is taken for co-morbidities.

Some studies of the effects of self monitoring for Type 2 patients suggest better long term outcomes, others show no positive effects. Closer examination of these studies has led to the conclusion that the really important issue is the use made of self monitoring results – knowing what to do about the BG level, or in other words education for living with diabetes. But even if education is limited, the starting point for self management must be a regular and frequent feedback of BG information.

3.2 Pharmaceutical Schedule

In 2004 PHARMAC restricted availability of BG test strips for all Type 2 patients not liable to 'hypos'. Subsidised test strips are limited to 50 per three month prescription. In some circumstances multiple prescriptions may be written, but the assumption has been made that there is no need for self monitoring more than 2-3 times a week. At a time when it is increasingly being realised, here and overseas, that self management can lead to striking improvements in BG control, PHARMAC has greatly limited an important tool for helping prevent the kidney damage, lower limb amputations and other expensive consequences of poorly controlled high blood glucose. Savings on test strips per person, would be approx \$176p.a. (based on PHARMAC figures for 2005-2006) There is obviously not a one to one relationship, but these savings look rather minor when viewed against the cost of renal dialysis at about \$50,000 per patient per year, and 40% of kidney dialysis patients have diabetes.

B) Poor Access to Breast Cancer Treatments

Prepared by Breast Cancer Aotearoa Coalition (BCAC) February 2007

Summary

There are a number of treatments that are known to improve health outcomes for women with breast cancer. We consider three examples where PHARMAC's decisions to fund these products and/or the clinical indications for their use are quite inconsistent with the clinical practice recommended by New Zealand experts, and differ significantly from the access afforded to these medicines in other developed countries. Heated debates on the clinical appropriateness of these decisions are unresolved, without any clear process to move them forward. Furthermore, many of these decisions are not made in a timely manner.

Many women diagnosed with breast cancer feel PHARMAC's decisions result in them being unfairly denied access to life saving medicines and they are going to extraordinary lengths to fund the treatment themselves. These decisions are frustrating for health professionals, and causing extreme distress for the individuals, their families and their communities. Furthermore, PHARMAC delays sometime for years, making decisions on funding treatments following receipt of affirmative clinical recommendations. This situation is particularly unacceptable for the women diagnosed with cancer who believe they urgently need to commence such treatment to maximize their chance of survival.

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WHO Guidelines on cancer screening clearly state it is unethical for the New Zealand Government to fund a screening program for Breast cancer and then to fail to provide the necessary treatment to ensure the best health outcomes for the women diagnosed with the disease. This situation appears to be currently the case, and urgently needs to be addressed.

1. Aromatase Inhibitors

Anastrozole-Arimidex®, Letrozole-Femara® & Exemestane-Aromasin® (collectively known as the Aromatase Inhibitors) in Early Breast Cancer

Medicine & Disease	<p>Anastrozole-Arimidex®, Letrozole-Femara® & Exemestane-Aromasin® (the aromatase inhibitors) are given orally for 2.5 to 5 years post surgery to reduce recurrence of breast cancer in post-menopausal women who have oestrogen receptor positive tumours.</p> <p>At diagnosis, breast cancer may be designated “<u>early breast cancer</u>” where disease has not advanced beyond the breast or “advanced” (metastatic) disease where it has already spread to other organs.</p> <p>Patients with early disease who are successfully treated have the prospect of being <u>disease-free</u> for the rest of their lives given appropriate treatment.</p>
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<p>Availability in New Zealand</p>	<p>In New Zealand, letrozole and anastrozole are <u>fully subsidised</u> for patients with <u>advanced</u> breast cancer <u>or</u> where the patient is intolerant to tamoxifen <u>or</u> where tamoxifen is contraindicated.</p> <p>Exemestane is not subsidised at all in New Zealand.</p>
<p>Benefits and Costs</p>	<p>The data showing <u>improved survival</u> for aromatase inhibitors are compelling and superior to the standard 5 years of tamoxifen. All trials of aromatase inhibitors versus tamoxifen have consistently shown significant benefit over tamoxifen in relapse-free survival. Reductions in recurrence range from 26% to 58%. This is quite remarkable because tamoxifen is an excellent drug that has been consistently shown to improve survival in hormone dependent breast cancers. The side effect profile of aromatase inhibitors overall is also better than tamoxifen and hence improves quality of life for women.</p> <p>Anastrozole and letrozole are only <u>partially subsidised</u> for patients with early breast cancer. Therefore, the patient must pay between \$30 and about \$100 per month to get access. Treatment therefore currently costs the patient at least \$360 per year for 2-5 years. Exemestane is accessible only in the private market and costs more than \$3,000 per year.</p>
<p>Health Consequences without Treatment</p>	<p>The health consequences without treatment are more likely recurrence of cancer and more likely death from cancer.</p>

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<p>Financial and Social Consequences for Patients Having to Pay</p>	<p>These drugs are only available for patients with the means to pay the part charge on the partial subsidy. This treatment is for post-menopausal women and many of these patients are living on a fixed income such as New Zealand Super with a limited ability to absorb additional expenses related to their medication. Often doctors do not offer the patient access to the best treatment because it is not fully subsidised.</p>
<p>Comparison of Availability in Other Countries</p>	<p>Aromatase inhibitors have now replaced tamoxifen as the standard of care for hormone-sensitive early breast cancer in post-menopausal women in most countries.</p> <p>Anastrozole and letrozole are fully subsidised in Australia for early breast cancer and exemestane is subsidised for metastatic disease.</p> <p>NICE guidance (UK) recommends use of aromatase inhibitors.</p> <p>US treatment guidelines also recommend their use.</p> <p>Applications have been made to PHARMAC for funding and BCAC has approached PHARMAC and the Minister of Health on the funding of these drugs on several occasions over the past 3 years.</p>

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2. Docetaxel (Taxotere): Recommended treatment denied in early breast cancer

Medicine & Disease	<p>Taxanes are a class of chemotherapeutic agent administered intravenously along with other chemotherapy (such as doxorubicin and cyclophosphamide). Two taxanes are available in New Zealand; paclitaxel (Taxol®) and docetaxel (Taxotere®).</p> <p>At diagnosis, breast cancer may be designated “<u>early breast cancer</u>” where disease has not advanced beyond the breast or “advanced” (metastatic) disease where it has already spread to other organs. Patients with early disease who are successfully treated have the prospect of being <u>disease-free</u> for the rest of their lives given appropriate treatment.</p>
Availability in New Zealand	<p>PHARMAC’s advisory committee CATSOP recommended access to taxanes for early breast cancer with a <u>high priority in November 2004</u>.</p> <p>Currently, docetaxel is <u>fully subsidised</u> only for patients with metastatic breast cancer. Paclitaxel (Taxol) became funded for patients with node-positive early breast cancer in 2006. The latter occurred when the product’s patent expired and it could be bought cheaply. Having just one taxane available is not a satisfactory situation for patients.</p>
Benefits and Costs	<p>Taxanes improve relapse-free survival and survival in breast cancer compared with standard chemotherapy.</p> <p>The infusion time for docetaxel is 1 hour compared with 3 hours for paclitaxel. This is relevant for patients and hospital services.</p> <p>The adverse effect profile of these agents is different so that some patients may be able to</p>

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	tolerate docetaxel when they cannot tolerate paclitaxel. The cost of docetaxel is around \$20,000 per patient in the private market.
Health Consequences without Treatment	The health consequences without treatment are more likely recurrence of cancer and more likely death from cancer.
Financial and Social Consequences for Patients Having to Pay	Most patients are unable to afford private treatment or unable to access private oncology services therefore they cannot maximise their chance of survival. In some cases patients having to fund raise for Herceptin also need treatment with a taxane. This adds considerably to the cost of their treatment.
Comparison of Availability in Other Countries	<p>In Australia, docetaxel has been fully subsidised as adjuvant therapy in conjunction with AC (doxorubicin & cyclophosphamide) since February 2001. Paclitaxel is also fully subsidised for early breast cancer.</p> <p>Availability in New Zealand is in contrast with recommendations of NICE (UK) which recommended <u>only docetaxel (and specifically recommended against paclitaxel)</u> for treatment of node-positive early breast cancer. They did not believe that the clinical evidence supported use of paclitaxel compared with standard chemotherapy in the NHS.</p>

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3. Herceptin® (trastuzumab): Recommended treatment denied in early breast cancer

Medicine & Disease	Herceptin - Treats patients with early HER2 positive breast cancer, a particularly aggressive form of the disease. The 10 year survival rate from HER2 positive breast cancer is 50%, compared to 80% across all types of breast cancer. Herceptin is a specifically targeted monoclonal antibody which binds to the HER2 protein expressed at high levels in HER2 positive breast cancer cells, preventing the sending of accelerated growth signals. Unlike most other chemotherapy, Herceptin does not attack the body's cells and so does not cause side-effects such as depressed immune system, hair loss etc.
Availability in New Zealand	Herceptin is currently funded in New Zealand for the treatment of metastatic cancer but not early breast cancer.
Benefits and Costs	<p>Evidence of strong survival benefits of Herceptin have been shown from 12 month treatment regimens in several large international studies involving over 12,000 women (HERA, Picart 2005; Smith 2007; combined US study, Romond 2005 - both published in peer reviewed journals - and BCIRG 006, Slamon 2006 - presented at San Antonio Breast Cancer Symposium). The HERA regimen of 12 months of Herceptin following chemotherapy was associated with a 33% reduction in the risk of death, compared with women not receiving it 2 to 3 years after treatment, an absolute difference of 2.7%.</p> <p>Twelve months of Herceptin was associated with a</p>

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	<p>36% decrease in the risk of recurrence of breast cancer, estimated to be an absolute difference of 6.3% at 3 years. There is some evidence from the above studies that the survival benefits of Herceptin administered for 12 months concurrently with chemotherapy may be greater.</p>
<p>Health Consequences without Treatment</p>	<p>In New Zealand around 400 people a year could benefit from a decreased likelihood of developing metastatic disease. This in turn would reduce the huge social cost of terminal illness on the patients, their families, the community and the health budget.</p>
<p>Financial and Social Consequences for Patients Having to Pay</p>	<p>The estimated annual cost of administering this drug to approximately 400 patients is \$22-25 million dollars @ \$55,000 to \$62,500 per person, varying according to their weight. At present, variation in costs to patients also depend on geographical factors, as oncologists in private practice in Auckland charge tens of thousands of dollars more than those in Palmerston North and Dunedin. Only around 10% patients with early HER2 positive breast cancer are currently accessing Herceptin because of the prohibitive costs.</p> <p>Individual Experiences</p> <p>*A. - in early 30s - purchased, did the artwork and tried selling tee shirts to fundraise for Herceptin, finally realised she couldn't raise enough money. She gave up trying as it was too stressful. She has gone without this life-saving medicine.</p> <p>*J - a mother, early 40s with young children - her parents are getting a Sentinel-type loan that comes</p>

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	<p>off J's inheritance so she can have the treatment.</p> <p>* J - a mother, young children and a lifesaver whose lifesaving club are selling teddies to raise money through a special website</p> <p>* D - mother in her mid 40s with school age children had 3-4 weekly garage sales from donations from her immediate community to fundraise. Once this dried up she added to the mortgage on her home.</p> <p>* J - in early 50s - had 6 months only of Herceptin, funded by her ex husband. She couldn't afford more so stopped Herceptin. Subsequently she had a recurrence of breast cancer.</p> <p>* A - in late 50s, mortgaged her home to take Herceptin. After 6 months she stopped because of guilt feelings over cost of treatment, which was consuming retirement funds.</p> <p>* C whose family and friends have set up a trust account for donations to pay for her Herceptin.</p> <p>* M - mother and fully employed woman borrowed to fund Herceptin. She flies from Auckland to Palmerston North for treatment, at a lower cost than taking it in Auckland. This means her oncologist is a telephone call or plane ride away.</p>
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Comparison of Availability in Other Countries	Unlike New Zealand, 23 OECD countries fund 12 months of Herceptin treatment for patients with early HER2 breast cancer, including Australia, Canada, and the UK as well as less economically strong countries such as Portugal, Greece, Hungary, Iceland and Mexico.
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C) Poor Access to Growth Hormone Treatment for Prader-Willi Syndrome

PRADER-WILLI SYNDROME ASSOCIATION (NZ) INC (PSWA)
March 2007

Summary

In September 2006, PHARMAC approved the use of Growth Hormone for treating children with Prader-Willi Syndrome (PWS) after considerable lobbying by the PWSA. The new access criteria specified by PHARMAC, however, are overly restrictive. Currently two-thirds of children with PWS do not meet these criteria and are therefore denied access to treatment. This situation has arisen despite PHARMAC's stated intent to ensure access to GH for the vast majority of these children. We believe these criteria need to be urgently reviewed and adjusted to reflect internationally accepted clinical practices.

At present only 7 of the potentially eligible 20 children with PWS qualify for treatment. The majority of these children do not meet the height criteria (they must be below the 3rd percentile), which are considered to be overly restrictive compared with criteria used in other developed countries. The majority of PWS children in New Zealand are therefore denied the significant benefits of this treatment unless their parents can afford to pay for it.

There is well documented evidence of the health benefits of treating children with PWS with Growth Hormone in preventing development of morbid obesity and maximising their ability to participate in society.

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Without treatment, by their late teens they will almost certainly develop serious health complications associated with gross obesity that prevent them living independently and their life expectancy will be limited to approximately 40 years.

Benefits of Growth Hormone Therapy

Since 1995, PWSA lobbied PHARMAC to obtain access to funded Growth Hormone Therapy (GH) for New Zealand children with PWS. GH has been used to create improvements in linear growth for many years. International research showed in the early 1990's that GH therapy also created significant improvements in body composition through improved muscle mass and decreased fat.

For children with PWS the known health benefits of GH include:

- Improved muscle mass (increasing strength and ability to exercise)
- Decreased fat (reducing likelihood of obesity related illnesses including heart disease, diabetes, kidney problems etc)
- More normal appearance
- Improved linear growth

PHARMAC Access Criteria to GH

Children who meet the following general criteria are eligible for GH:

- (a) are growth hormone deficient
- (b) are in the lowest 1% for height
- (c) have had severe renal problems
- (d) have PWS confirmed by genetic testing and meet certain criteria including being <3rd percentile for height.

These criteria for children with PWS are so restrictive that only one-third of PW children currently qualify. We believe the criteria for PWS are

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significantly more restrictive than criteria applied in most other Western nations.

Poor Levels of Access to GH for Children with PWS

We believe the PHARMAC access criteria for children with PWS are significantly more restrictive than those of other OECD countries. In particular, the inclusion of rigid height criteria has ensured that the access rate is considerably lower at only 20%, despite PHARMAC estimates that almost 70% of PWS children would qualify.

There are approximately 20 children between the ages of 2 years (entry qualifying age) and 12 years old (the latest point a child is likely to qualify for funding) who would immediately benefit from GH therapy. Of these 20 children:

- 7 children currently receive funded GH therapy.
- 13 children do NOT currently qualify for funded GH therapy, in nearly every case because they are too tall to meet PHARMAC's overly restrictive height entry criteria.
- Two families are paying privately for GH therapy, as their children do not meet Pharmac's height criterion

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Cost to treat all PWS Children with GH

To provide GH for all children with PWS under the age of 17 years of age, the estimated total costs would be not more than \$885,000 p.a.

The approximate cost per child ranges from \$10,000 per annum for very young children (1-2 years old) to \$35,000 per annum for older children (12-14 years old)

Impact of Poor Access to GH on Children with PWS

For those few PWS children that do receive GH there are:

- Significant health benefits (as above)
- Significant improvement in ability to live a normal life
- Normalised appearance

For those that don't receive treatment:

- Clinical obesity and related health consequences
- Weakness of muscle and corresponding inability to exercise and participate in active lifestyle
- Shortened life expectancy

Financial and social consequences for those that pay for the treatment privately:

- Significant cost of providing treatment places significant financial pressure on families.
- Constant stress about how to provide funds required – treatment is not just for a year or two, but for many years.
- Consequences impact on entire family as many other things or events need to be sacrificed.

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- Long term impact on families ability to provide for other children, their education, parents retirement etc

Countries that fully fund GH for children with PWSA

- United Kingdom
- America
- Brazil
- France
- Ireland
- Italy
- Mexico
- The Netherlands
- Poland
- Sweden
- Switzerland
- Taiwan
- Australia - expect to be fully funded in within 3 months

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PWSA Relationship with PHARMAC: Timeline of Events

November 2001	Submission to PHARMAC outlining benefits of GHT.
December 2001	PHARMAC decline funding.
April 2002	Discrimination case taken up with HRC and IHC Advocacy re criterion of “absence of mental retardation”.
April 2002	Correspondence and meetings with IHC Advocacy, Human Rights Commission, Ministers of Health & Disability (Hon Annette King and Ruth Dyson), PHARMAC, other MPs and Prime Minister .
July 03	PHARMAC refuses request to include PWS as separate category.
September 2003	Further request to PHARMAC by HRC to remove MR clause and consider PWS as separate category.
November 2003	PHARMAC refusal to make any change to criteria.
May 2004	Invitation from PHARMAC to make new submission.
June 2004	Discovery that no paediatric endocrinologists, or endocrinologists on PTAC panel.

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June 2003	Information under OIA declares only 2 patients in New Zealand receiving funded GH treatment, one of whom paying privately.
17 July 2004	PHARMAC agrees to removal of MR clause (2 years later).
July 2004	PWSA presents new submission to PHARMAC.
September 2004	PHARMAC declines PWSA Submission.
April 2005	Meeting with Human Rights Commission, PHARMAC, IHC Advocacy and PWSA seeking mediation.
May 2005	Presentation of Petition to Parliament, 10,000+ signatures requesting separate category for PWS under Access to GHT.
May 2005	Select Health Committee request for submission from PWSA.
July 2005	Select Health Committee recommends PTAC reconsider PWSA Submission by a subcommittee comprising experts on GHT.
August 2005	PHARMAC increases spending cap on GHT.

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December 2005	Subcommittee of PTAC meets and draws up draft criteria for separate category for PWS to be approved/not approved by next PHARMAC meeting.
May 2006	Not on PTAC agenda.
May – Oct 2006:	Strong PR campaign including meetings with MPs, media coverage, etc.
August 2006	Not on PTAC agenda as undertaken,
October 2006	PHARMAC agrees to separate category for PWS to access GHT, but with strict height criteria which still denies treatment to all children with PWS.

D) Enzyme Replacement Therapy for Gaucher disease

Lysosomal Diseases New Zealand (LDNZ) is the support group for patients affected by the more than 45 diseases known as Lysosomal storage diseases. All of this disease group are characterised by a failure of the Lysosome in the cells of the body, to perform the correct “recycling” function and break down complex sugars and proteins used in normal cell function. Storage of these un-degraded substrates accumulates in cells (different cell types according to which particular lysosomal diseases the patient has), leading to a variety of severe physical or neurological symptoms for the patient. More information about these diseases is available at www.ldnz.org.nz

In the 1990s the first enzyme replacement therapy for one of these Lysosomal diseases, Gaucher disease, became available. Gaucher is a serious disease characterised by enlargement of the liver and spleen and by significant problems with bone health. The treatment is very high cost per patient (perhaps the highest cost medicine subsidised through the pharmaceutical schedule) but Gaucher disease is very rare and the therapy is used to treat fewer than 20 patients in New Zealand.

When the enzyme replacement therapy was first approved for Gaucher disease, PHARMAC set the standard dose for New Zealand patients at less than one-third of the standard dose recognised internationally.

There was very limited evidence to back the dose level PHARMAC chose, and therefore a need for close scrutiny of patient progress over time. A specialist panel reporting to PHARMAC’s PTAC committee was set up to monitor progress.

In April 2003 the Gaucher treatment panel made recommendations for increased dose of Cerezyme for three named patients. These recommendations were endorsed by the PTAC committee and referred to Pharmac the following month. In April 2004 the Gaucher panel again reviewed the cases and confirmed its recommendations for increased

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doses for three patients.

Since August 2003 LDNZ was in regular contact with PHARMAC to try and get this issue dealt with. Regrettably despite several meetings, much correspondence and numerous phone messages, and an eventual promise in late November 2004 that the matter would be decided in "the first quarter of 2005", PHARMAC's responded in mid-May 2005 showed there is no immediate prospect of a decision being made.

LDNZ had to complain formally to the Minister of Health before PHARMAC would give proper attention to the issue and even then it was mid-September 2005 before they approved the recommended dose increase. The result of this delay, and the time taken to get the decision implemented, meant the increase in dose took nearly three years from the time the first clinical indications suggested an increase would be needed.

LDNZ believes that PHARMAC had been grossly negligent in allowing this process to be unresolved for such a long time. They neglected to deal efficiently with their prime objective of getting treatment for those who need it for this group of patients. In doing so, PHARMAC has failed to meet its public law obligation of fair process and has, therefore, failed to adequately address (on behalf of government) the duty the state has to its citizens.

E) Delays in funding medicines for HIV/Aids

Survival of the richest - Article published June 2006

If you're an HIV-positive New Zealander in need of treatment, the chances of you receiving the appropriate medication is less than that of your counterparts living in Australia, just a few hours away.

In Australia, there are currently 6 fully funded antiretroviral medications that aren't available in New Zealand - and there are more on the way.

Are the Australians that much sicker than us? The answer, of course, is no. This is (surprise, surprise) a funding issue. Three of these medications – used extensively around the world to good effect – are sitting with the Pharmac, New Zealand's drug funding body. What are they?

FUZEON (enfuviride, also known as T20)

This is a new class of antiretroviral, a fusion inhibitor, which has been available in Australia since December 2004.

Fuzeon was reviewed by PTAC (Pharmacology and Therapeutics Advisory Committee) at their meeting on May 19 last year. They deferred their recommendation, pending further advice from the anti-retroviral subcommittee, who did not meet until November 25.

This sub-committee noted that Fuzeon was a difficult medication to administer (it requires twice-daily injections), and because of this approximately 50% of people would decline treatment. In real terms, only 8-10 people would be accessing Fuzeon in New Zealand, with a possible four more each year as they became resistant to other therapies.

Despite this, the sub-committee believed Fuzeon was a significant step forward in the treatment of HIV-positive

people with multi-class resistant HIV, and considered that it should be used in addition to other antiretroviral medications, rather than replacing them.

They recommended that Fuzeon be listed as “high priority” under a new funding category, covering those who have developed resistance to other drugs and are failing treatment; as well as being available subject to “special authority” criteria.

The cost of funding this will be around \$36,000 a year per patient.

ATAZANAVIR SULPHATE (Reyataz)

Available in Australia since December 2004, an application was made in New Zealand to Pharmac on January 11, 2005, and was reviewed by PTAC (Pharmacology and Therapeutics Advisory Committee) at their meeting in February 2005.

After reviewing the results of the Reyataz drug trials, PTAC advised they needed to be treated with caution, as the drug trial entry criteria didn't fit New Zealand's treatment guidelines.

They also recommended that this medication be listed on the pharmaceutical schedule only if the cost were the same as existing antiretroviral medications.

Another review by the antiretroviral subcommittee on November 25 noted that Reyataz had some advantages over existing protease inhibitors, such as once-daily dosing and fewer metabolic side effects.

They recommended that atazanavir sulphate be listed in the pharmaceutical schedule with “moderate priority” and the same special access criteria as other antiretroviral medications.

Once introduced, the subcommittee estimated between 36 and 50 people would be eligible for access to Reyataz over a five-year period.

TENOFOVIR DISORPOXIL FUMARARATE (also known as Viread, common name: Tenofovir)

This has been available in Australia since December 1, 2002, and was approved in Europe in May 2003 as a first-line therapy.

In August 2004, the FDA in the United States approved a new combination medication containing FTC and Tenofovir, under the name Truvada. This combination has since been approved in Europe (November 2004) and Australia (February 2006).

Meanwhile, New Zealand is still waiting. In February 2005, PTAC recommended that Tenofovir be listed with a “moderate priority” for treatment-experienced people only.

As far as I can ascertain there are currently only nine patients able to access tenofovir under the “exceptional circumstances” scheme. However given the number of treatment-experienced patients in NZ (approx 700) access for this small number of patients is inadequate.

The only reason this is not available here in New Zealand is that it is awaiting an agreement between Gilead (the manufacturer) and Pharmac over pricing.

There are over 1800 people living in New Zealand with a diagnosis of HIV, and a significant number are receiving antiretroviral medications. Many more are, as yet, undiagnosed.

The nature of HIV is such that resistance develops, and the ability to have alternative medications available is one that can mean the difference between life and death for some.

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The medications named here are all needed by people living today here in New Zealand, and widely used elsewhere in the world.

The people of Australia and New Zealand may disagree on some things. Rugby, sport and who has the best beaches are points that can be argued, but discussions over where you have the best chance of survival are not ones I think anyone should have to have.

Eamonn Smythe

National Positive Health Manager,

New Zealand AIDS Foundation

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APPENDIX 3: CONTRIBUTORS' DETAILS

The ATM combines the voices of a large number of non-government organisations advocating for increased access to medicines in New Zealand. Members of the coalition are all disease-specific groups that provide support, information/education, health promotion or clinical services to their constituent groups.

Members of ATM

- [ADDvocate](#)
- [Alzheimers New Zealand](#)
- [Arthritis New Zealand](#)
- [Asthma New Zealand/The Lung Association](#)
- [Balance NZ – Bipolar and Depression Network](#)
- [Breast Cancer Aotearoa Coalition](#)
- [Cancer Society](#)
- [Carers New Zealand](#)
- [Continence Association](#)
- [Cystic Fibrosis Association New Zealand](#)
- [Diabetes New Zealand](#)
- [Diabetes Youth](#)
- [Epilepsy New Zealand](#)
- [IDFNZ - the Immune Deficiency Foundation](#)
- [Kidney Kids](#)
- [LAM trust](#)
- [Leukaemia and Blood Foundation of New Zealand](#)
- [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 Association](#)
- [Prostate Cancer Foundation](#)
- [Schizophrenia Fellowship New Zealand](#)

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Working Group

The ATM working group has overseen the development of this submission and is made up of the following members: John Forman (NZORD), Florence Leota (Schizophrenia Fellowship NZ), Sarah Perry (IDFNZ), Eamonn Smythe (NZ AIDS Foundation), Margaret Earle (Diabetes NZ), Roger Sowry (Arthritis NZ), Deirdre O'Sullivan (Parkinsons NZ).

Secretary: Carolyn Macal tao (NZ AIDS Foundation).

Additional advice and input was received from Gerald Williams (Prader-Willi Syndrome Association); Pru Etcheverry (Leukaemia and Blood Foundation); Nola Rawson (Multiple Sclerosis Society of New Zealand); Alison Davies (Breast Cancer Aotearoa Coalition).

Expert Consultants Brief CVs

1. Roger Palaret, Public Lawyer
2. Maurice Ormsby, Ethicist and Public Policy Consultant
3. Dr Lynne Lane, Public Health Physician

1) Roger Palaret

Roger Palaret is the principal of Palaret Law, which is a specialist public law firm. Roger spent 5 years as the Director Legal Services for MED, and has been the Acting Chief Legal Counsel for the Ministry of Justice. He is currently the Acting Chief Advisor Legal for the Department of Building and Housing.

Roger's clients include a range of government departments and Crown agencies, as well as organizations in the non-profit and voluntary sectors. He provides advice on issues management and problem solving, including on developing and implementing policies through legislation.

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He has extensive experience in regulation of specific industries and business generally, and a large part of his practice involves documenting funding and other commercial arrangements with the Crown and among Crown agencies.

2) Maurice Ormsby

D.Phil. (Philosophy), Oxford University, 1977.

MA (First class honours in Philosophy), University of Canterbury, 1970.

Background:

2003 Partner, Orapiu Farm Partnership

2002 Director, Waiheke Bike Hire Ltd (Current 2006)

2001 Member, Health Research Council Ethics Committee (Current at 2006)

2000 Consultant, New Zealand Wool Board

Expert Witness on Ethics for the NZ Wool Board in the hearings of the Royal Commission of Enquiry into Genetic Modification.

2000 Consultant, Auckland City Council

This job involved preparing a report to identify issues causing conflict in Otahuhu, recommending how to resolve them, and preparing a plan of action for doing so.

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3) Dr Lynne Lane MBChB DComH AFPHM

Public Health Physician, working as an independent consultant primarily in health services development to a range of private sector and state owned organisations in the health sector. Currently holding the following positions:

- Chair of NZ Committee Australasian Faculty of Public Health Medicine (AFPHM).
- Member of the Council of Medical Colleges.
- CEO of Affordable Healthcare Ltd which is establishing a New Zealand market presence for Dr Reddy's Laboratories Limited, a global generic medicines producer.
- Chair of Procure Public Health Advisory Group.
- Member of the Health Research Council National Ethics Committee.
- Member of the Counties Manukau DHB Community and Public Health Advisory Committee.
- Member of the national Pandemic Planning Implementation Committee.
- Advisor to the Northern Region Mental Health Director on service planning and development.

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Lynne has in excess of ten years experience in funding, planning and health service development and previously 7 years experience in General Practice. She held the position of National Director of Public Health in the Ministry of Health and a number of senior management roles in Government funding organisations including Acting CEO and GM Public Health of the Central RHA, and GM Funding for Auckland DHB. Lynne was a Director of the Problem Gambling Research Foundation, 2002.

Expert Peer Reviewers

- Bruce Scoggins, previous CEO of the Health Research Council
- Jim Thornton, Ethicist

APPENDIX 4: SECTOR ROLES AND RESPONSIBILITIES

The following table attempts to show the key activities undertaken across the health sector that determine access to medicines for people who need them. This table demonstrates the complexity of the system and that multiple agencies share responsibility for multiple activities. These arrangements make it difficult for Government to ensure accountability for these activities. This situation is further compounded by a lack of meaningful clinical outcomes information with which to monitor performance.

Key Activities to Ensure Access to Medicines for People who Need Them			
	Action	Responsible Organisation	Accountability
Planning	Overarching Medicines Policy	MOH Develops sector strategies DHBs local strategy	MOH DHB
	Implementation plans	MOH DHB PHARMAC Suppliers Primary Care Sector NGOs	MOH DHB PHARMAC Suppliers Primary Care Sector NGOs
Funding of medicines	Budget Setting for Medicines	MOH DHBs PHARMAC	MOH DHBs PHARMAC
	Clinical Effectiveness Assessment	PHARMAC (PTAC) DHB provider	PHARMAC (PTAC) DHB provider

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		arm Researchers PHOs Professional Bodies	arm Researchers PHOs Professional Bodies
	Rationing Medicines – cost effectiveness and affordability	PHARMAC	PHARMAC DHBs PHOs
	Value for money	PHARMAC	PHARMAC
	Expenditure on medicines	Clinical staff in ○ DHBs ○ PHOs	PHARMAC DHBs
	Exceptional circumstances	PHARMAC	PHARMAC DHBs PHOs
	Private Purchasing / out of pocket expenditure	PHARMAC – subsidy level on PBS MEDSAFE – classification Individual Choice	Individual patients

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Quality and Safety	Ensure Quality	Suppliers	MEDSAFE
	Certify Quality and Safety for import	MEDSAFE	MEDSAFE
	Classify meds (General Sales, Pharmacy, Pharmacist, or Prescription only)	MEDSAFE	MEDSAFE
	Safe Dispensing	Pharmacy	DHBs
	Adverse effects Monitoring	CALM	MOH
	Research new products – clinical trials Improve clinical effectiveness	Suppliers Clinical researchers Universities NGOs	
Continuity of Supply	Continuity of Supply	PHARMAC MEDSAFE Suppliers Distributors	PHARMAC
Optimal Use	Health Promotion	MOH - funding and planning PHARMAC – supply side management DHBs – providing programs NGOs PHOs	MOH - funding and planning PHARMAC – supply side management DHBs – providing programs NGOs PHOs
	Development of Clinical Guidelines	MOH Professional colleges	MOH Professional colleges

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		Universities NGOs DHBs	Universities NGOs DHBs
	Training to support Clinical Best Practice	PHARMAC (PBAC) MOH DHBs PHOs NGOs Professional Organisations e.g. RNZCGP Universities	PHARMAC (PBAC) MOH DHBs PHOs NGOs Professional Organisations e.g. RNZCGP Universities
	Medicines Reviews	Pharmacy	Pharmacy
	Patient Adherence	Pharmacy	Pharmacy
Monitoring and Evaluation	Health Outcomes Related to Access to Medicines	MOH	MOH
	Service Utilisation	DHBs PHOs	