AUCKLAND UNIVERSITY OF TECHNOLOGY
TE WANGANGA ARONUI O TAMAKI MAKAU RAU

This thesis is submitted to the Auckland University of Technology in part-fulfilment of the degree of Master of Health Science

Thesis Title: A thematic analysis of recent PHARMAC new medicines' subsidy decisions.

Submitted by: Trevor Villers

April, 2008

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Attestation of Authorship

I hereby declare that this submission is my own work and that, to the best of my knowledge and belief, it contains no material previously published or written by another person (except where explicitly defined in the acknowledgements), nor material which to a substantial extent has been submitted for the award of any other degree or diploma of a university or other institution of higher learning.

Signed: …… Date: ……

Trevor R. Villers

Acknowledgements

This work is dedicated with love to my father, Bryan Villers.

Completion of this study was made possible by a small group of people blessed with a large measure of generosity, for whose support I am deeply grateful. I especially want to thank my principal supervisor, Associate Professor Kate Diesfeld, for her wisdom, enthusiasm and painstaking attention to detail throughout. Kate has curbed my rhetorical excesses and has helped me bring a degree of coherence to this work. She has been a constant source of encouragement, for which I am extremely grateful. Special thanks also to my co-supervisor, Dr Debbie Payne. I am indebted to Debbie for her practical guidance and 'devil's advocacy'. More than anything, Debbie helped me to step back and take in the big picture. Thanks also to Bob Hesketh for his insights into the workings of the law, and to Mark 'PCPeople' Floro for retrieving my manuscript when all seemed lost. Thanks also to 'Drew South, Dr David Parker and Margaret Linzell-Jones for jiggling the words around. And to Steffan Crausaz at PHARMAC for providing the minutes that provided the story.

Most of all, love and thanks to dear Helen for maintaining the home front while I attempted to answer a question Bob Dylan posed some while ago.

> "Because something is happening here
>
> But you don't know what it is
>
> Do you, Mister Jones?"
>
> (Ballad of a Thin Man, 1965)

You can have the computer back now kids…

Abstract

PHARMAC, the Pharmaceutical Management Agency, manages the Pharmaceutical Schedule on behalf of the Government. The Agency is tasked with securing the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided (§ 47 NZPHD Act, 2000). The Agency reports that it continues to improve New Zealanders' access to funded medicines. In determining which pharmaceuticals to fund, PHARMAC's Operating Policies and Procedures (OPPs) state that nine criteria guide its decision- making. The OPPs further state that PHARMAC can apply whatever weight it sees fit to the application of these criteria.

I undertook a thematic analysis of 20 cases referred by PHARMAC's principal medical advisory body, the Pharmacology and Therapeutic Advisory Committee (PTAC), to PHARMAC during the period February 2004 to November 2006 to determine whether these criteria were acknowledged in the official minutes of the respective bodies. PTAC is similarly required to take account of the abiding decision criteria. I also sought to determine whether other factors were apparent in guiding the decisions. There was evidence that PHARMAC consistently applied the decision criteria. PTAC was less assiduous in recording its application. In addition, I found that PHARMAC takes account of factors outside the stated criteria. I noted that PHARMAC takes particular account of the degree to which a decision might be publicly, politically or medically contentious in its decision-making. I also found evidence that consistency with prior decisions is another factor which PHARMAC takes into account, though does not apply routinely. This research indicates that PHARMAC does take account of its abiding decision criteria, applying health needs as well as fiscal criteria, though the weighting given each criterion is nowhere apparent in its official minutes. There remains an opportunity for evaluative research to determine whether fiscal considerations 'outweigh' needs considerations in PHARMACs decision-making. .

Chapter One

Introduction

The Pharmaceutical Management Agency (PHARMAC) is a Crown Entity responsible for ensuring that "New Zealanders have access to a wide range of affordable medicines" (PHARMAC Annual Report, 2006 p.4). In undertaking that role, PHARMAC has charge of the Pharmaceutical Schedule, a list of subsidised medicines which PHARMAC administers on behalf of the Crown. Each year the Agency considers proposals from pharmaceutical suppliers and other parties for pharmaceutical subsidies.

During 2006 alone, PHARMAC provided new or expanded access to 41 subsidised products. As a consequence, the Agency claims in its Annual Review for 2006, "nearly 250,000 more New Zealanders will receive subsidised medicines in the following year as a result of decisions taken during 2005/06" (p.3).

The impetus for this study was my chance exposure, in early 2006, to a women's group who were actively lobbying PHARMAC for wider access to Herceptin, a drug used in the treatment of breast cancer. Their sense of resolve, and perseverance, has been salutary, and got me thinking about other instances where PHARMAC appeared to impede the availability of other new innovative drugs. I could recall less well publicised instances involving drugs used to treat hypertension, elevated cholesterol, ulcers and schizophrenia.

From my time as an employee of a pharmaceutical company, I was aware that PHARMAC assessed proposals for new listings according to an established decision tree which has a heavy reliance, on pharmaco-economic tools.

I am interested in establishing the reasons given by PHARMAC to affirm or decline subsidy for new medicines. In particular, I examine the degree to which PHARMAC applies the decision criteria which purportedly guide its decision-making process. I use an inductive thematic analysis focused on the official PHARMAC Board minutes and

recommendations from its principal advisory body, the Pharmacology and Therapeutics Advisory Committee (PTAC). Thematic analysis is adopted as an appropriate methodological basis for this study because the focus is on texts. My research aims to extend the understanding of PHARMACs decision-making.

This study seeks to ascertain whether stated intentions are reflected and applied in the respective minutes. Moreover, it examines the formal decisions for factors outside the nine criteria. Therefore, the twin aims of this research are to determine whether the written decision reflects the stated criteria, and whether other factors are reflected in the decision.

Background

In this section I outline the statutory role and obligations PHARMAC fulfils and the strategies it employs in meeting its objectives. This necessarily entails an analysis of various "supply side" interventions aimed at lessening the drug bill, in particular "reference pricing", as well as an array of "demand side" interventions which primarily focus on prescribers and consumers. Also, I examine the various advisory bodies with which PHARMAC consults, in particular the Pharmaceutical and Therapeutics Advisory Committee (PTAC), and the structure and composition of the organisation. In the remaining section I provide an overview of the legal framework in which PHARMAC operates (including cases), with particular emphasis accorded the New Zealand Public Health and Disability Act 2000 and the Commerce Act 1986. Other rights-based legislation is considered.

In the prologue to the book, *For Health or Profit? Pharmaceuticals and Public Policy*, editor and health policy analyst Peter Davis describes the policy environment which ultimately gave rise to the creation of PHARMAC, the Pharmaceutical Management Agency. The "steady state" that had characterised health care provision for almost fifty years "was rudely jolted by the deregulation of the economy and the reforms of the public health sector by the Fourth labour Government" (1992, p. 9).

A series of interconnected events, including the emergence from a price freeze instituted by the previous National Government and the lifting of price control over medicines, were associated with a hitherto "unprecedented increase in pharmaceutical expenditure" (1992, p.9).

> In the decade to 1990, pharmaceutical expenditure doubled to $500 million and as a percentage of Vote: Health increased from 10 to 15% (1992, p.9). Moreover, it is contended, the State was paying more for pharmaceuticals than it ought too, certainly more than our Australian counterparts (King, 2000, Moore, 2003).

Prime Minister Helen Clark, reminiscing on her then role of Minister of Health, provides an insider perspective. This "growth in pharmaceutical expenditure in the 1980s was of considerable concern to the Government" (1992, p.53). Tellingly;

> the Government was under considerable fiscal pressure, given that the 1988 cuts in taxation were producing less revenue than spending commitments demanded. Pharmaceutical bills in excess of half a billion dollars to the state were an obvious target for expenditure reduction. Both the Minister and the Department of Health redoubled their efforts to that end (1992, p.53).

The notion of a Crown agency with responsibility for improving the management of Government expenditure on pharmaceuticals appears to be non-partisan. Whilst the impetus for it was doubtless stimulated under Labour, the final form evolved, and was instituted, under National, which won the ensuing election. Certainly, in the ensuing "health reforms" which characterised the 1990s, neither party sought major modification or "reform" of this fledgling agency, which was to be known as the Pharmaceutical Management Agency, or, more commonly, by the acronym PHARMAC. Latterly, in December 2007, the Government announced details of its new *Medicines New Zealand* strategy which will have a direct bearing on the way PHARMAC conducts business in the future. Foremost among the changes that have been signalled is the adoption of six overarching principles which will inform (but not replace) specific processes already in place such as PHARMACs decision-making criteria. Reflecting *Medicines New Zealand* principles, PHARMAC will be required to increase opportunities for 'stakeholder' input, including input from consumers, and to enhance transparency in its decision-making process so that people can more readily access information (Dunne, 2007). In future it will be required to publish

summaries of its subsidy decisions, a situation which already pertains in Australia and the United Kingdom.

PHARMAC was originally set up under the Health and Disability Services Act (1993), being owned by the then Health Funding Authority. In 2000, the agency was reconstituted as a stand-alone Crown entity under the New Zealand Public Health and Disability Act. Its specific aim, as delineated under Section 47 of the Act is 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" (New Zealand Public Health and Disability Act, 2000).

To achieve this end, PHARMAC assumed the functions of the [now defunct] Drug Tariff Section of the [then] Department of Health in managing and maintaining the Drug Tariff[1]. The Drug Tariff, a formulary of subsidised pharmaceuticals, was converted to the Pharmaceutical Schedule, which PHARMAC now administers on behalf of the Crown.[2] Prior to the emergence of PHARMAC, admissions to the Drug Tariff were ministerial decisions (Moore, 2003), with prices being subject to the Department of Trade and Industry's approval. PHARMAC became a stand-alone vehicle responsible for all funding decisions. The role of the agency is therefore to determine what pharmaceuticals are funded, the level of funding they should receive, and any guidelines or conditions which should relate to their prescription. This situation, in which PHARMAC acts as the sole purchaser, is referred to as a monopsony. In contrast to a monopoly, where there is only a single seller, and prices will theoretically be higher than otherwise, a monopsonistic situation is intended to ensure that prices are lower than otherwise (NHC, 2004). In other words, PHARMAC does not purchase pharmaceuticals, but it does determine the conditions of supply and level of subsidy that each product receives.

[1] New Zealanders have long enjoyed access to State subsidised medicines - a legacy of the Social Security Act 1938.

[2] Prescription medicines which are included under the Pharmaceutical Schedule may be either fully or partially subsidised. There are two main components which make up the price of a prescription medicine; the manufacturer's surcharge and the patient co-payment (Ransom, 2004). If the subsidy covers the manufacturer's price in full then the manufacturer's surcharge will be nil, the medicine fully subsidised and the customer will pay only the patient co-payment. On the other hand, if the subsidy does not cover the entire manufacturer's price, the medicine will be only partially reimbursed with the customer required to pay both the manufacturer's surcharge as well as the normal patient co-payment.

There are approximately 2600 medicines and related products currently receiving at least some level of subsidy under the Pharmaceutical Schedule (PHARMAC website, 2007). The schedule is adjusted at regular intervals to reflect changes in subsidy and as medicines are either added or deleted (see tables 1 and 2 below). Additionally, in late 2001, PHARMAC was charged with managing the purchase of hospital pharmaceuticals (PHARMAC, 2002).

PHARMAC Decisions made

During the period 1999/00 – 2005/06 PHARMAC listed 86 new chemical entities (NCEs) on the Pharmaceutical Schedule, and widened access to 110 [existent] products. At the same time access was restricted to an additional 22 products, and 955 were de-listed altogether (c.f. Table #1 below).

Table #1 PHARMAC Subsidy Decisions

Decision type	1999/00	2000/01	2001/02	2002/03	2003/04	2004/05	2005/06
New Chemical entity listed	18	20	7	3	15	9	14
New Presentation listed	21	13	11	15	27	14	42
New Product listed	39	28	60	45	49	51	49
Total new listings	**78**	**61**	**78**	**63**	**91**	**74**	**105**
Derestriction or expanded access	17	19	17	7	9	16	24
Changing access to improve outcomes	0	0	0	0	0	0	1
Changes that restrict or limit access	6	6	4	1	2	3	0
Delistings	362	135	89	196	72	59	43

Source: PHARMAC Annual Review, 2006

It is not possible to provide figures for applications that were declined over the corresponding period as PHARMAC has not made these data publicly available since 2003. However, in the period for which figures are available (1999-2003) the PHARMAC Board declined subsidy for 58 NCEs, implying a rejection rate of 48% (see table #2 below).

Table #2 Applications declined by PHARMAC

Decision type	1999/00	2000/01	2001/02	2002/03	2003/04	2004/05	2005/06
New Chemical entity	20	1	32	4	1	-	-
New Presentation	0	2	1	0	1	-	-

New Product	0	0	0	0	0	-	-
Derestrictions	3	0	0	0	0	-	-
Totals	**23**	**3**	**33**	**4**	**2**	**-**	**-**

Source: Adapted from PHARMAC Annual Reviews, 1999-2006

In assessing which pharmaceuticals to subsidise, PHARMAC takes into account the following [9] decision criteria:

1. The health needs of all eligible people within New Zealand; (eligible defined by the government's then current rules of eligibility)
2. The particular health needs of Maori and Pacific peoples[3]
3. The availability and suitability of existing medicines, therapeutic medical devices and related products and related things
4. The clinical benefits and risks of pharmaceuticals
5. The cost-effectiveness of meeting health needs by funding pharmaceuticals rather than using other publicly funded health and disability support services
6. The budgetary impact (in terms of the pharmaceutical budget and the government's overall health budget) of any changes to the Schedule
7. The direct cost to health service users
8. The government's priorities for health funding, as set out in any objectives notified by the Crown to PHARMAC, or in PHARMAC's Funding Agreement, or elsewhere
9. Such other criteria as PHARMAC thinks fit. PHARMAC will carry out appropriate consultation when it intends to take any such "other criteria" into account.

(PHARMAC, 2007).

These guiding criteria are predominantly fiscal, though two are motivated by societal considerations and another two by clinical issues. It could even be argued that the ninth criterion renders the others superfluous.

This heavy reliance on pharmaco-economic tools is essentially a consequentialist or utilitarian approach, wherein the value of treatment is determined in terms of measurable consequences or "outcomes". Priorities for funding are established on the projected cost-quality adjusted life year (QALY) ratio, with low ratio products having higher priority. At

[3] This criteria was included in 2000.

the present time, if a product is calculated to cost less than $10,000 per QALY produced it is funded. As observed by Gillon (2006), it does not seem to matter whether the need being met by the drug is a minor one (he instances the itching and soreness between two sore toes as in athlete's foot) or a major one (heart attack) as long as the treatment costs less than $10,000 per QALY gained the drug should be subsidised. As the cost per QALY is essentially a function of the cost of treatment and the life years gained, cancer treatments by their very nature will rate poorly against other medicines vying for PHARMAC funding. New drug treatments for cancer are expensive and the life years gained, after adjusting for side-effects, can still be relatively few by virtue of the often terminal nature of the condition. From this rigid cost-benefit perspective, PHARMAC's analysis may therefore more often then not conclude that the limited funds available for new medicines are better invested in other disease areas.

PHARMAC has wide discretion in choosing how to apply these criteria, with the agency "giving such weight to each criterion as Pharmac considers appropriate" (PHARMAC, 2006). This indeterminate "weighting", as well as the explicitness of the core criteria will be the subject of further exploration in Chapter Two.

The Pharmaceutical and Therapeutic Advisory Committee (PTAC), pharmaceutical suppliers, District Health Boards (DHBs) and other interested parties can make application for possible amendments to the Pharmaceutical Schedule. The attached flow chart (Appendix #1) provides an indicative guide to the process that PHARMAC typically follows when considering an amendment to the Schedule. Except in very rare instances, a product must first be approved by Medsafe before it will be considered for inclusion under the Schedule. Herceptin (trastuzumab) for HER-2 positive early breast cancer is a notable exception (S. Knight, Roche Products, personal communication, October 27, 2006).

The process is also protracted. Compared to Australia, New Zealanders wait longer for access to any new medicines that are ultimately funded. For instance, it has been shown that it takes on average 30.5 weeks from recommendation by the Australian equivalent of PTAC, the PBAC, for a medicine to be listed on the Australian Benefits Schedule, whereas it takes 103 weeks for PHARMAC to endorse a positive PTAC recommendation (Wonder, 2006). It appears that while New Zealanders may have access to many of the drugs our

Australian counterparts do, it just takes longer to get them. This prolonged approval process is viewed by some as a calculated rationing strategy by PHARMAC designed to save money (Holt et al, 2005).

There is no appeal mechanism if a sponsor's application for inclusion under the Schedule is rejected, although the sponsor can reapply at a later date, taking account of the reasons for rejection. There is, however, provision by which, under rare and exceptional circumstances, medical practitioners can apply on behalf of their patients for access to pharmaceuticals that are not funded. Three separate schemes have been developed under PHARMAC's policies and procedures – the Community Exceptional Circumstances (CEC), Hospital Exceptional Circumstances (HEC) and the Cancer Exceptional Circumstances scheme (Ca EC). Each of these schemes has been developed for different reasons and to meet different needs, and different criteria apply. The specific rules and detailed processes for these schemes are outlined in the introductory notes to the Pharmaceutical Schedule (2007) and described more fully in an explanatory information sheet (PHARMAC, 2007). In essence, approval under the schemes is sought via an application form completed by the medical practitioner treating the particular patient. This requires the medical practitioner to indicate whether or not specific eligibility criteria are met. The criteria for the respective schemes are outlined in full in Appendices #2-3.

In summary, the CaEC procedure requires consideration of applications by PHARMAC staff in the first instance. In the event that the application meets the criteria, they are approved. Where PHARMAC consider the criteria are not met the application can be referred to the Exceptional Circumstances panel for review. As a final arbiter, the application can be referred to the PHARMAC Medical Director for review. There is a certain "catch 22" aspect to this decision-making process. The DHB cannot approve funding unless PHARMAC approves, yet PHARMAC will not approve funding unless the DHB has given prior approval. In practice, however, PHARMACs Medical Director makes the final decision.

Applicants under the CEC and HEC schemes also have the right of appeal. In the case of the CEC scheme this is referred in the first instance back to the Exceptional Circumstances

Panel and, in the event that the Panel still declines the application, the applicant can then request a review by PHARMAC's Medical Director.

Under the HEC scheme the applicant must demonstrate that the drug is cost-effective relative to alternative interventions. Cost-effectiveness is the sole criteria. In practice, the same circuitous process is involved. Funding is provided from the DHB's Hospital budget, yet the DHB cannot approve funding unless PHARMAC approves and PHARMAC will not approve unless the DHB approves. The same appeal provisions [as with the other two schemes] apply with the PHARMAC Medical Director being the final arbiter.

Such circumstances are, by definition, "exceptional". In normal circumstances, PHARMAC has adopted entirely different mechanisms to achieve its role. Typically these strategies aim at influencing supply or, alternatively, demand.

PHARMAC's strategies

Supply side strategies

PHARMAC has traditionally adopted a broad range of strategies to achieve its statutory purpose. Foremost among them are supply side interventions aimed at lessening the drug bill. These include, but are not confined to:

- Reference pricing (defined below)
- Fixed cap expenditure contracts
- Tendering, or issuing requests for proposals (RFPs) for sole or preferred supply
- Rebates, and
- Package deals across a range of therapeutic groups
- Various pricing arrangements including parity pricing between different therapeutic sub-groups
- Restricted access e.g. 'Specialist only', or 'Hospital Pharmacy only'

These interventions all have the potential to influence the supply of pharmaceuticals, and to skew the market in favour of one supplier over another. However, the extent to which some

of these individual strategies have succeeded in lessening the drug bill is hotly debated (see for example, Woodfield, 1999; Martin & Begg, 2000). I will examine this debate in more detail below.

Reference Pricing

By far and away the most contentious of these measures is reference pricing, a strategy not exclusive to New Zealand, but perhaps more rigorously applied here[4]. Reference pricing is an adaptation of the [then] Department of Health's "uniform subsidy" and "therapeutic group pricing" policies. By this process, medicines are divided into "therapeutic groups" or sub-groups which include all medicines used to treat the *same* or *similar* condition(s). All medicines in a given sub-group are subsidised at the level of the lowest priced drug in that sub-group, regardless of patent status, this drug, in effect becoming the 'reference price' drug. New products that don't readily fit into an existing therapeutic group may, however, be included on the Pharmaceutical Schedule once agreement has been reached on pricing. There have been instances too, when reference pricing has been augmented by various cross-product arrangements which require suppliers seeking subsidy for new medicines to significantly reduce their prices for products in unrelated markets. Examples of this have involved the HMG-CoA reductase inhibitors, (a group of anti-cholesterol drugs known colloquially as the 'statins'), the Angiotensin Converting Enzyme inhibitors (ACEIs), and the calcium channel blockers (CCBs). These three distinct categories of drugs are all used in cardiovascular disease.

Reference pricing has its advocates. Kletchko and colleagues, for instance, assert that it was one of PHARMAC's; "most powerful tools" (1995, p.5) in that under reference pricing suppliers "tend to lower their price to the new subsidy level rather than risk [losing] market share", and if not, "patients tend to switch to fully subsidised alternatives rather than pay a premium" (1995; p.9). Davis also sees it as a "powerful" and "sustaining" technique for achieving savings (2004, p.176). But critics assert that it is a flawed policy tool. Woodfield

[4] For example, reference pricing has been adopted in various European countries including the Netherlands, Germany and Italy. It has also been adopted in Australia, Canada and Croatia (Woodfield, 1999). To the best of my knowledge, regulatory bodies in these other countries have not sought to reference price new products to existent products as PHARMAC has done.

(1999) notes, for example, that reference pricing only temporarily checked spending growth in Europe and at no time has it satisfied an initial target growth rate of zero in New Zealand since its introduction. And, contrary to Kletchko et al's assertion, he found (in the case of the statins at least,) most suppliers were prepared to accept a reduction in market share rather than reduce prices beyond a certain point (p.26). Woodfield attributes this in part to the "Roaring Mice" phenomenon, whereby local subsidiaries of major pharmaceutical companies (with miniscule shares of world markets) are unlikely to make pricing decisions that might compromise prices the parent company achieves in major international markets.

Others assert reference pricing encourages compensatory behaviour patterns that negate primary health gains (Martin & Begg, 2000). For instance, the process takes no account of the resultant transfer of costs to the patient who is maintained on a non-reference priced drug. More tellingly, the notion of 'same or similar', which underpins reference pricing, is ill-defined. Martin and Begg question whether it refers to surrogate or true endpoints of treatment. Does it, for instance, "take into account side effect profile, drug interactions, clinical effect or compliance? Is it primarily a funding tool for subsidisation purposes, or is it supposed to direct clinical prescribing?" (2000, p.422)

Reference pricing also pays scant regard to the disruptive impact of "switching" large numbers of patients to the "reference price" drug (Begg et al, 2003; Bosanquet, 2000; Maling, 2002; Martin & Begg, 2000; Swinburn et al, 2000). Again, in reference to the statins, Begg et al (2003) contend that large numbers of patients have been inconvenienced by this particular intervention for what they describe as a "short-term, narrow focussed, financial reasons"(p.361). In a process which they describe as "reference-pricing dominoes" (p.360), in some instances "patients were forced to change from simvastatin or pravastatin to fluvastatin, then atorvastatin, and for many back to simvastatin"(p.360). Inconvenience aside, Maling (2002) points to a much more harmful consequence of "switching". His retrospective study of the impact of switching large numbers of patients to the ACE inhibitors quinapril and cilazapril provides evidence that brand switching may potentially result in significant health loss[5]. This study, commissioned by PHARMAC, showed that 30% of patients did not sustain the initial switch and 11% of those with

[5] In an extreme case, Burt and Conaglen (2000) report a fatality associated with substituted carbimazole.

previously stable blood pressure, remained uncontrolled six months after the switch. He postulates that brand substitution on such a broad scale will not happen again in New Zealand. Earlier, in another retrospective audit, Thomas and Mann (1998) suggested a deterioration of lipid control in most patients following the initial switch to fluvastatin in 1997. At the same time, the authors also observed an increase in adverse cardiovascular events associated with fluvastatin (when compared to simvastatin.)[6]

The ACE inhibitors and the statins are two of the major cardiovascular drug groups affected by reference pricing with its attendant problem of patient switching. The other major group that has been subject to this intervention is the CCBs. When taken together, the numbers are indeed large. As a measure of scale, Swinburn (2000) estimates that in these three categories alone, some 150,000 patients have been directly affected, most of whom have switched medications as a result (p.426).

More recently, in a press announcement dated September 14, 2007, PHARMAC conceded that "a small proportion of people do experience genuine difficulties" when changing brands and proposed greater flexibility to allow people continued access to the brand they were first prescribed. Under the proposed change, up to 1% of patients would be able to remain on an existing brand with the proviso that they can demonstrate clinical need (PHARMAC, 2007).

At the very least reference pricing then has been disruptive to both medical practitioners and patients alike. It may even have had deleterious effects on health in some instances (Reti, 2006). But has it achieved its endpoint of significantly reducing the drug bill? As a singular measure it seems not. If we accept Woodfield's contention that reference pricing is, of itself, "insufficiently powerful" to achieve this end, it would explain why PHARMAC has subsequently sought to augment reference pricing by adopting package deals and various other supply side interventions.

[6] While acknowledging that switching patients to other medications 'was not ideal', PHARMAC's initial justification for switching patients (from simvastatin to fluvastatin) was that it held the potential to give benefit to many more patients (Moodie et al, 2003, p.363).

Package deals

By this expedience, PHARMAC is able to negotiate with suppliers across a range of unrelated therapeutic categories. Hence, a supplier seeking a listing for a new product in one therapeutic category might be prepared to sacrifice its price for an existing product (typically with a low market share) in another category (thus establishing a new benchmark, or reference price, in that category). An example of this process is outlined below.

On the face of it, this arrangement would seem to allow PHARMAC considerable leeway in achieving savings. Some package deals, especially involving a reference price component, have lowered the price of some drugs in some categories quite dramatically. However, the strategy has not always achieved this end. To reinforce this point, Woodfield (1999) again instances the statins. In June 1998, Warner-Lambert Parke Davis introduced Lipitor (atorvastatin), a statin, as part of a package deal with PHARMAC. The deal involved a 60% reduction in price for Accupril (quinapril) which is an ACE inhibitor from an entirely different therapeutic group. What is significant about this arrangement is that it signalled a shift in PHARMACs policy. Previously, PHARMAC had typically only agreed to list new products if the supplier met the then current reference price, but in this instance PHARMAC listed Lipitor with a premium over other competing statins.[7]

Very rapidly, Lipitor achieved a dominant market position, achieving 59.12% share by value in just six months (Woodfield, 1999, p.21). Over the corresponding period the ACE inhibitor market fell 44.80% in value, indicating some very significant savings in expenditure for these drugs. Contrary to expectations however suppliers in this market did not meet the new benchmark price established by Accupril. Whilst this certainly brought about a loss in share in the case of the leading brands, by not decreasing beyond a certain point local companies ensured that local ACE inhibitors prices did not in effect become "Roaring Mice" in markets where, "unlike NZ, quantities sold are more than just a drop in the bucket. Foregoing profits in the NZ market is a credible signal of this threat, whether or not the threat is real" (Woodfield, p.26). Subsequently, both the statin and ACE inhibitor

[7] At that time the other statins were uniformly subsidised on the basis of an average daily cost of $1.05, whereas Lipitor was initially listed at $1.60/day reducing over successive years (2) to $1.05 (Woodfield, 1999;, p.19)

markets have experienced many shifts in dynamics due to changing competitive forces. These shifts in dynamics are however beyond the scope of this inquiry.

Contracts

Through contracts PHARMAC is able to secure a fixed price for a product or group of products under specified terms over a given time-frame. In some instances this may entail detailing the precise terms of listing under the Schedule ("listing contracts"). For instance, listing contracts may include risk-sharing arrangements with the supplier, restrictions on access, and protection against de-listing. Other forms have included price/volume contracts which require the supplier to pay a penalty (rebate) in the event that budgeted sales volumes are exceeded.

Tenders

Tendering is another method favoured by PHARMAC for achieving price reductions[8]. Where products are off patent, PHARMAC has been able to call for tenders or requests for proposals (RFPs) for the supply of one or more subsidised brands of the chemical entity, or one or more members of a therapeutic sub-group. Usually this will entail the delisting of other brands of the same chemical entity or other products within the sub-group. Also, some tendering arrangements have obliged pharmacists to dispense a particular brand of a drug to the exclusion of others. The tendering process is not however confined to off-patent pharmaceuticals and has been extended to encompass such diverse things as vaccines and intravenous fluids. Sole supply contracts and tendering arrangements are, however, not without risk. This was illustrated in 2005 when supply problems (due to manufacturer's error) greatly disrupted the influenza vaccination programme. The commercial arrangement which PHARMAC had entered into with Sanofi-Pasteur for sole-supply of the vaccine was held to have precipitated the crisis (Blackmore, 2005; MacKay, 2005). Perhaps ironically, in this instance the "crisis" was largely averted when GlaxoSmithKline (GSK), who had supplied the vaccine prior to losing the tender in 2005, was able to make up most of the shortfall. As a consequence of the 2005 experience PHARMAC subsequently announced that future influenza vaccine tenders will call for more than one supplier (McNee, 2005).

[8] According to the PHARMAC website almost one third of the 2600 products listed on the Pharmaceutical Schedule are sourced through sole-supply tenders (http://www.pharmac.govt.nz)

Whilst PHARMAC primarily seeks to influence the supply of pharmaceuticals, as a secondary goal it also seeks to influence demand.

Demand side strategies

Various demand side strategies are also employed. These focus on influencing both physician and consumer behaviour. These initiatives "aim to have a positive outcome in terms of either fiscal and/or health gains" (PHARMAC, 2005, p.21). Over time, various initiatives have been employed, including opposition to the extension of pharmaceutical patent terms and opposition to direct-to-consumer advertising of prescription medicines. In both instances, it is assumed, PHARMACs interest was primarily fiscal. In its Annual Plan for 2004/05 PHARMAC identified four broad areas of focus, among them, the development of information technology (IT) tools for physicians with the express purpose of encouraging informed and responsible prescribing. Specific items identified for implementation in the Plan were development of an electronic form of the Special Authority system and investigating the feasibility of producing the Pharmaceutical Schedule on CD.

Another core initiative aims at eliciting change in the demand for the use of pharmaceuticals in defined therapeutic areas, either by doctors, patients or both. The therapeutic areas targeted by PHARMAC in 2004/05 were the statins, atypical anti-psychotics, anti-bacterials and diabetes management, which together had a combined value of $129.24 million (PHARMAC, 2005, p.21). In the case of the statins, it was proposed to continue with the cardiovascular risk awareness programme, originally piloted in 2002/03, which promoted lifestyle modification (diet and exercise) and the role of statins in reducing cardiovascular risk. Other campaigns sought to promote the appropriate use of atypical antipsychotics, the "Wise Use of Antibiotics" and appropriate levels of diabetes testing among non-insulin dependent adult diabetics. Previous consumer information campaigns have included an asthma management plan initiated in 2002/03 and continued into 2003/04, and a gout management plan.

The third area of focus for 2004/05 was to continue contracting external parties, through the aegis of RFPs, for services to promote the responsible use of medicines. PHARMAC

currently works with Independent Practitioner Associations (IPAs), and Primary Health Organisations (PHOs) to ensure national programmes are implemented at a local level and to ensure consistency across organisations. With this in mind, PHARMAC has contracted with the Best Practice Advocacy Centre of New Zealand (BPAC NZ) to deliver services which promote prescriber change. Among the services BPAC NZ provide are general practice prescribing audits and best practice guides. The contract extends for three years.

The fourth priority area for the 2004/05 year was continuance of support for the Consumer Advisory Committee and continuance of promotions directly aligned with the Maori Responsiveness Strategy such as the reduction of smoking and obesity and in improving nutrition and physical activity (PHARMAC, 2005, pp.21-22).

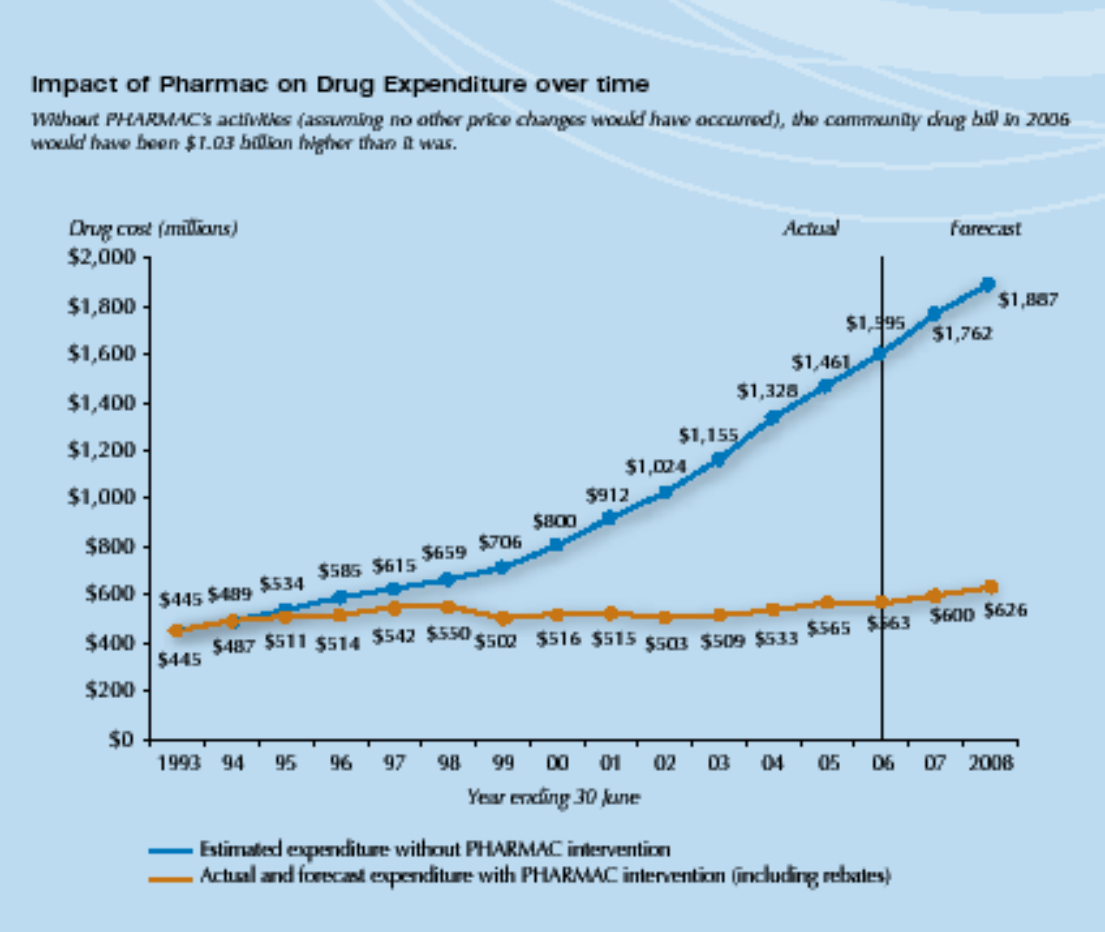
Through such interventions, PHARMAC exhibits significant influence over the supply of pharmaceuticals in New Zealand. Private medical insurance companies do not provide cover for unsubsidised medicines, meaning that PHARMAC, as monopsony purchaser, effectively controls which prescription medicines will be sold in New Zealand, and, to a large extent, at what price they will be sold. At the present time the Government pays about two-thirds of overall pharmaceutical expenditure (Ministry of Health, 2005). Although subsidies benefit those who can tolerate subsidised drugs, patients who require an unsubsidised drug must meet the full cost themselves. PHARMAC measure this as a cost saving, in that they do not have to meet any costs, but it is an additional cost to the individual who cannot take the subsidised drug. In effect, this equates to cost-shifting.

Since its inception PHARMAC has approved 168 new medicines (PHARMAC, 2006). Yet other drugs have been declined subsidy leading to considerable controversy. There is little doubt that PHARMAC has succeeded in lowering the drug bill, but there is an inherent tension between “best health outcomes” and “amount of funding provided”, and controversy exists as to whether PHARMAC has succeeded in securing the best health outcomes for eligible New Zealanders (Ellis & White, 2005; MacKay, 2005; Mann 2005, Begg et al 2003).

When PHARMAC was established, its avowed aim was to hold the rate of growth of pharmaceutical expenditure to half that of the previous year. That did not happen. The

growth rate continued to increase as a constant proportion of overall Vote Health. It was not until 1999 that actual expenditure showed a decrease over the previous year. This recurred in 2001, and in 2006. Without PHARMACs interventions, it is claimed, growth in 2006 would have been in the order of 9.2%. This, it is conjectured, represents a "saving" of some $1.03 billion (see Table #2 below). Whether, in fact, this a real saving, is a matter of debate. For instance, Martin and Begg (2000) assert that by estimating savings against projected costs on the basis of previous rates of growth, "PHARMAC fails to take into account any compensatory behaviour and assumes that all other variables remains constant/ In health care this rarely happens" (p.423).

Table #3



Source: PHARMAC. Annual Review for the year ended 30 June 2006, p. 7.

PHARMAC Organisational Structure

All decisions relating to PHARMAC's operations are made by or under the direction of the Board. Similarly, strategic decisions affecting listings, subsidy levels and prescribing guidelines and conditions are made by the Board with input from PHARMAC staff[9]. Members of the Board are appointed by the Minister of Health. Initially the Board was made up of the CEOs of the Regional Health Authorities (RHAs). More recently, the Board has comprised a non-voting Chair, one independent director, three members of the RHA and two alternate directors. When the four RHAs were represented, it was deemed necessary to have unanimous decision-making, so as to ensure that no one RHA could commit the funds of another. However, in the new environment majority decision-making is deemed more appropriate (King, 2005). Consistent with this change, the Chair now has voting rights, but cannot have a casting vote (King, 2003). The Board presently comprises six members[10]. It is assumed that the value of having additional members rests on their contribution to decision making (Perkins, 2003). What is not known is the contribution each member makes to the decision making process.

To assist in its decision making, PHARMAC can also draw on the expertise of a number of independent advisory bodies, including the Pharmaceutical and Therapeutic Advisory Committee (PTAC), the Consumer Advisory Committee (CAC) and the Hospital Pharmaceuticals Advisory Committee (HPAC). Their specific composition and functions are briefly described below.

Pharmaceutical and Therapeutic Advisory Committee (PTAC)

PTAC was formally constituted under § 121 of the Social Security Act 1964, as an advisory body to the [then] Minister of Health. However, under the provisions of the New Zealand

[9] While the Board has a governance role for the corporate functions of PHARMAC, Board members accord their greatest emphasis to decisions relating to the Pharmaceutical Schedule.
[10] The composition of the current Board is appended as Appendix # 5. A list of PHARMAC staff is appended as Appendix # 6.

Public Health and Disability Act 2000,[11] PTAC is now funded by and is fully accountable to PHARMAC.

PTAC (and its specialist sub-committees) comprises vocationally registered medical practitioners with expertise in clinical pharmacology, internal medicine and general practice (PHARMAC, 2006). Presently, the Committee is made up of ten members, all medical, all of whom are practitioners[12]. Appointments are made by the Director General of Health acting on the advice of the PHARMAC Board.

PTAC's primary purpose is to provide PHARMAC with objective advice on the pharmacological and therapeutic consequences of proposed amendments to the Pharmaceutical Schedule. However, PTAC is obliged to follow the same nine decision criteria as PHARMAC in its deliberations. This means that, in addition to considering clinical issues, PTAC is also obliged to take account of cost and cost-effectiveness of pharmaceuticals in its deliberations. Because its members are drawn from the medical community and have no apparent expertise in pharmaco-economics, it could be contended that PTAC is not equipped to do this.

PTAC, however, draws on specialist sub-committees with expertise in particular therapeutic areas. At the present time there are sixteen sub-committees, encompassing such diverse therapeutic areas as cardiology, analgesia, special foods through to mental health and cancer[13]. PHARMAC is not bound to accept or act on decisions made by PTAC or any of its sub-committees (PHARMAC, 2007). PTAC meets on four occasions throughout the year (December, March, June and September) and the official minutes of these meetings are published on the PHARMAC website. PHARMAC reserves the right to withhold portions of the minutes on grounds of "commercial confidentiality" (PHARMAC, 2007).

[11] Section 50 (1) (a)
[12] The composition of the current committee is appended as appendix #7
[13] A full list of the sub-committees is appended as appendix #8

Consumer Advisory Committee (CAC)

Additionally, PHARMAC maintains a Consumer Advisory Committee to ascertain a consumer or patient perspective on funding decisions (s 50 (1)(b). The committee currently comprises nine members from a diverse range of backgrounds. These members are also appointed by the PHARMAC Board.[14] The Committee is required to meet at least twice each year and meetings are held in PHARMAC s Wellington office or via electronic conferencing. Issues addressed by CAC in 2005/2006 included prescribing patterns for statins and SSRI antidepressants and initiatives to assist PHARMAC with its consultation database (PHARMAC, 2006). CAC's functions do not extend to providing input on the clinical evaluation of pharmaceuticals or any of the consultation or commercial contracting processes that PHARMAC engages in, unless specifically requested (PHARMAC, 2006).

Hospital Pharmaceutical Advisory Committee (HPAC)

PHARMAC was given responsibility for managing expenditure on hospital pharmaceuticals in 2002 and has maintained a hospital pharmaceuticals advisory committee to advise in relation to national procurement strategies for hospital drugs since that time. The committee is made up of six District Health Board (DHB) pharmacy managers and funding and purchasing managers from across the DHBs[15].

The importation, manufacture, supply and distribution of pharmaceuticals into New Zealand is strictly prescribed – but not by PHARMAC. Rather it is the fundamental function of Medsafe, a business unit of the Ministry of Health. Medsafe's role and where it interfaces with PHARMAC is briefly outlined below:

[14] The full list of CAC members is appended as appendix #9
[15] The membership of the HPAC is appended as appendix #10

Role of Medsafe

Medsafe regulates therapeutic products in New Zealand (Medsafe, 2007). Medsafe administers the Medicines Act 1981 and the Medicines Regulations 1984, and parts of the Misuse of Drugs Act 1975 and Medicines Regulations 1977 (Medsafe, 2007). Foremost among its many functions, Medsafe assesses the safety and efficacy of new (and changed) medicines and medical devices. New medicines cannot be marketed in New Zealand without the consent of the Minister of Health (or his delegate). Sponsors are required to submit data establishing the quality, safety and efficacy of the product, for the purpose for which it is intended, to Medsafe for evaluation. Once approved, a new (or changed) product is gazetted and the sponsor is then able to distribute the product. Similarly, pre-marketing approval for changed medicines must also be sought.

Medsafe and PHARMAC work independently and Medsafe is not involved in funding issues. Rarely is a product distributed without prior approval from Medsafe. The anti-neoplastic drug Herceptin® provides one such instance, where the sponsor sought to by-pass normal channels and applied directly to PHARMAC for approval to distribute. (Personal communication, Roche Products, 2006).

Legal framework

In New Zealand, the right to health is affirmed in a variety of legislation. Of these laws, the most directly applicable to the right to health (and healthcare in particular) is the New Zealand Public Health and Disability Act 2000. The right to health is further attested in a variety of rights-based legislation including the New Zealand Bill of Rights Act 1990, the Human Rights Act 1993 and the Health and Disability Commissioner Act 1994 and accompanying Code of Health and Disability Services Consumers' Rights. I will look at each piece of legislation in greater detail but, before doing so, it is important to recognise that the provision of health services has undergone considerable structural change since the early 90's. The most fundamental change has been the switch away from the 'purchaser/provider' split which characterised the reforms introduced in 1993, to the more

community based model that is in place today. The current system was implemented through the New Zealand Health and Disability Act 2000 which allowed for the creation of District Health Boards. This, in turn, had direct consequences for PHARMAC.

The New Zealand Public Health and Disability Act 2000

The New Zealand Public Health and Disability Act (NZPHD) 2000 came into effect on 14 December 2000 repealing and replacing the Health and Disability Services Act 1993 (Ministry of Health, 2007). The purpose of the Act is to provide for the funding and provision of personal health services, public health services, and disability services (NZPHD, 2000).

District Health Boards (DHBs), some 21 in total, officially came into being on 1 January 2001. The NZPHD Act dissolved and supplanted the previously existent Hospital and Health Services (HSSs) and the Health Funding Authority (HFA) and divided their responsibilities between the DHBs and the Ministry of Health (Ministry of Health, 2007). As a consequence, the purchase and provision of health services were amalgamated within the same organisations and decision-making was effectively decentralised to the community-focused DHBs.

The NZPHD Act was designed to help facilitate the Government's avowed aims of strengthening the public health system, achieving the best health and disability outcomes for New Zealanders and reducing disparities between population groups (§ 3). Similarly, the Act included arrangements for PHARMAC. Where PHARMAC was previously owned by the HFA, the Act established PHARMAC as a stand-alone Crown Entity with the avowed objective of "[securing] 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" (§.47).

To achieve this, under §. 48 of the Act, PHARMAC is expressly required to manage and maintain the Pharmaceutical Schedule (and an important part of this function is determining eligibility and criteria for the provision of subsidies). Section 52 provides exemption from

Part 2 of the Commerce Act 1980. The significance of this exemption is discussed below in relation to anti-competitive practice.

Beyond its statutory obligations, scrutiny of PHARMAC subsidy decisions might also be viewed through the wider lens of consumer rights legislation. One manifestation of this is the Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996.

The Health and Disability Commissioner Act 1994 (Code of Health and Disability Services Consumers' Rights) Regulation 1996 (HDC)

The Code of Rights was established as a regulation under the Health and Disability Act 1994. The Code defines the rights of consumers and the obligations of providers. The Code gives rights to all consumers when they are receiving a health or disability service. Ten rights are provided for under the HDC, one of which has direct relevance to the provision of health care:

Right 4
Every consumer has the right to have services provided in a manner that minimises harm to, and optimises the quality of life of, that consumer (HDC, 1996).

Under §.4 of the Health and Disability Services (Safety) Act 2001, a "provider" is defined as [a person] in charge of providing health care services of any kind. Whether PHARMAC meets that definition is yet to be tested. What is clear, however, is that under the Code there is no express right for consumers to demand or to receive their drug or treatment of choice.

The New Zealand Bill of Rights Act 1990

It has been contended that the New Zealand Bill of Rights Act 1990 has some application to PHARMAC's subsidy decisions (Walsh v Pharmaceutical Management Agency, 2007). The Act is designed to limit the power of government by creating rights for individuals, but has a balancing clause to allow the government to discriminate if doing so constitutes a "reasonable limit", which is prescribed by law "as able to be demonstrably justified in a

free and democratic society"(§.5). Among the many civil rights accorded New Zealanders is the right 'to refuse to undergo medical treatment' (§ 11). Conversely, the right to receive medical treatment (drugs) is not specified as a discrete right, although a basic right to natural justice is recognised under § 27 (1). The first case brought by individual patients challenging a decision by PHARMAC not to fund a particular drug (Herceptin) sought relief under this section (Walsh v Pharmaceutical Management Agency, 2007). Details of this case are provided below.

Other legislation has been invoked to challenge some of PHARMACs decisions. For example, the Commerce Act 1986 has been cited.

The Commerce Act 1986

The Commerce Act 1986 was enacted to promote competition in New Zealand markets. The promotion of competition is deemed beneficial to the public. However, the Commerce Act also recognises that, in certain circumstances, practices which may be anti-competitive, may have counter-balancing benefits. Therefore, the Commerce Act allows for certain exceptions (§ 58 – § 74). Other statutes similarly provide exemptions from the Commerce Act.

PHARMAC has a partial exemption from the Commerce Act which arises under § 53 of the New Zealand Health & Disability Act 2000. This exemption was formally given under § 2 of the Public Finance Act 1986. This exemption means that PHARMAC cannot be challenged on the basis that it is abusing its market power or that, through its activities, it lessens competition in a given market. In a memo to the Cabinet Social Policy and Health Committee, [then] Minister of Health Annette King explains the rationale for this exemption as follows:

> **Key reasons for PHARMAC having a Commerce Act exemption include:**
>
> **i. Allowing PHARMAC to perform centralised purchasing role**
>
> Under the 1993 health restructuring, the four RHAs [Regional Health Authorities] established PHARMAC as their agent to operate a common, national Pharmaceutical Schedule. This was seen as the only practical way for a country of

New Zealand's small size to exercise sufficient market power to obtain lower pharmaceutical prices from multinational pharmaceutical companies, which at the time were charging New Zealand well above world prices. However, since the centralised purchasing role might be seen as involving price fixing or collusive behaviour on the part of the RHAs, it was considered desirable to provide PHARMAC with a partial exemption to avoid challenges under the Commerce Act.

ii. **Economic efficiency is not the only goal**.

The Commerce Act is based on a series of assumptions, such as the desirability of competition as a mechanism to promote economic efficiency. With pharmaceuticals and health this is only one objective. Importantly, the Government has decided that equity of outcomes is also important. Hence, the Government chooses to provide subsidies to patients.

iii. **Avoiding vexatious litigation**.

Defending Court proceedings involves considerable cost to PHARMAC (King, 2000).

Thus, the Commerce Act exemption is clearly intended to give PHARMAC added leverage in its commercial negotiations with the affiliates of multinational pharmaceutical companies and to lessen the likelihood of costly litigation. Up until that time, pharmaceutical companies had been prepared to challenge PHARMAC under the provisions of the Commerce Act 1986. However, a decision of the Court of Appeal in 1998, confirming PHARMAC's exemption (under the Public Finance Act 1986), brought an end to a number of proceedings that were in progress against PHARMAC at that time (PHARMAC, 2005). Details of this case, together with subsequent cases brought under different legislation, are examined in more detail below.

As indicated, there is no appeal mechanism in the event that PHARMAC declines to subsidise a particular pharmaceutical, though suppliers can reapply at a later date. Suppliers have, however, sought to challenge individual PHARMAC decisions via the courts. Interestingly, the application of the nine decision criteria do not feature, but various other grounds such as alleged anti-competiveness, lack of even-handedness and rights-based arguments have been cited. The pivotal anti-competitive action involving the Commerce Act was brought by the Researched Manufacturers Industry (RMI) in 1997 (Researched

Medicines Industry Association of New Zealand v Pharmaceutical Management Agency, 1997).

In this case, the plaintiffs alleged PHARMAC[16] abused its dominant position as a purchasing agent within the pharmaceutical market. The action was brought under Part II of the Commerce Act 1986 which deals with anti-competitive practices. However, the Court found that § 2 of the Finance Act 1994 gave PHARMAC limited immunity from claims under the Commerce Act 1986 and, as a consequence, the case was struck out.

The RMI appealed the above decision, but the Appeal Court upheld the judgement of the High Court and the appeal was dismissed. As a consequence, this decision brought an end to court challenges under the Commerce Act, though it did little to assuage the feeling amongst pharmaceutical suppliers that PHARMAC uses the exemption and its monopsony position to impose restrictions that deter or eliminate competition.

Other actions attempted to challenge PHARMAC on different grounds. These have met with varying degrees of success, but generally the Courts have upheld PHARMAC's autonomy in its decision-making processes. In the first two cases which follow, pharmaceutical suppliers alleged (successively), "a lack of even-handedness"(Roussel v PHARMAC, 1997), and "unreasonableness" on the part of PHARMAC (Reckitt & Colman v PHARMAC,1997).

In August 1997, Roussel sought judicial review of PHARMAC decisions regarding subsidy of its antibiotic Rulide. PHARMAC reclassified the subsidy on Rulide prior to completing a review on competitors' products. The basis of Roussel's claim was that PHARMAC had breached its obligation to act even-handedly by not reviewing the subsidies on comparable products (Augmentin, Ceclor and Klacid). The Court granted Roussel judicial review on the grounds that in the reclassification process (which lowered the subsidy on Rulide and therefore affected its marketability) PHARMAC's decisions relating to Rulide were unlawful. This case was not without sequel.

[16] And the Transitional Health Authority as second defendant

In December of the same year, PHARMAC appealed against the High Court finding, and in a majority decision, the Court of Appeal overturned the High Court decision. The Court held that due to PHARMACs resource limitations, a progressive reclassification process, beginning with Rulide, was not improper.

In Roussel's subsequent appeal the Privy Council upheld the Court of Appeal's decision.

Another plaintiff, Reckitt and Colman, sought judicial review of a decision PHARMAC took which affected the subsidy on its product Gaviscon under § 51 of the Health and Disability Services Act 1993 (Reckitt and Colman v Pharmaceutical Management Agency, 1997). In 1996 the company introduced a new, lemon flavoured, variant of the original (peppermint flavoured) Gaviscon, a product which had been fully subsidised. PHARMAC held that only the original Gaviscon would continue to be subsidised and that the new lemon flavoured version would not receive subsidy. It was the basis of the Reckitt and Colman case that there was no new product and that Gaviscon should continue to attract subsidy regardless of flavour. The case thus turned on the issue of "sameness".

The judge concluded that there were no therapeutic, pharmacologic or clinical differences between the two products but noted that PHARMACs guidelines included having regard to cost considerations and in this respect the two products could be differentiated as the lemon-flavoured Gaviscon was more likely to be used and therefore cost PHARMAC more in subsidies. Accordingly, he held that lemon-flavoured Gaviscon was not the same as peppermint-flavoured Gaviscon for the purposes of the Pharmaceutical Schedule and this disposed of the plaintiff's case. The application for judicial review was thus dismissed.

This case is significant because the court held that PHARMAC could justifiably take cost, and the overall budgetary impact of changes to the Pharmaceutical Schedule into equal consideration (to the pharmacological and therapeutic ramifications) of their decision–making. As a consequence, pharmaceutical manufacturers were sent a very clear message by Justice Gallen that future litigation along these lines would be unsuccessful. Hence, this decision has a further dampening effect on those contemplating challenging PHARMAC decisions.

In the years immediately following this decision there were a number of actions brought against PHARMAC (Astra v PHARMAC, February 1999; Astra v PHARMAC, November 2000; GlaxoSmithKline v PHARMAC July, 2003)[17]. As these actions involved alleged breach of agreement and supply issues with existing drugs they fall outside the scope of this inquiry. More recently, however, in Walsh v PHARMAC High Court (August, 2007), the Court addressed a new issue – that of patient entitlement.

In this application for judicial review brought under s 8 of the Judicature Amendment Act 1972 the plaintiffs sought to overturn a decision taken by PHARMAC declining their application for funding under the CEC scheme for the anti-cancer drug, Herceptin. The plaintiffs also sought compensation for breach of their right to natural justice under § 27(1) of the New Zealand Bill of Rights Act 1990.

The plaintiff's position was that they had been receiving Herceptin treatment for early-stage breast cancer and should continue to receive it. Counsel submitted that that position was jeopardised "because the plaintiffs are or may be unable to continue to meet the cost of treatment from their own resources and may be forced to stop" (p. 6).

While recognising that each of the plaintiffs was in fact receiving Herceptin treatment, the Court reported that:

> none of the plaintiffs is currently receiving publicly funded Herceptin and that there is therefore no position to preserve as a matter of law; their current position as a matter of law (and fact) being that they do not have public funding (p.6).

In other words, they do not have a legal entitlement to receive subsidised Herceptin treatment. For this reason the plaintiff's application was dismissed.

The courts have upheld PHARMACs autonomy to make decisions affecting drug subsidies. For example, in the Reckitt and Colman case involving Gaviscon, the High Court ruled that PHARMAC is both entitled to, and required, to take cost into account in reaching its decisions, and that it has statutory authority not to have its day-to-day commercial decisions scrutinised (pp.10-13). In the recent Walsh case, the High Court similarly upheld

[17] And counter claims (PHARMAC v Astra Court of Appeal (1999); PHARMAC v Astra Zeneca (formerly Astra) High Court (2003).

PHARMAC's license to make funding decisions through the HEC scheme and held that it was not for the Court to direct PHARMAC to provide funding (p.8). Challenges based on even-handed treatment of similarly placed drugs, or breach of contract, have been successful in some cases (Roussel, 1997; Astra, 1999; Astra, 2003).

Summary

In the preceding pages I have proved an overview of the background that gave rise to the emergence of PHARMAC as a stand-alone Crown entity responsible for the maintenance of the Pharmaceutical Schedule. I have discussed the various demand and supply side strategies PHARMAC employs to meet its statutory objectives, in particular the contentious issue of reference pricing. PHARMAC's decision criteria and the "exceptional circumstances" schemes are similarly described. In addition, I have summarised the subsidy decisions taken by PHARMAC during the period 1999/00 - 2005/06. The organisational structure of PHARMAC, together with its various advisory bodies is described, as is the legal context in which it operates. PHARMAC's exemption from the Commerce Act 1986 is high-lighted. Because PHARMAC decisions are not open to appeal, suppliers have sought to challenge decisions through the courts. Generally, the courts have held in favour of PHARMAC.

Chapter Two - Literature Review

Introduction

The issue of drug funding is emotionally charged. It is recognised that there are tensions between the disparate groups which make up the health care sector. Sometimes this has spilled over into acrimonious exchanges between the competing interest groups (Clark, 1992; Davis, 2004). Pharmaceutical suppliers have an interest in securing funding for their products, and PHARMAC, as the funding body, has an obligation to ensure that its funding decisions provide value for money. The financial viability of pharmaceutical suppliers is not PHARMAC's concern. But other groups have an interest too. Patients have an obvious interest in receiving the best and most appropriate treatment, and increasingly patient groups are lobbying in the lay press and elsewhere. However, since the majority of treatment decisions are made on their behalf by doctors on patients' behalf, doctors also have an interest in what they are allowed to prescribe. First and foremost, doctors have a fiduciary responsibility to their patients which can bring them into conflict with the funding body. These tensions between fiscal and fiduciary imperatives have also become quite antagonistic at times, even in the medical literature. It is important therefore to recognise that each speaker has a vested interest in ensuring that his or her voice is heard.

A broad search utilising Google Scholar (encompassing PubMed) was initially conducted on 21.01.07 (keywords**: Pharmac, funding, pharmaceuticals, subsidy, decisions**). This yielded 413 citations. A complementary search of the PHARMAC website using the same search criteria yielded 157, mainly parallel, citations. More tailored searches initiated at regular stages identified emergent issues such as reference pricing, the effects of drug switching and the ethics of drug rationing. An additional search of the Te Puna website revealed that PHARMAC had been the subject of prior research on three occasions. Of these, one study looked at ethical and legal ramifications associated with some of PHARMAC's decisions prior to 2000 (Sims, 2000).[18] As a result of her study, Sims (2000) proposed a public review of PHARMAC and its policies for managing the Pharmaceutical

[18] The two other manuscripts concern drug metabolism and are not considered germane to this inquiry.

Schedule and concluded that rationing of pharmaceuticals [and other health services] should be based on need.

It is evident that there is a healthy debate in the literature concerning drug funding policies. This has been generated by a variety of sources including social policy theorists, economists and medical practitioners (Burgess, 2006; Crown, 2001; Davis, 2004; Eichler et al, 2004; Evans, 2002; Gauld, 2002, 2004; Hansen, 2006; Lexchin, 2000, 2002; Martin & Begg, 2000; Neyt et al, 2005; NICE, 2006; Peterson, 2006; Rasiah, 2006; Rosevear, 2006; Singer et al, 2001; Tensenbel, 2004; Woodfield et al, 1997). Moreover, there is a large and increasing body of literature concerning the ethics of rationing and issues of distributive justice in relation to pharmaceuticals (Gillett, 2005; Gillon, 2006; Lamont, 2007; Moore, 2006; Parfitt, 1997; Rawls, 1971; Seddon et al, 1999; Veatch, 1991; Wilkinson, 2006). Whilst these issues are relevant to a broader study, my primary focus is to analyse PHARMACs funding decisions against PHARMACs assessment criteria. Beyond a broad acceptance that some form of rationing is inevitable, given the finite level of available Government funding, I do not propose to enter the wider pharmaco-economic debate. Similarly, there is a wide body of substantive ethical theory concerning the principles of distributive justice. Other than to accept Gillon's (2006) observation that no one theory commands even wide acceptance, much less universal acceptance, I will not enter the broader ethical debate either. I will, however, examine the mechanics of specific interventionist policies employed by PHARMAC in so far as they affect drug supply.

Much of the information about drug funding decisions within the New Zealand context in the medical literature has been generated by PHARMAC, either anticipating, or in reaction to specific criticism.[19] Generally, the focus of the PHARMAC articles has been on justifying decisions not to fund new medicines (Crausaz & Metcalfe, 2005; Metcalfe, Crausaz, Moodie, McNee, 2005; Grocott & Metcalfe, 2005; Metcalfe, Brougham, Moodie, Grocott, 2005; Metcalfe & Crausaz, 2005; Metcalfe, Crausaz, Moodie, McNee, 2005; Metcalfe, Moodie & McNee, 2005). Very often in these responses, *cost-efficiency*, or

[19] Dissatisfaction with [some] PHARMAC decisions is not solely the domain of clinicians. Individual patient groups have formed active lobby groups with the express purpose of gaining increased access to various medicines. Among them, are the Breast Cancer Aotearoa Coalition, established in 2004, and the Access to Medicines Coalition (ATM), which was established in 2005. However, consumer reaction to PHARMAC funding decisions is beyond the scope of this enquiry.

budgetary impact are the most often encountered topics. The *health needs of New Zealanders*, and possible *risk factors* are also recurrent themes.

There have been at least two attempts by PHARMAC to explain their decision-making processes (Braae et al, 1999; Metcalfe et al, 2003). In both instances cost-effectiveness is held to be the primary determinant of successful pharmaceutical management. Challenges to PHARMAC's processes and decision-making are becoming more commonplace in the medical literature (Bosanquet, 2000; Frizell, 2005; Holt et al, 2005; Krebs, 2005; Martin & Begg, 2000; Milne, 2005; Peterson, 2006; Porter & Mulder, 2002; Simpson, 2005; Swinburn et al, 2000; Whyte & Ellis, 2005). Invariably, the subject of these challenges is a specific process, as for example reference pricing (Martin & Begg, 2000), or a specific medication or group of medications, such as clopidogrel (Whyte & Ellis, 2005) or cardiovascular drugs (Swinburn et al, 2000).

My analysis focuses on some of the most common criticisms in the medical literature relating to PHARMAC processes and decisions. Where such criticisms evoked a response from PHARMAC, details will also be included. Broadly speaking, eight themes emerged relating to PHARMAC decisions.

Reaction to PHARMAC decisions affecting particular drugs: Common themes

Two of the most pervasive themes to emerge in the literature review are *inconsistency* , where the authors identify PHARMAC decisions as being at odds with avowed Government health priorities or being out of step with decisions taken by other regulatory bodies, and *inequity* where a decision is held to be unjust relative to prior decisions. There are, however, instances where both issues are cited simultaneously. For example, White (2005) claims PHARMAC's decision not to fund bosentan, a drug used to treat a life-threatening, though rare form of, hypertension is both inconsistent (with Government policy) and iniquitous (to patients requiring high-cost drugs). Carter and Clay (2006) blur the distinction even further, claiming that the decision not to fund the drug erythropoietin for cancer is both iniquitous (for cancer sufferers) and inconsistent with overseas markets,

as well as being inconsistent with local Government policy. Therefore, whilst the following represents an attempt at separating out manifest themes, it is recognised that there is considerable interplay and over-lap between them.

Theme: Inconsistency

In my review of the medical literature, a recurrent criticism levelled at PHARMAC is that many of its decisions appear inconsistent or incongruent with Government health priorities. As previously alluded, White (2005) disagrees with PHARMACs decision not to fund bosentan, a decision he finds inconsistent with Ministry of Health policy. By his critique, one of the stated goals of the Ministry is to "reduce inequalities in health outcomes" yet, in this instance, no attempt is made to address inequalities in access [to high-cost] bosentan. Further, he contends, the Ministry of Health has stated that it will give substantial weight to interventions for which there is strong scientific evidence of effectiveness. Bosentan is effective, he claims, yet "the New Zealand Health system via its agent PHARMAC refuses to consider funding" (p.1762). Therefore, PHARMAC is inconsistent. PHARMAC's response again underlines its utilitarian ethos:

> These are very expensive treatments that may offer significant benefits to a small group of people. Such very expensive treatments have to compete for limited funds with less expensive medicines that treat large numbers and achieve greater population health gains for the same total costs (Metcalfe et al, 2005, p.1806).

White and Ellis (2006) mounted a similar argument in respect of the antiplatelet drug clopidogrel. Again, in this instance, the authors assert there is strong clinical evidence to support more widespread use of the drug which is presently only funded for a short period after coronary artery stenting. They contend that New Zealanders are being denied treatment by PHARMAC's policy of delaying funding. The PHARMAC response is to reinforce a recurrent theme, that of cost.

> There are also issues of scope- that is, the affordability (and opportunity costs) of providing clopidogrel to the 30,000 patients that [White & Ellis] advocate, as it would mean not funding many other investments (Moodie & Dougherty, 2006, p.1872).

The decision not to expand the availability of Lamotrigine, an antipsychotic, has also attracted controversy. Lamotrigine is an anticonvulsant and mood stabiliser which, although approved for use in the prevention of depression in bi-polar disorder and for treatment-resistant epilepsy, only receives funding for epilepsy. Ellis et al (2006) hold this to be both iniquitous and inconsistent, particularly because it appears to run counter to the New Zealand Mental Health Strategy's objective of providing effective treatment for bipolar depression. Hence, Ellis and colleagues provide another illustration of inconsistency.

Similarly, Krebs (2006) asserts that PHARMAC's decision not to fund Lantis, a long-acting insulin pump, is equally inconsistent with government policy. Reducing the incidence and impact of diabetes is one of the stated aims of the New Zealand Health Strategy and "the complete lack of funding for pharmaceutical agents such as insulin glargine severely limits accessibility to patients with diabetes and would seem in contradiction of this aim"(p.1641). Moreover, he claims that the assessment process adopted by PHARMAC has resulted in unacceptably long delays – a claim rejected by PHARMAC who assert the supplier was responsible for the long approval process (Metcalfe et al, 2005). Further, Metcalfe et al (2005) claims PHARMAC were in step with Australia and Canada in declining funding, citing an "uncertain" and only "modest extent of clinical benefit" over existing treatments, and "unfavourable, albeit uncertain cost-effectiveness" (p.1716). Despite this uncertainty, PHARMAC ultimately announced that Lantis would be funded under Special Authority provisions for those intolerant of, or unresponsive to, conventional insulin (Moodie, 2006). Therefore, Krebs identifies another inconsistency.

Likewise, Holt et al (2005) conclude that the decision not to fund bupropion, a drug used to abet smoking cessation, is also inconsistent, being directly contrary to Government policy and the practice of evidence-based medicine. They see this as an example of the 'adverse effect PHARMAC has on the health of New Zealanders through restricting availability of medicine' (p.1502). PHARMAC refutes this, claiming that there are two fully funded treatment options already available for smoking cessation, nortriptyline and nicotine replacement therapy (patches and gum). Rather than adversely impact the health of New Zealanders, they contend that their actions serve to enhance health outcomes, "Perversely,

by siphoning funds from other better potential investments, funding bupropium would have adversely affected the health of New Zealanders by restricting the availability of those [unspecified] agents" (Metcalfe et al, 2005 p.1545). Holt et al remain unconvinced. They reiterate their previous charge that PHARMAC is either unaware of, or chooses not to follow, Government policy:

> …PHARMAC has not provided any substantive justification as to why it has ignored the Ministry of Health's five year plan for tobacco control, in particular to give substantial weight to interventions for which there is strong evidence of effectiveness and to those which give benefit to large proportions of the community, and to maximise the benefit of targeted interventions (people with the greatest health needs such as Maori and low income New Zealanders) and minimise potential adverse effects (Holt et al, 2005 p.1546).

Further illustrations of inconsistency are apparent in the literature relating to anti-cancer drugs. Access to many of these drugs, particularly the newer ones, is similarly restricted. Gemcitabine, a drug used to treat bladder cancer, is one such example; Temozolomide (brain tumours), another. In the case of the latter, Hamilton (2005) claims there is ample evidence of efficacy yet PHARMAC has declined to provide funding. He asserts that this is in direct contravention of a Health and Disability Commissioner ruling that in discussing therapeutic options with patients the attending physician should "include options not necessarily available in the treating centre, or even New Zealand." (p.1775). According to Hamilton, standard treatment therefore has to take account of world standards. This charge elicited a [re]statement of PHARMAC's utilitarian position, wherein:

> At the moment, expensive treatments which may offer significant benefits to a small number of people, must compete for limited funds with less expensive medicines that treat large numbers and achieve greater putative population health gains for the same total costs (Metcalfe et al, 2005 p.1806).

Theme: International inconsistency

Being inconsistent with international medical convention is another commonly encountered theme. We see this, for example, in respect of PHARMAC's decision not to extend funding for the long-acting beta-agonists (LABAs), formoterol and salmeterol, and the long-acting

anticholinergic, tiotropium for chronic obstructive pulmonary disease (COPD) (Jones, 2005). Both LABAs are only funded for asthma and not COPD and tiotropium requires a "special authority" with a very prescriptive diagnosis. This situation evoked a strong reaction from Jones (2005) who contended this decision contravenes modern management practice. He contrasts the local situation with the United Kingdom where LABAs have been used commonly for COPD and asthma since 1997 and tiotropium has been available since 2003 with no restriction. Since they are superior to short-acting bronchodilators, he contends they are a logical treatment in COPD. Moreover, he contends, evidence would suggest tiotropium is probably superior to LABAs in treating COPD and should be used as first-line therapy. The ensuing response from PHARMAC is curious. They affirm that tiotropium is available under Special Authority provisions, and appear to accept that tiotropium is clinically effective (even cost-effective) in treating COPD, yet make the observation that 'uptake since the February listing has been low' (i.e. 29% of what they had predicted) (Metcalfe and Dougherty, 2005, p.1743). Jones would contend that the low uptake was a direct consequence of the very restrictive qualifying criteria. PHARMAC defends its decision not to widen access to the LABAs by claiming "the absence of good evidence of meaningful effects" (Metcalfe and Dougherty, 2005, p.1745).

International comparisons were also made in several articles critical of PHARMAC funding decisions affecting various rheumatological drugs. The anti-arthritic drug, Etanercept is one such instance. In New Zealand, PTAC first considered funding this drug in August 2002 and recommended that it be given a moderate priority for adult rheumatoid arthritis and high priority for juvenile inflammatory arthritis. Consequently, etanercept has received funding for juvenile arthritis since February 2004, but not for adult arthritis. This has led Grainger and Harrison (2005) to hold that this is inconsistent with the situation in the UK, Europe, USA and Australia where the drug (and others of its class) does receive funding for children and adults. Moreover, they hold that there is considerably more evidence to support the use of etanercept in adult rheumatoid arthritis than in childhood arthritis and that the initial PTAC recommendation for adults was "based on projected costs rather than science" (p.1707).

Another drug, raloxifene, used by post-menopausal women in the treatment of osteoporosis, is similarly available in other markets (Australia) but does not receive funding in New

Zealand (Gilchrist, 2006). In response, PHARMAC notes that discussions are ongoing with the supplier (Metcalfe et al, 2006).

Decisions affecting the availability of anti-psychotics have similarly evoked discontent and invited comparison with other markets by those practising psychiatry. For example, Porter and Mulder (2002), claim that due to lack of availability of a range of drugs for affective disorders, which are available in other developed countries (e.g. venlafaxine), New Zealand patients often receive treatment which they deem "substandard" (p.78). They argue that in the area of treatment-resistant affective disorder, the criteria employed by PHARMAC are problematic. Specifically, the criterion of demonstrable superiority over currently available drugs is difficult to meet (both ethically and practically) and even when evidence of efficacy is available, they contend that PHARMAC are sceptical of such evidence if it is sponsored by a pharmaceutical supplier, even though "they may be unable to find grounds to criticise the data itself" (p.80).

In contrast, Menkes (2002), is generally supportive of PHARMAC's purchasing policy, claiming that PHARMAC may be justified in its scepticism of company sponsored trial data. He does, however, support Porter and Mulder's plea for inclusion of venlafaxine, finding it 'extraordinary' that it is not available in New Zealand (p.62).

An international comparison was also central to the argument made by Carter and Clay (2006) in respect of the drug erythropoietin. Erythropoietin is another drug approved by Medsafe for cancer, yet it is not funded for this use. British and American guidelines advocate a wider use of erythropoietin than is the case here. It is possible to obtain the drug under the Hospital Exceptional Circumstances scheme, described earlier, but it is not uniformly available. Therefore, it is alleged, this situation is inconsistent with Government policy which requires equity of care across the public health system (Carter & Clay, 2006). PHARMAC consider that additional research is needed to confirm the risks and benefits of erythropoietin though notes it is currently assessing the cost-effectiveness of widening access to the drug (Grocott et al, 2006).

The issue of disparities between other countries is also raised by Sasidharan et al (2006) in respect of combined use of cisplatin and vinorelbine for non-small cell lung cancer. The

combination is funded in other countries but not here. Similarly, Fitzharris et al (2006), note that EpiPen is [also] not funded by PHARMAC, despite being available in Australia, the UK and US. However, in this instance, PHARMAC contend the product is not cost-effective, being greatly more expensive than the average cost per QALY that they currently accept (Moodie et al, 2006). Also mitigating against the device, PHARMAC claims that patients and caregivers are untrained with its use, though it could be similarly claimed that few are conversant with administering adrenaline via syringe in an emergency situation.

Leaving aside perceived iniquities with Australia, the UK and the US, the approval situation in New Zealand contrasts most markedly with that of Canada. In an illuminating paper, Martin and colleagues (2001) detail the framework by which the Canadian advisory group - Cancer Care Ontario Advisory Committee for the New Drug Funding Program – arrived at decisions to fund new cancer drugs in that province. They looked at 14 drugs in eight disease conditions, including trastuzumab, gemcitabine and vinorelbine, all of which were recommended for funding. How did they arrive at these decisions? It seems that if a drug was deemed efficacious it was approved. If there was not enough funding, they asked for more. In other words, rather than ask for a bigger slice of the pie, as is most often the case in New Zealand, they asked for a bigger pie (p. 1679).

A recent, highly contentious funding issue invited public comparison between New Zealand and other markets. PHARMAC's decision not to fund trastuzumab, the highly active antibody used in the treatment of HER2 - positive early breast cancer generated controversy. The drug is approved in many other markets, but not here. This has generated a raft of public pronouncements from the interest groups (various patient /consumer groups, PHARMAC, RMI, and the supplier), and a good deal of media interest. The debate in the medical press is only slightly less restrained (Burgess, 2006; Rosevear, 2006).

In June 2007 PHARMAC announced funding for a shortened, nine week treatment regimen for trastuzumab. Longer, 52 week duration therapies remain unfunded due to "uncertainty surrounding long-term benefits and risks; the high cost; effects on DHB service; and their consequential unfavourable relative cost-effectiveness" (Metcalfe et al, 2007). At the same time, PHARMAC added a rider that they were open to funding longer duration regimens if cost-effectiveness improves significantly. The fact that the product is funded in 22 other

OECD countries for 52 weeks as previously noted by the suppliers (Petersen, 2006), is deemed of little consequence.

Sub-theme: equity for the disadvantaged

Another emergent theme is that of equity, where the rights of the disadvantaged are held to have been compromised as a result of specific PHARMAC interventions. For instance, in his editorial in the New Zealand Medical Journal, Asher (2006) alleges that the decision to reference price Ventolin to Salamol (and the resultant part-charge for Ventolin) seriously disadvantaged those on low incomes and, in particular, Maori and Pacific Island children, who are already facing obstacles in accessing adequate asthma care. Prior to the introduction of Salamol, Ventolin was fully subsidised and available at no cost to the patient. He claims that PHARMACs decision-making is unjust in respect of Salamol because did not meet its own goals of identifying and eliminating health inequalities. To give weight to this claim he cites PHARMACs own Maori Responsiveness Strategy which acknowledges that:

> Cost was a significant barrier to Maori accessing their prescriptions. The $3 part-charge was considered a barrier to many whanau (families), particularly when they have other competing priorities for their very often low incomes, such as food and rent (PHARMAC, 2002)

Theme: Efficacy

The question of efficacy is another central theme identified in the literature. By this, authors invariably mean "clinical effectiveness', which often turns on the issue of bioequivalence. If two products are said to be bioequivalent it means they would be expected to be, for all intents and purposes, the same; that is, exert the same clinical effect.[20] By way of illustration, in their critique of the Ventolin® situation, referred to above, Gillies and colleagues (2005) question the efficacy of the generic product. They held that not only was

[20] The FDA has defined bioequivalence as " the absence of significant difference in the rate and extent to which the active ingredient of the active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study"(2003,p.7).

evidence of bioequivalence scanty (i.e. based on one study), but clinically the product was shown to be defective (in that it was prone to block), and therefore potentially dangerous. They questioned how such a poorly considered decision could be taken. PHARMAC, in response, point to a second study which they claim demonstrates bioequivalence and assert that any difference in the two products is "influenced by factors other than efficacy" (Metcalfe et al, 2005 p.1645). They attribute blockage to patients not cleaning the delivery device.

Reti (2006) also reported clinical differences in the two products. In an observational crossover study he assessed asthma stability in 36 patients converted from Ventolin to Salamol®. He concluded asthma stability was significantly worse with Salamol. This he attributed to a number of factors, including "true difference in active ingredient efficacy, physical differences in inhaler devices, and subject-related change anxiety" (p. 2279). Despite the methodological flaws in this study (study size, no "crossover" back to Ventolin etc), which the author himself recognised, the perception remains that Salamol is less effective than Ventolin[21].

It is rare to find instances in the medical literature where local physicians come out in support of a PHARMAC decision not to fund a particular drug. Even rarer are reports critical of decisions to approve funding. In the case of interferon beta however, a drug used to slow the progression of multiple sclerosis, a group of rehabilitative researchers from Auckland and Wellington assert that the evidence for cost-effectiveness of the drug is not compelling and suggest that the $5million currently being spent on the drug might be better directed elsewhere (McNaughton et al, 2006). Not surprisingly this drew an immediate response from the Multiple Sclerosis Society who argued that evidence of effectiveness could be attested by the 364 patients who continued to be prescribed the drug (Rawson, 2006).

[21] The Reti study also evoked a response from Taylor et al (2006). In this the authors were critical of the study design and the fact that it appeared not to have Ethics Committee approval. They claimed that because of its alleged deficiencies (lack of blinding etc) it shouldn't have been published in the NZMJ. Reti's response was that ethics approval was not required since the study only involved observing and recording the effects of PHARMAC policy on everyday people (2006). The editor of the NZMJ defended the journal's decision to publish the article on the basis that PHARMAC drug purchasing decisions had 'a lot of relevance to the New Zealand healthcare sector'(Frizelle, 2006)

Sub-theme: Equivalence

Another theme evident in the literature is the recurring claim that PHARMAC is "selective" in its review of the evidence base by which decisions are made. Invariably, this is tied up with the issue of "same or similar", by which it is meant that medicines with different pharmacological properties are regarded as being equivalent for the purposes of funding. In one such instance, Holt et al (2005) claim that PHARMAC attribute nortriptyline with the "same or similar" therapeutic effect as bupropium, both drugs being used for smoking cessation. Yet, these authors contend, bupropium has a much more benign side-effect profile than nortriptyline, and the only direct comparison study of the two agents does not provide evidence that nortriptyline is equivalent to bupropium (p.1545). Therefore, they contend, the comparison is both selective and erroneous. The issue smoulders on. In 2007, however, PHARMAC conceded that smoking cessation treatments can be highly cost-effective compared with other options for health spending, yet it persists with the claim that there is no significant difference between nortriptyline and bupropium (Metcalfe & Moodie, 2007).

Theme: *Delay*

The issue of delay is another commonly encountered theme. By this, medical practitioners imply that the PHARMAC approval process is unnecessarily protracted, certainly when compared to Australia (Wonder, 2006; MacKay, 2006). Some of this criticism is implicit, as, for example, in Wonder's (2006) comparison of the disparate approval times between New Zealand and Australia. Others see it as a deliberate rationing strategy. For instance, in relation to buproprion, Holt el al (2005) declare "PHARMAC appears to use delay in the approval of funding as a method to restrict the availability of medications" (p. 1547).

Theme: Procedural concerns

Another theme apparent in the literature is the way PHARMAC responds to criticism. There are some medical practitioners who clearly feel intimidated by what they see as stand-over tactics from PHARMAC. For instance, Holt et al (2005) charge PHARMAC with "...[having] an unfortunate tendency to personally criticise those who advocate the

availability of proven medications …[which are] not available or restricted [in] New Zealand." (p. 1546). This view is supported by the Editor of the New Zealand Medical Journal who in the same issue of the journal writes: "PHARMAC does not like criticism, if the intimidating phone calls and numerous emails I have been receiving are anything to go by" (Frizelle, 2005; p.1547).

In yet another example, Ellis and White (2006) observed:

> …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 (p.2040).

Whether such criticism is justified, there is certainly a perception amongst some medical practitioners that PHARMAC is very reactive to criticism.

Theme: Safety

Yet another recurrent theme is the issue of safety. Usually it is PHARMAC that invokes this issue to justify a decision not to subsidise a particular medicine as, for example, in the case of the cyclo-oxygenase inhibitors (COX-2) which are used in the treatment of rheumatoid arthritis and osteoarthritis. Examples of the class are celecoxib and rofecoxib, neither of which currently receive funding in New Zealand. PHARMAC evaluated these drugs over a four year period, and ultimately declined to list any drugs in this category in September 2003. By not listing these agents, PHARMAC claimed [retrospectively] to have prevented approximately 740 to 4220 excess myocardial infarctions and averted approximately 330 to 1900 excess deaths due to myocardial infarction (Grocott & Metcalfe, 2005 p.1690). Such claims of increased cardiotoxicity are rejected by Merck Sharp & Dohme (the distributor of rofecoxib) who maintain that establishment of the number of patients potentially injured by taking rofecoxib or any other COX-2 inhibitor is nothing more than speculation (Woolner, 2005).

The argument cuts both ways. The safety theme is also invoked by medical practitioners querying the advisability of some of PHARMACs funding decisions. An example is

provided by Ellis and White (2006) in relation to the statins. They contend that patient safety has been seriously compromised by PHARMAC's policy decisions. They state:

> Of all the mismanagement of medicines by the Pharmaceutical Management Agency Limited (PHARMAC), arguably the worst episode has been their woeful handling of the statin drugs. It is probable that PHARMAC's bizarre and short-sighted approach has caused more harm and premature deaths to New Zealand patients than any of their other manoeuvres (p.2033).

Likewise Mann (2005), in describing the disruption caused by the substitution of Pacific Pharmaceutical's brand of felodipine, FeloER® for Plendil® (and back again) which occurred in 2002, raises similar issues of patient safety being compromised[22].

Theme: Quality

The issue of product quality also arises, usually in relation to decisions to award particular sole supply tenders. The quality theme is explicit in the writings of MacKay (2005). She highlights specific instances where difficulties have arisen such as with generic paracetamol (being almost impossible to swallow), generic enalapril (disintegrating), and an inferior version of slow-release morphine (unpredictable blood levels) (p.1434).

Other times this theme is implied rather than stated, as for example in some of the claims referred to earlier- particularly in relation to safety, but also to the issue of bioequivalence, where it is held that the substituted generic product is not bioequivalent and is therefore therapeutically inferior to the branded product that it displaced. Examples of this are generic FeloER (Mann, 2005) and generic Salamol (Gillies et al, 2005; Reti, 2005).

Theme: Inaccuracy

Another recurrent theme in the literature is that PHARMAC makes statements which are inaccurate. For instance, Holt et al (2005) state that PHARMAC cannot persuasively claim that it was unaware of evidence that buproprion was more cost-effective than other

[22] He queried the slow-release characteristics of Felo ER – which he held to be "an important consideration given concern over the safety of short-acting [CCBs]" (p.1570).

treatments it currently funds, when the National Health Committee Guidelines for Smoking Cessation (cited in PHARMACs letter) provided (contradictory) evidence of this (p.1545). Moreover, Holt et al contend, in 2001 the supplier provided PHARMAC with a comprehensive cost-effectiveness analysis which showed that for buproprion the cost per life year saved ($1,540) was similar to that of nicotine replacement therapy ($1,570) and considerably less than other common treatments. These assertions are contrary to the PHARMAC position that it was unaware of the existence of this cost-efficacy data.

Grainger and Harrison (2005) provide another, though more muted, example of this theme. They high-light "erroneous" cost-benefit data and inappropriate choice of comparators which they claim PHARMAC circulated to District Health Boards (DHBs) in respect of etaneracept. "Whether intended or not", they allege circulation of this data has served as a barrier to DHBs funding etanercept (p. 1707) In response, PHARMAC affirmed its previous economic analysis and decision to circulate the discussion document to DHBs on a confidential basis (Metcalfe et al, 2005).

As indicated previously, few of the nine criteria employed by PHARMAC receive close scrutiny in the literature, although Swinburn et al (2000) do make the observation that PHARMAC decision-making processes generally need be more explicit and more transparent. When the criteria are cited in publications, either directly or by implication, the most common citations relate to inconsistency with criterion **i** (the health needs of all eligible New Zealanders) and criterion **viii** (the Government's health priorities). Less frequently, reference is also made to criterion **iii** (The availability and suitability of [alternate] medicines), criterion **vii** (the direct cost to users), criterion **ii** (the particular health needs of Maori and Pacific peoples), criterion **vi (**budgetary impact) and criterion **iv (**clinical benefits and risks). Instances where the decision criteria are cited are outlined in Table #4 below:

Table #4 Criteria cited by Medical Practitioners in Medical Literature

Criterion	Description	Author
i	Health needs of eligible New Zealanders	Begg et al (2003); Burgess (2006); Carter and Clay (2006); Fitzharris et al (2006); Gilchrist (2006); Grainger and Harrison (2005); Hamilton (2005); Krebs (2006); Mann (2002); Martin et al (2001); Porter and Mulder (2002); Sasidharan et al (2006); Swinburn et al (2000).
ii	Health needs of Maori and Pacific peoples	Asher (2006); Reti (2006).
iii	Availability & suitability of existing medicines	Gillies et al (2005); Jones (2005).
iv	Clinical benefits & risks	Ellis and White (2006); Grocott and Metcalfe (2005); Mann (2002).
v	Cost-effectiveness of drugs versus other services	
vi	Budgetary impact	McNaughton (2006); Rosevear (2006).
vii	Direct cost to users	Asher (2006); Holt et al (2005); Reti (2006).
viii	Governments health priorities	Carter and Clay (2006); Ellis et al (2006); Holt et al (2006); Krebs (2006); Whyte (2005).
ix	Any other criteria	

In the medical literature PHARMAC often justify decisions not to subsidise or extend the availability of a particular drug, or group of drugs, by reference to cost considerations or budgetary impact (criterion **vi)**. The agency specifically cites this criterion in relation to the statins, ACEs, bosentan, clopidogrel, trastuzumab and temozolomide. Clinical uncertainty or adverse side effects (criterion **iv)** is invoked in reference to erythropoietin and the COX-2 inhibitors, and in relation to trastuzumab and the LABAs. Criterion **i** (Health needs of eligible New Zealanders) is cited in reference to bosentan and temozolomide.

Summary

In this section, I have undertaken an analysis of the literature relating to PHARMAC subsidy decisions. It is recognised that the issue of drug funding is emotionally charged and that it attracts many diverse perspectives. Although consumers are affected by PHARMAC's decisions, my focus is primarily on the perspective of prescribers. It is rare to find instances of support for PHARMAC decisions in the medical literature. Challenges

to PHARMAC's decision-making are increasingly common. Another feature of the literature is that much of it is generated by PHARMAC, either in anticipation of, or in reaction to specific criticisms.

Reactions to PHARMAC's decisions are thematically analysed. Eight broad themes and two sub-themes emerge from this analysis, though there is considerable over-lap between them. The most recurrent themes are ***inconsistency,*** both with Government health priorities, and with international medical convention. Other themes include ***inequity***, where a decision is held to be unjust relative to prior decisions; ***efficacy***, where it is contended the reference priced product is clinically less effective than the comparator; ***delay***, where PHARMAC delays decisions as a deliberate rationing strategy; ***procedural concerns***, centring on PHARMACs reaction to criticism, product ***safety*** and ***quality*** and the ***inaccuracy*** of some of PHARMACs statements.

PHARMAC's decision criteria receive some attention in the literature. When the criteria are cited, most commonly the citations relate to criterion **i** (health needs of eligible New Zealanders) and criterion **viii** (Government's health priorities).

Whilst decisions affecting individual drugs or groups of drugs are rigorously debated by interest groups, there is a paucity of literature taking an over-arching, systematic view of PHARMACs funding decisions. Sims (2000) study looked at legal and ethical issues associated with PHARMACs operating procedures prior to 2000. There is no research in the literature that I am aware of which systematically analyses these decisions against PHARMACs stated assessment criteria. Martin & Ellis (2000) perhaps come closest with their examination of the effects of reference pricing, though consistency with PHARMAC's own operating policies and procedures is a secondary focus of their enquiry. This research aims to address this gap.

Chapter Three - Method

Introduction

I will begin this chapter by describing the methodological basis for this study. In particular, I have been influenced by the writings of Boyatzis (1998) and Luborsky (1994). The focus will then move to the method employed and inclusion criteria for the sample. The process of data gathering and analysis will be described in detail. I will then conclude the chapter with a discussion of how trustworthiness and credibility were achieved before noting limitations inherent in the study design.

Purpose of Study

This thematic analysis describes and analyses decisions taken by PHARMAC affecting the subsidy (and thence availability) of new prescription medicines. The goals of the research are to determine whether PHARMAC decisions reflect the stated criteria and whether other factors are reflected in the decisions.

Methodology

A researcher's epistemology is that person's theory of knowledge (Creswell, 2003; Crotty, 1998) which determines how a social phenomenon will be studied. The epistemological position which informs this research is that illuminating data are contained within the minutes of PHARMAC and PTAC meetings. My focus therefore is with the views of the decision-makers, as reflected in their minutes. It is recognised that decisions affecting the availability of pharmaceuticals have a direct impact on patients and prescribers. The views of patients, reflected in the lay media, would therefore provide a rich vein of data. Similarly, the medical literature, reflecting the perspective of prescribers, would provide an equally rich source of data. Both (potential) sources are, however, beyond the scope of this enquiry.

Qualitative research is defined by Creswell (2003) as "an inductive process of building from the data to broad themes to a generalised model or theory" (p. 132). The logic of this inductive process is thus:

> The researcher begins by gathering detailed information from participants and forms this information into categories or themes. These themes or categories are developed into broad patterns, theories, or generalisations that are then compared with personal experiences or with existing literature on the topic (pp.132-133).

Although founded in the qualitative paradigm, this study did not seek to gather data from "participants", rather texts in the form of minutes provided the analysable data-base from which broad patterns and themes subsequently emerged. I sought to understand the rationale behind PHARMAC's decisions and to determine patterns of consistency (or inconsistency) in relation to its decision criteria. I identified thematic analysis as an appropriate methodological basis for this study as it allowed me the flexibility to organise and summarise my findings derived from this large data-base.

Thematic Analysis

Thematic analysis, defined by Berg (1995) as a systematic process for categorising the content of texts and identifying relationships among the categories, is the methodological basis for this qualitative research. Boyatzis (1998) expanded on Berg's definition by describing thematic analysis as a progression:

> Thematic analysis is a way of seeing. Often, what one sees through thematic analysis does not appear to others, even if they are observing the same information, events, or situations. To others, if they agree with the insights, it appears visionary. If they disagree with the insights, it appears delusionary. Observation precedes understanding. Recognising an important moment (seeing) precedes encoding it (seeing it as something), which in turn precedes interpretation. Thematic analysis moves you through these three phases of inquiry (p. 1).

Themes are described by Taylor and Bogdan (1994) as being variously units derived from patterns such as conversation topics, vocabulary, recurring activities, meanings, feelings or

folk sayings and proverbs. Alternatively, Luborsky (1994) defines themes as the "manifest generalised statements by informants about beliefs, attitudes values or sentiments" (p. 195).

This latter definition is particularly helpful, since it provides a clear direction to understand and reflect the perspectives contained within the data, and it directs researchers to distinct and explicit statements rather than inference as the basis for designating a particular statement a theme. Luborsky (1994) further distinguishes themes from *patterns* and *topics*, terms which are often used interchangeably. He holds that "patterns" should be best used to describe findings from the researcher's own frame of reference. Patterns derive "from the researcher's observations and analyses of a regularity, structure or inferences but without direct concern for their meaningfulness to the people being observed" (p. 195). "Topics", on the other hand, should be used to describe the content of replies to a question. They are not in themselves themes.

Theme identification

Boyatzis (1998) delineates three primary approaches to developing themes systematically. The first is theory driven; the second, prior data or prior research driven; and the third, inductive (i.e. proceeding from the raw data) or data driven (p. 29). It is his view that the inductive method is the most fundamental way to develop themes. He allows that following existent theory, or using codes already developed by other researchers are obviously the most direct ways of developing themes, but a potential downside is that the researcher accepts possible assumptions, projections and biases inherent in the theory or other researcher's data (Boyatzis, 1998, p. 37).

Luborsky (1994) discerns two basic approaches to theme identification. One is to search out those statements that recur most often. The other way is to identify those statements that are flagged in some way as having particular meaning to the author. The first approach is weighted towards counting the most frequently occurring statements. The second approach is more interpretive, requiring the researcher to attach a value or degree of significance to the author's own statements. In their decision-making process PHARMAC and PTAC have

adopted a decision tree involving nine criteria. These criteria provide the basis of my thematic analysis.

The fact that thematic analysis provides a direct representation of the author's own viewpoint is one of the reasons for adopting this method. The minutes of PHARMAC and its advisory body, PTAC, serve as an official record of the decision and, in many cases, the justification for the decision. Unlike qualitative studies involving participants, thematic analysis involving minutes of meetings where decisions were made need not require verification from the authors, as the documents themselves are a direct reflection of the author's position. Moreover, they provided a constant record that I was able to refer to verify recurrent or significant themes.

As an aid to identifying patterns and themes, I adopted Luborsky's (1994) idea of a worksheet on which a running record of topics is noted. Whilst it was the author's intention that this be used for reviewing transcripts, it served equally well in tracking recurrent topics and phrases in the formal minutes. The worksheet was simply an Excel spreadsheet designed to record key words and phrases as they occurred, and recurrent topics and strong assertions or important meanings. Provision was also made within the worksheet to record the nine decision criteria cited in the minutes, and patterns. Whether the decision was consistent with the criteria cited, or reflected the reasons given, was noted. On a separate worksheet, new products were aligned by therapeutic category and patterns noted.

In quantitative research, the term *data* has different connotations than used here. It has come to mean "bits" of information, where data is viewed as numbers. I use the term as a broad descriptor for the *minutes.* Also, "minutes" is used to describe the official record of PTAC or the PHARMAC Board meetings. Similarly, the term *author* designates the person who authorised the respective minutes. By *new*, I simply mean a new chemical entity (drug) that has not been generally available in New Zealand, as opposed to a modified version of a product.

Many of the terms used in the medical literature have acquired colloquial meaning. For example, the term *generic* is most commonly used as an adjective to describe a whole group or class of objects. For consistency, I have adopted the medical terminology, where

"generic" is taken to mean an identical (or similar) copy of an off-patent drug. Similarly, the term *indication* is used in the medical sense where it is taken to mean approved use (rather than a pointer or clue). The term *intervention* encompasses drug therapies (and other measures) used to influence the course of a particular medical condition.

Research Design

Method

This study employed documentary minutes as the units of analysis. Data were collected from the PHARMAC website encompassing the official minutes of PTAC meetings over the period 2000–2006. These data were cross-referenced against the corresponding minutes of the PHARMAC Board obtained under the Official Information Act. The advantage of this is that these documents are the formal official depiction of PHARMACs and PTAC's decision making. They therefore provide the most direct and clear cut means of gaining insights into PHARMAC operations. Another advantage of using this method is that it is unobtrusive. Instead of directly observing or interviewing, or asking someone to fill in a questionnaire, in this instance I was able to deal with something produced by others for some other purpose.[23] The minutes of both PHARMAC and its agent PTAC are intended to summarise and validate decisions taken in respect of drug subsidies. They provide, as Robson (2002) would have it, "unobtrusive measure[s]" which are unreactive, in the sense that the documents (minutes) are not affected by the fact that I am using them (p.349). A possible disadvantage with using documents for purposes other than for which they were intended is that it is difficult to allow for any biases that this might introduce to the analysis[24].

In choosing to employ thematic analysis as the study method, it was recognised that there were a number of analytic issues to be addressed concerning subjectivity and selectivity (as

[23] Lincoln & Guba (1985) draw a distinction between *documents* and *records* on the basis of whether the text is proposed for an official rather than personal reason. Thus official minutes, along with bank statements, drivers' licenses and the like would be deemed records, in that they attest to a formal transaction, whereas diaries, letters, field notes and so on have a personal function (p.277).

[24] PHARMAC Board minutes were intended for internal circulation within PHARMAC and were obtained under the Official Information Act 1982.

well as “projection” and the introduction of bias). To counter any suggestions of subjectivity and selectivity, decisions to affirm and decisions to decline subsidy were chosen in equal number. A reverse chronological approach to data collection was adopted. Working backwards from December 2006, PTAC minutes were examined and the first ten decisions affirming subsidy and the first ten decisions declining subsidy were selected. The corresponding PHARMAC Board decisions were then cross-matched with the PTAC decisions as a measure of congruence.

Sample size and criteria

Subsidy decisions taken by PHARMAC during the period 2000 – 2006 were initially deemed eligible for the study. Such decisions endorsed, deferred or declined subsidised access to new drugs. Alternatively, they extended, deferred or declined access to drugs already receiving some level of subsidy - but for another medical indication. However, it became apparent that archival records of PTAC recommendations were only made available on the PHARMAC website from August 2002, thus reducing the range and extent of the original estimate. It transpired that some 130 individual decisions were taken in the intervening period to December 2006, so it became necessary to reduce this list to a more manageable, but representative, level. Of these, approximately 53 related to new drugs, the remainder to widened access or new forms of existent drugs. Based on Creswell’s (2003) recommendation to have a sample of at least ten, this study examined 20 individual decisions, including ten that affirmed subsidy and ten that declined subsidy. Again, for practical reasons, the decision was taken only to include new drugs in the sample base.

Data Gathering

I undertook an Internet search of the PHARMAC website to locate a prospective data base. This resource provided one arm of the core data – the formal minuted PTAC decisions. However, the PHARMAC Board minutes were not contained within the website and it was necessary to invoke the Official Information Act to obtain details of PHARMAC Board decisions directly from the Agency. The process by which each data set was obtained is described below.

PTAC minutes

The individual minutes for all decisions for the period 2002-2006 were located from the PHARMAC website and arranged in reverse chronological order. Relevant details of each decision were recorded on an Excel spread-sheet (see Appendix # 11). Such parameters included the date of each decision, details of the status of the product under consideration (whether it was a new or existing product), the outcome of the decision (whether to endorse, defer or decline subsidy), the priority accorded the decision (whether low, medium or high), and any criteria cited (1-9). The data was then examined to determine eligibility, and products that did not meet the inclusion criteria excluded. Deferred decisions were similarly excluded.

Consequently, the range of decisions was reduced considerably. Working backwards from December 2006 with this reduced list, the first ten decisions to affirm subsidy and the first ten decisions to decline subsidy were isolated and details of each recorded in another Excel spread-sheet. To achieve this sample, the range extended from November 2006 back to February 2004. The decisions were then arranged in reverse chronological order according to outcome on another Excel spread-sheet (see Appendix# 12). Chronological sampling was chosen because it both decreased the likelihood of selectivity referred to earlier, and allowed me to achieve a cross-section of agents within close proximity of time so as to make sound and accurate analysis of the themes.

PHARMAC minutes

To obtain copies of the PHARMAC Board minutes it was necessary to make a formal request under the provisions of the Official Information Act 1982. This application was lodged on November 18, 2007 and the documentation ultimately received on February 21, 2008. Details of the PHARMAC decisions were recorded on Excel spread-sheets in the manner described for the PTAC decisions.

The official minutes of the Board meetings, and the corresponding PTAC minutes were the units of analysis. Both sets of minutes provided a constant context upon which I could make inductive observations.

The PTAC minutes were analysed in relation to the nine decision criteria and emergent themes defined and synthesised. The same process was repeated for the PHARMAC Board minutes and emergent themes compared and contrasted with the PTAC minutes for consistency. Commonalities and differences were noted.

The PHARMAC Board minutes are important as they are the official outcome of the Board's deliberations. The decisions are subsequently conveyed to the drug company seeking subsidised entry to the Pharmaceutical Schedule by PHARMAC staff. They may provide an indication as to which criteria influenced the decision, but they often do not provide a clear-cut indication to the drug's sponsor as to which aspects of their submission were accepted or rejected.[25] In this sense they are different from a legal decision where the judge typically examines arguments and comments on their relative merit.

Sample characteristics

The sample comprised 20 decisions affecting 19 different products. The majority of the decisions affected anti-neoplastic drugs, in 6/20 instances (30%); followed by anti-retrovirals (HIV) in 4/20 instances (20%); and cardiovascular drugs in 3/20 instances (15%). The remainder were for opioid-induced constipation (1), iron overload (1), enzyme replacement (1), macular degeneration (1) and Alzheimers (1).

[25] Sponsors submissions are generally very extensive, encompassing requisite therapeutic, epidemiologic and pharmaco-economic considerations as determined by PHARMAC. In contrast, the PTAC minutes are typically brief and expressed as "snap shots". The PHARMAC Board minutes were anywhere between 2-7 pages and essentially only noted the resolution and any conditions attached to prescribing. The accompanying assessments from PHARMAC staff were more comprehensive and noted the rationale for the decision and the relevance of each of the decision criteria.

Data Analysis

In qualitative research the word "analysis" may be taken to mean any treatment of the data in which the data are configured into a coherent whole (Polkinghorne, 1995). I undertook an iterative analysis, drawing on, and revisiting data to identify themes. The minutes provided a distillate of decisions taken in respect of drug subsidy. I followed Luborsky's (1994) procedural steps of analysis:

Step 1: An initial reading of the minutes is undertaken to locate recurrent or important topics. At first reading no notes are taken.
Step 2: A second reading is undertaken to confirm main points and topics. Summarise and record the gist of the major topics with a phrase (these are used further in the analysis as code words or descriptive labels).
Step 3: Next, narrow down the field of candidates by frequency and recurrence.
Step 4: After a series of candidate themes are identified, the main themes can be analysed using both analytic definitions in combination (frequency and importance). (1994, p. 203).

To identify themes in terms of frequency, it is a simple enough task to count up all the topics and record the most frequent ones, but to identify the most relevant or important "candidates" Luborsky (1994) helpfully suggests the researcher look for "markers" in terms of direct statements. Other criteria he suggests include the "pervasiveness" or "importance" of a theme across many different topics (p. 204).

An initial analysis of the minutes was conducted according to Luborsky's steps 1-4. Patterns and themes were established by analysing commonalities across the two data sets (minutes). By comparing and categorising emergent themes a number of common and pervasive "markers" were revealed.

When the themes and thematic categories had been determined, I read all the decisions once again to ensure the structure and meaning of the themes and thematic categories. These were then cross-matched against PHARMAC's nine decision criteria.

Rigour

The need to incorporate rigour into the process of qualitative research has been vigorously debated in the literature. Some have suggested that concern about the demonstration of rigour results from a struggle for legitimacy in a discipline that has been traditionally dominated by the positivist paradigm (Aroni et al, 1999). Others have argued that by its very nature "rigour" is an empirical analytical term and therefore it does not fit into an interpretive framework (van Manen, 1990, Denzin & Lincoln, 2000).

Rigour is the means by which the researcher shows integrity and competence regardless of the paradigm. The attributes of rigour span all the research approaches (Tobin & Begley, 2004), however, some authors have rejected the term completely and use other terms such as "trustworthiness" (Lincoln & Guba, 1985).

According to the latter, the basic question addressed by the notion of trustworthiness, is straightforward: "How can an inquirer persuade his or her audiences that the research findings of an inquiry are worth paying attention to?"(p. 290). For Lincoln & Guba (1985), the notion of trustworthiness is demonstrated through *credibility, transferability, dependability* and *confirmability*. These are analogous to *internal validity, external validity, reliability,* and *objectivity,* terms used in conventional quantitative inquiry.

Thus, *credibility* is paired with *internal validity*, by which researchers seek to establish confidence in the "truth" of their findings. To establish credibility, researchers use a variety of techniques. One is prolonged engagement, that is "the investment of sufficient time to achieve certain purposes; learning the 'culture' [of the authors], testing for misinformation introduced by distortions either of the self or of the authors…" (Lincoln & Guba, 1985, p. 301). Another is 'member checks' where [participants] are given their interview transcripts and the research reports and invited to comment on the researcher's findings.

Transferability is analogous to *external validity*. By transferability it is meant that what is found in one setting may have application in another. Lincoln and Guba (1985) remark that to achieve transferability:

> …the burden of proof lies less with the original investigator than with the person seeking to make an application elsewhere. The original inquirer cannot know the sites to which transferability might be sought, but the appliers can and do. …the responsibility of the original investigator ends in providing sufficient descriptive data to make similarity judgements possible. (p. 298).

In other words, the aim here is to provide sufficient information about the setting in which the research was conducted for the reader to determine whether the findings have applicability to other settings.

Dependability is the equivalent of *reliability*. In the quantitative researcher's lexicon, reliability equates to replicability. By this it is meant that the same tests should yield the same results. However, according to Lincoln and Guba (1985) this sort of replication is impossible under the qualitative framework because the research findings are produced by constantly changing interactions between researchers and participants. On the other hand, *confirmability* equates to *objectivity* in the quantitative paradigm, and is concerned with establishing that the research findings hold up under scrutiny. Researchers need to be able to link their findings to the data in a "discernible" way (Schwandt, 1997, p. 164).

Both *dependability* and *confirmability* correlate to different aspects of quantitative research and they are achieved using similar techniques. Of these techniques, auditing is most commonly invoked by methodologists (Lincoln & Guba, 1985; Schwandt, 1997). Auditing within the context of qualitative research is akin to a fiscal audit. In the words of Lincoln & Guba (1985):

> "The creation of an 'audit trail' is a systematized approach to reflexive methodological accounting …[the aim of which is] to provide a critique of the procedures used and a check on their clarity and consistency" (p. 382).

Trustworthiness

The trustworthiness of the study was attested both in relation to the process of data collection, and in the process of data analysis (Crotty, 1998). For example, to overcome any researcher bias in the interpretation of data, and as an auditing measure, I maintained

detailed notes on decisions made throughout the process. This added to the study's "auditability" and, therefore, trustworthiness (Roberts, 2006; Koch, 1994).

The way the data was collected is equally transparent. The PTAC minutes were (catalogued by date) and first reviewed to determine the outcome of the decision. Those affirming subsidy were colour coded and separated out from those declining subsidy, and reviewed again to determine whether they met the "new product" inclusion criterion. The PHARMAC minutes were similarly initially catalogued by date. From this data set the minutes corresponding to the PTAC decisions were selected and the two sets of minutes arranged in pairs. Worksheets pertaining to these individual decisions were similarly catalogued.

Qualitative content analysis is a particularly reliable approach to handling data (Luborsky 1994; Roberts, 2006). By this process specific codes were created to describe statements from the minuted transcripts, and these were subsequently found to be stable over time (Luborsky 1994, Roberts, 2006).

Credibility

Prospectively, the most serious threat to thematic analyses is *projection*, by which it is meant "reading into" or "attributing to" another person, something that is your own construct or value judgement (Boyatzis, 1998). To overcome this possibility, I consciously challenged any potential biases and predispositions that may have influenced the study design or the conclusions that I ultimately came to.

It is recognised that researcher bias, deriving either from selective collection and recording of data, or from interpretation based on personal perspectives, can potentially compromise credibility. In arbitrarily choosing December 2006 as the starting point for this research, and in analysing decisions to both affirm and decline subsidy in equal measure, I have sought to avert any charges of selectivity. Equally, I have no personal involvement with, or interest in, any of the products being considered.

It is recognised too, that being familiar with the field can be both advantageous and potentially disadvantageous for the researcher. From my experience within the pharmaceutical industry, I am aware of processes and procedures associated with drug registration and reimbursement. Such insights may be useful in authenticating responses and findings, but, as I have observed, familiarity also carries with it a risk of projecting my own constructs or biases (Boyatzis, 1998). To guard against this I reanalysed the minutes when I thought bias might influence my analysis.

In the Husserlian tradition, bias is avoided through recourse to "bracketing", wherein the researcher attempts to suspend his or her "pre-suppositions" (experience, judgement and beliefs), (Crotty, 1998). Given my familiarity with the field, it would be very difficult to suppress my "pre-suppositions". However, by reflecting on them, and by considering the effect that this might have on the research, I have added a further measure of credibility.

The reduction of bias was also facilitated by following Luborsky's (1994) steps of analysis as described above. In accord with his recommendations, interpretations were checked, and re-checked and amended as appropriate, with my supervisors providing feedback as to whether they were recognisable and consistent accounts. This process also allowed me to reflect on my interpretations. Koch (1994) has recommended that an audit trail should be evident in the study to achieve rigour. This was achieved through preserving the raw data (minutes and other documents), together with my work sheets and analysis notes.

Patton (1990) held that credibility can also be enhanced through (among other things) triangulation of data. By this he meant the use of multiple data sources to understand a phenomenon. I was conscious of this while the study was still in proposal form and therefore thought to widen the data base to include PTAC minutes as well as the official PHARMAC Board minutes. Other techniques suggested by Patton (1990) for improving credibility include making segments of the raw data available for others to analyse (investigator triangulation), and the use of "member checks," by which "respondents" are invited to corroborate findings (Lincoln and Guba, 1985, pp. 313-316). However, neither technique was appropriate in this instance, as the study design only involved one researcher and did not involve participants, or "respondents", in the sense that Lincoln and Guba (1985) had in mind.

Deficiencies/Limitations

Using minutes as the units of analysis could be problematic as they are not formulated for the purpose of research. In documentary analysis, a distinction is sometimes made between "witting" and "unwitting" evidence. Witting evidence has been defined by Robson (2002) as being that which the author intended to impart - unwitting evidence being "everything else that can be gleaned from the document" (p. 353). In this instance, the minutes are formulated to record decisions. PTAC minutes convey an explicit (witting) recommendation to PHARMAC and how that recommendation accords with the nine PHARMAC decision criteria. The minutes provided by the PHARMAC Board are extremely important because they communicate the official decision regarding whether to subsidise the drug to the drug sponsor. This is also manifestly "witting", except where the criteria by which the decision was arrived at are not disclosed, in which case they are open to "unwitting" conjecture.

By following Luborky's procedural steps I sought to provide useful and trustworthy research findings. Whilst multiple source triangulation was employed as a measure of establishing trustworthiness, other forms of triangulation could not be attempted due to practical considerations. For instance, neither PTAC meetings, nor PHARMAC Board meetings are open, so it was not possible to observe the participants in these settings. Researcher triangulation was not an option, as I was the sole researcher. Nor was member checking deemed appropriate in this instance.

Whilst there were no major health policy changes during this period, and no significant changes to the PHARMAC decision criteria, it cannot be concluded that the decisions were necessarily representative of decisions taken over the wider timeframe 2000 – 2006. A comparison of decisions across this wide period would be informative.

Chapter Four – Findings

Introduction

PHARMAC is charged with a difficult task. Managing expenditure on subsidies for pharmaceuticals requires lengthy deliberation and complex decision-making processes. The combination of therapeutic, economic and societal values into a reasoned, justified and consistent approach to decision-making is a challenge in itself, but it is complicated even further by weight of Government fiscal restraints, public expectation, prescriber autonomy, and supplier expectations.

During any given year PHARMAC considers numerous subsidy requests. For instance, during 2005/06 PHARMAC received 71 applications from suppliers for new or extended access to medical treatments. Not all were approved, but as a result of decisions taken over this period the Agency claimed that almost 250,000 more New Zealanders will receive subsidised medicines than before (PHARMAC, Annual Review 2006, p. 3). Yet PHARMAC is not immune to criticism.

There is a perception amongst at least some medical practitioners that PHARMAC is both "inconsistent" (Krebs, 2006; White, 2005; White & Ellis, 2006) and "selective" in its review of the evidence base by which some decisions are made (Holt et al, 2005). Others variously charge that some PHARMAC decisions are "iniquitous" (Carter and Clay, 2006), or that they are based on scanty evidence of "efficacy" (Gillies et al, 2005; Reti, 2006). Moreover, it has even been contended that PHARMAC delays the decision-making process itself as a deliberate rationing strategy (Holt et al, 2005). Also, a number of individual pharmaceutical manufacturers (and their industry body, the RMI) have at various times challenged individual PHARMAC decisions as being either "unreasonable" (Reckitt & Colman v Pharmaceutical Management Agency, 1997), lacking in "even-handedness" (Roussel v Pharmaceutical Management Agency, 1997), or an "abuse of its dominant position" as a purchasing agent (Researched Manufacturers Industry Association of New Zealand v Pharmaceutical Management Agency, 1997). Whilst none of these cases specifically addressed the nine decision criteria as discrete grounds for judicial challenge, it

is of significance that in the Reckitt & Colman case involving Gaviscon the Court ruled that PHARMAC is required to take cost into account in its subsidy deliberations.

At the outset of this analysis it was not known whether evidence would emerge that would support each or any of these assertions, though it was not thought likely as the data set involved different products than those on which these allegations were based. Nor was this the research aim. The research objective was to see whether PHARMAC took the nine criteria into account in its decision-making. Does PHARMAC consistently take account of the decision criteria, or are there other factors outside the criteria which influence its decision-making? As PHARMAC's principle advisory body, PTAC is similarly obliged to follow the same decision criteria in its deliberations. As PTAC recommendations both precede and inform PHARMAC decisions, I assessed the PTAC recommendations prior to commencing my analysis of the PHARMAC Board decisions. In this chapter I describe themes that have emerged from the PTAC and PHARMAC Board minutes. These will be assessed relative to the nine criteria which purportedly underpin all subsidy decisions. I begin by making some general observations about the nature of the data base before reporting on the thematic analyses of the respective minutes.

PTAC Decisions

General considerations

As outlined in the previous chapter, the core PTAC decisions ranged across an array of different therapeutic categories. Most affected were the anti-neoplastics (n=6), followed, in rank order, by; antiretroviral drugs (n=4); cardiovascular drugs (n=3); and drugs for, variously, constipation (n=1); iron overload (n=1); hepatitis (n=1); organ rejection (n=1); enzyme replacement (n=1); macular degeneration (n=1) and Alzheimer's (n=1) (see Table # 5 below). PTAC recommended subsidising anti-neoplastics in equal measure (PTAC 01+; PTAC 07+; PTAC 08+), and in three of four cases recommended subsidies for antiretrovirals (PTAC 04+; PTAC 09+ and PTAC 10+), and in two of three cases for cardiovascular drugs. Whether these decisions are representative of all decisions within the respective categories is beyond the scope of this study.

Code	Product	Date	Therapeutic Use
PTAC01+	Faslodex	Nov-06	Breast cancer
PTAC02+	Movicol	Nov-06	Opioid-induced constipation
PTAC03+	Tracleer	Nov-06	Pulmonary arterial hypertension
PTAC04+	Viread	Aug-06	HIV
PTAC05+	Exjade	Aug-06	Iron overload
PTAC06+	Micardis	May-06	Hypertension
PTAC07+	Arimidex	Feb-06	Early breast cancer
PTAC08+	Temodal	Nov-05	Glioblastoma
PTAC09+	Keppra	Aug-05	HIV
PTAC10+	Viread	Feb-05	HIV
PTAC01-	Baraclude	Nov-06	Hepatitis B
PTAC02-	Caelyx	Nov-06	Breast cancer
PTAC03-	Alimta	Aug-06	Lung cancer
PTAC04-	Certican	Aug-06	Organ rejection
PTAC05-	Tarceva	May-06	Lung cancer
PTAC06-	Fabrazyme	May-06	Enzyme replacement
PTAC07-	Visudyne	May-06	Macular degeneration
PTAC08-	Emtiva	May-05	HIV
PTAC09-	Exiba	Aug-04	Alzheimers
PTAC10-	Crestor	Feb-04	Lipid lowering

Table # 5 PTAC Decisions (Product and Therapeutic Use)

Note: Two decisions were made in respect of one product (Viread) above.

The range of therapeutic categories is therefore wide, but it is it known whether they are representative of the categories.

As noted previously, both PTAC and PHARMAC are obliged to take account of the nine criteria listed in the PHARMAC OPPs in pharmaceutical subsidy decisions. However, in five of the 20 cases referenced above, there is no reference to <u>any</u> of the criteria as having influenced the PTAC decision. If PTAC did give the criteria due consideration in these instances it is not apparent in its minutes. In the remaining 15 cases, one or more criteria were cited, and in only two cases was one criterion cited (PTAC10+; PTAC08-). Often multiple criteria were cited (see Table #6 below).

Table #6 PTAC Decisions (Criteria cited)

		Criteria									
Code	**Product**	**Nil**	**i**	**ii**	**iii**	**iv**	**v**	**vi**	**vii**	**viii**	**ix**
PTAC01+	Faslodex		1		1			1			
PTAC02+	Movicol		1		1	1					
PTAC03+	Tracleer	1									
PTAC04+	Viread		1		1	1					
PTAC05+	Exjade		1		1	1					
PTAC06+	Micardis					1		1			
PTAC07+	Arimidex		1		1	1		1	1	1	
PTAC08+	Temodal		1		1				1	1	
PTAC09+	Keppra		1		1	1					
PTAC10+	Viread				1						
PTAC01-	Baraclude		1		1	1					
PTAC02-	Caelyx		1		1	1					
PTAC03-	Alimta		1		1	1					
PTAC04-	Certican		1		1	1				1	
PTAC05-	Tarceva		1		1	1					
PTAC06-	Fabrazyme	1									
PTAC07-	Visudyne	1									
PTAC08-	Emtiva					1					
PTAC09-	Exiba	1									
PTAC10-	Crestor	1									
Total		5	12	Nil	13	12	Nil	3	2	3	Nil

Criteria **ii** (*the particular health needs of Maori and Pacific peoples*); **v** (*cost-effectiveness*) and **ix** (*such other criteria as PHARMAC sees fit*) were not cited at all. However, as criterion **ix** is a discretionary criteria pertaining solely to PHARMAC, this is to be expected.

In the 45 instances where criteria were cited, overwhelmingly the preference was for criteria **iii** (*availability and suitability of existing medicines*); **i** (*health needs of New Zealanders*) and **iv** (*clinical benefits and risks*). And in most cases (11 of 13), the three criteria were cited together.

PTAC recommendations to affirm subsidy were generally included reference to a minimum of three criteria (in eight of ten cases), and in one case, six (PTAC07+). In only one instance (PTACO3+), were no criteria cited at all. On the other hand, when opting to decline subsidy PTAC only cited three or more criteria on five occasions. In one instance

(PTAC08-) only one criterion was cited, and in four cases no criteria were cited at all. Whether PTAC took the criteria into account in these cases cannot be confirmed as no criteria were recorded.

PTAC considered a diverse array of products from within a range of therapeutic categories. In the majority of cases (15 of 20) reference was made to the PHARMAC decision criteria, but in a significant number of cases (five of 20) PTAC did not reference any criteria in their decision-making. Beyond these general findings, a number of recurrent and important themes were also apparent in the PTAC minutes. These will be described in the following section.

Thematic analysis

In accord with Luborsky's procedural steps of analysis, a number of main themes were analysed according to frequency and recurrence (importance). Overlaying these considerations was the important issue of fittingness with the criteria that the decision-maker cites as the basis for the decision. In other words, does the decision reflect the stated criteria?

Given PTAC's expertise in pharmacology and therapeutics, it was not surprising that most of its deliberations were taken up with comparisons with existing therapies, clinical efficacy, or perceived patient benefits. This is reflected in the preponderance of citations for criteria **i, iii** and **iv,** which together account for 37 of the 45 citations (see Table #6, above). PTAC members have no apparent vocational expertise in pharmaco-economics, yet they are also required to take cost-related issues into account. There is evidence that they do this, but they are much less inclined to cite cost-related criteria directly. In fact, there are only five instances where cost-related criteria are expressly referred to (see Table #6, above). Other factors too are drawn on such as the Government's health priorities, which is at the heart of criterion **viii**.

What emerge are four broad themes. The first theme is decisions in which the decision maker state and apply the criteria from the list. In the second theme, the decision-maker

claims it applies criteria from the list but does not. The third theme identifies that the decision-maker does not state any of the criteria from the list. The fourth theme identifies that the decision-maker applies stated criteria, but also apply unstated criteria. The analysis of the PHARMAC decisions revealed some variations on these themes which will be fully explored separately. For the moment I will examine PTAC decisions through the lens of the four themes. Each theme will be described and illustrations provided.

Theme#1: PTAC state and apply criteria

The cases were examined to determine whether the decision-maker applied the criteria it claimed as the basis for its decisions. By ”apply”, I simply mean that the decision-maker determined a criterion as relevant, expressly cited it, and the minutes reported why it was relevant to the decision. In nine cases, this occurred. The following examples will be described to demonstrate how this decision-making operated.

The Viread decision

In the case of Viread, PTAC stated that it made the decision to recommend subsidy on the basis of three criteria. It cited criteria **i, iii** and **iv** as underpinning its decision (PTACO4+). Criteria **i** takes account of *the health needs of New Zealanders*. As expressed, this particular criterion is somewhat ambiguous, but I interpret it as applying to the particular patient group for whom the drug has application and not the population at large. Given this definition, the decision reflected this criterion when it reported that: “The Committee noted that [Viread] is currently in development for the treatment of chronic Hepatitis B and may prove to be of particular use in HIV/Hepatitis B co-infected patients” (PTAC04+, para. 8), and: “The Committee recommended that [Viread] be listed on the Pharmaceutical Schedule with a moderate priority for use in treatment-experienced and treatment-naïve HIV infected patients and with a high priority for treatment of patients with HIV/Hepatitis co-infection” (PTAC04+, para. 11).

Criteria **iii** concerns *the availability and suitability of existing medicines,* which I interpret as meaning how the drug compares with subsidised drugs in a given therapeutic category.

The decision reflected this criterion when it reported "[The Committee] considered that differences in favour of the [Viread] and emtricitabine treatment group were evident across all the efficacy endpoints presented" (PTAC04+, para. 6). The Committee also noted that "…significantly more patients on [Viread] and emtricitabine reached the primary endpoint of HIV RNA <400 copies per mL compared with patients on Combivir" (PTAC04+, para. 6).

The next criteria cited was criteria **iv** which reflects the clinical benefits and risks of the drug. There is no ambiguity attached to this criterion, which was reflected in the Committee's decision to recommend subsidy on the basis of clinical superiority over the comparator Combivir. No counter-balancing risks are identified, quite the opposite, with the Committee noting that "withdrawal due to adverse events was higher and adherence was lower in the Combivir treatment group" (PTAC04+, para. 7).

Viread was previously considered by PTAC for use in treatment-resistant HIV (PTAC09+). In that instance the Committee based its recommendation to list the drug for this indication solely on criterion **iii** (*availability and suitability of existing medicines*) because "there are few options for therapy for treatment-experienced patients" (PTAC09+, para. 6). This is one of the few instances where there is no ambiguity as to the criterion underpinning the decision.

The Micardis decision

Another example of PTAC applying stated criteria related to the antihypertensive drug, Micardis. In this instance PTAC claimed that it based its decision to recommend subsidy on two criteria. The first criterion was **iv** (*the clinical benefits and risks of pharmaceuticals*). The decision reflected this criterion when it noted that: "[Micardis] was another angiotensin II antagonist and that it is as effective as the [other] angiotensin II antagonists currently listed ..." (PTAC06+, para. 2). The Committee might also have noted criterion **iii** (*availability and suitability of existing medicines)* in drawing this parallel, but did not.

The second stated criterion is criterion **vi** (*the budgetary impact* (*in terms of the pharmaceutical budget and the Government's overall health budget*). There is a clear

indication of this criterion in the minutes with the Committee recommending that "…[Micardis and the other drugs of its class] could be reference priced for hypertension" PTAC06+, para.6.). Also, PTAC recommended that Micardis be listed on the Pharmaceutical Schedule, "but only if it is cost neutral to the Pharmaceutical Budget" (PTAC06+, para. 7).

The Keppra decision

The anti-epileptic drug Keppra provides another example of the decision-maker applying stated criteria. In this instance PTAC again cited criteria **i**, **iii** and **iv.** Criterion **i** (*health needs of eligible New Zealanders)* is reflected in the Committee's acknowledgement of the group for whom Keppra has application "patients aged 16 years and over" (PTAC10+, para. 1). PTAC also noted that Keppra may prove beneficial for an additional group of patients "who continue to have frequent seizures despite current therapy" (PTAC10+, para. 6).

Criterion **iii** (*availability and suitability of existing medicines*) is reflected in the Committee's recognition of the supplier's claim that "…[Keppra] would mainly replace lamotrigine, which may be a potential advantage, given the risk of Stevens-Johnson syndrome with lamotrigine". The third criterion, criterion **iv** (*clinical benefits and risks of pharmaceuticals)* is reflected in the acknowledgements that "[Keppra] could be more efficacious than [comparators], with an improved safety profile" (PTAC10+, para. 4), and that it had "a good short-term safety profile" relative to other antiepileptic agents (PTAC10+, para. 5).

Theme #2: PTAC state criteria but do not apply them

The Arimidex decision

PTAC stated criteria but did not fully discuss them in relation to the anti-cancer agent Arimidex. There is a distinct lack of detail evident in the minutes relating to this drug. PTAC indicated that six criteria were relevant to its recommendation to list the drug. Yet

the minutes do not reflect this, except in a rather oblique way. Three of the criteria can be directly accounted for (criteria **i, iii, iv**), but the minutes do not expand on how the remaining criteria were relevant to the decision (criteria **vi, vii** and **viii**). The minutes do indicate that the Committee had considered an application for funding Arimidex previously and it was assumed that these criteria might be apparent in the minutes of the earlier decision. However, this could not be confirmed, as a review of all PTAC decisions tracing back to August 2002 failed to locate any such reference. It was concluded that the product must have been first considered prior to August 2002, when PTAC minutes were first posted on the PHARMAC website. Consequently, it cannot be confirmed whether PTAC took account of "*the budgetary impact (in terms of the pharmaceutical budget and the Government's overall health budget*" Arimidex might have (as in criterion **vi**), nor can the *"direct cost to health service users"* be assessed (criterion **vii**). Finally, it can only be assumed that anti-cancer agents are a priority for health funding (as delineated in criterion **viii)**, though the minutes do not expand on this.

Theme #3: PTAC do not state criteria (specificity)

There were five instances where PTAC did not cite any criteria as being germane to their recommendations (Tracleer, Fabrazyme, Exiba, Crestor, Visudyne). Despite this apparent oversight, the minutes invariably provide some reflection of the Committee's reasoning.

The Tracleer decision

In the case of Tracleer, where the decision was to recommend subsidy, no explicit reason was given, but the committee clearly recognised the significance of the disease for which the drug was indicated. This is reflected in its concluding remark "…The Committee noted that PAH is a serious condition requiring planned treatment" (PYAC03+, para.17). Thus, leaving aside any other considerations, criterion **i** (*health needs of eligible people*) might have been cited as being relevant to this decision. In the remaining four cases PTAC declined subsidy.

The Fabrazyne decision

No criteria were ascribed to PTAC's decision not to recommend subsidy for Fabrazyme, despite the fact that the Committee clearly had some issues about the product's cost-effectiveness. This is evident from its recognition of:

> …the non-pharmaceutical costs of [Fabrazyne] treatment, such as infusion cost, nursing and medical costs, diagnostic testing, blood tests, imaging, organ biopsies and costs associated with infusion reactions and adverse effects would be significant (PTAC06-, para. 13).

The fact that PTAC thought the product might best be considered under PHARMAC's High Cost Pharmaceutical review (PTAC06-, para.13) is also explicit recognition that cost-effectiveness was an overriding consideration. So, given this very clear acknowledgement, one might expect that criterion **v** (*cost-effectiveness of meeting health needs by funding pharmaceuticals.*…) would have been cited as being relevant to this decision.

The Visudyne decision

In the case of Visudyne the Committee did not to record any cost-related criteria, although the minutes indicate that it had concerns about how the product might be funded. In this instance too, its reaction was also to refer the funding issue back to PHARMAC by stating that "…the Community Pharmaceuticals Budget was not the appropriate funding mechanism for [Visudyne]…" (PTAC07-, para. 6). Both decisions are illuminating as they indicate a general reluctance on PTAC's part to make decisions based largely on cost considerations.

The Exiba decision

The Committee similarly omitted any reference to guiding criteria in reference to Exiba, though the members' reasoning is abundantly clear in the minutes. For instance, the

minutes report "…it would be difficult to justify the listing of [Exiba] on cost-effectiveness grounds" (PTAC09-, para.4). And cost-effectiveness is the basis for criterion **v**.

The Crestor decision

In the remaining case, Crestor, no criteria are identified, though they might well have been. In this case the Committee's reasoning is similarly clear as indicated by the statement "…other agents for the treatment of raised cholesterol levels with good safety and clinical outcome data were available…" (PTAC10-, para. 6). Thus, criterion **iii** (*availability and suitability of existing medicines…*) and criterion **iv** (*clinical benefits and risks of pharmaceuticals*) might appropriately have been reported as being relevant to the decision not to recommend subsidy.

Theme #4: PTAC apply stated criteria but also apply unstated criteria

The Caelyx decision

In the case of the anti-cancer agent Caelyx, PTAC cites three criteria which it claimed to be the basis for its decision not to recommend subsidy. The minutes clearly reflect the stated criteria, but they also point to other, unstated, criteria as the basis for the decision. For example, whilst the minutes do note aspects of the drugs side-effect profile relative to comparators (criteria **iii, iv**), they do not record criteria pertaining to cost considerations (criteria **v, vi, vii**) which are apparent in the statement "…given its high cost and unfavourable toxicity profile in what is essentially a palliative setting the Committee recommended that the application be declined" (PTAC02-, para. 9). Unequivocally, cost, as much as toxicity, would seem to be at root of this decision, yet none of the criteria pertaining to cost are recorded in the minutes.

The Alimta decision

The same pattern is evident with another anti-cancer drug, Alimta. PTAC cite the same three criteria as being relevant to their decision not to recommend subsidy, and again the minutes clearly reflect the stated criteria. However, the Committee also appear equally influenced by cost when they state "…[they] did not consider that the difference in the adverse effect profile justified the extra expenditure for [Alimta]." (PTAC03-, para. 7).

The Exjade decision

This pattern is also evident with Exjade, which the Committee also recommended for subsidy. The criteria deemed relevant to the decision all pertain to perceived clinical benefits (criteria **i, iii, iv),** yet it is equally apparent that other, unstated criteria were also taken into consideration. As in the case of Alimta, these unstated criteria also relate to cost. For instance the Committee noted, on the one hand "…that the use of [Exjade] would result in a reduction in the infusion services required and may represent a saving to DHB service budgets" (PTAC05+, emphasis added, para. 6). In other words, they recognised the potential for a cost saving which is at the heart of criteria **v** (*cost-effectiveness of meeting health needs by funding pharmaceuticals rather than using other publicly funded health and disability support services*). Yet criteria **v** was not directly cited. On the other hand, the Committee also considered "…that the cost of [Exjade] represented a substantial risk to the Pharmaceutical Budget as there was major potential for use in inappropriate settings" (PTAC05+, emphasis added, para. 7). This is a direct reflection of criterion **vi** (*the budgetary impact in terms of the pharmaceutical budget and the Government's overall health budget),* yet this specific criteria was not recorded as being relevant. However, that the Committee accorded more weight to the impact on the Pharmaceutical Budget than it did to any potential savings to overall Vote Health, is implicit in its recommendation that Exjade be targeted under (restrictive) Special Authority criteria.

The Movicol decision

The case of the laxative Movicol is somewhat contradictory. In this case, no explicit reason is given for recommending subsidy but the Committee reference criterion **i, ii** and **iv** as being relevant to their decision. There is no issue with criterion **i** (*health needs of New Zealanders*). This criteria is clearly reflected in the Committee's recognition that, with danthron having been discontinued from the New Zealand market, "some patients may benefit from an alternative treatment" (PTAC02+, para. 4). The problem arises when PTAC chooses "lactulose as the principal comparator in New Zealand" PTAC02+, para. 3) despite the fact that there is "no evidence to compare [Movicol] to lactulose" (para.3). It is appropriate that it should cite criterion **iii** (*availability and suitability of existing medicines*) and criterion **iv** (*clinical benefits and risks*) as being relevant, but the recommendation to approve subsidy is questionable in light of this perceived lack of evidence.

I will now switch the focus to how these recommendations were collectively received by PHARMAC. Did the PHARMAC Board adhere to the PTAC recommendations, or did the Board incorporate other factors? Were the same themes evident in the PHARMAC decision process?

PHARMAC Decisions

General Considerations

By February 2008, PHARMAC had made decisions relating to a minority of the recommendations referred by its advisory body, PTAC. Of the 20 funding recommendations referred by PTAC, PHARMAC had resolved to list five, with decisions pending for the remainder (c.f. Table 7 below).

Table # 7 PHARMAC Decisions Following PTAC Recommendations

Product	Relevant PTAC Meeting	PHARMAC Decision Date
Faslodex	Nov 06	No decision
Movicol	**Nov 06**	**Sept 07 (Chief Executive)**
Tracleer	Nov 06	No decision
Baraclude	Nov 06	No decision
Caelyx	Nov 06	No decision
Viread	**Aug 06**	**Feb 07 (Board)**
Exjade	Aug 06	No decision
Alimta	Aug 06	No decision
Certican	Aug 06	No decision
Micardis	May 06	No decision
Tarceva	May 06	No decision
Fabrazyme	May 06	No decision
Visudyne	May 06	No decision
Arimidex	Feb 06	No decision
Temodal	**Nov 05**	**Mar 06 (Board)**
Keppra	Aug 05	No decision
Emtiva	**May 05**	**Feb 07 (Board)**
Viread	**Feb 05**	**Feb 07 (Board)**
Exiba	Aug 04	No decision
Crestor	Feb 04	No decision

There are significant time lapses in some instances between PTAC making a recommendation to PHARMAC, and the Board ultimately making a decision affecting subsidy. In the extreme case of Crestor, PHARMAC has yet to make a decision after 48 months. Only Movicol, Viread and Temodal were acted upon within six months of PTAC's recommendation. Why the approval process is more protracted with the remaining products is not known. This may be worth examining in further research. Nor is it within the scope of this inquiry to determine whether PHARMAC takes longer to endorse the recommendations of its advisory body than with other regulatory authorities as charged by Wonder et al (2006).

What is known is that PHARMAC staff does take the decision-criteria directly into account in their assessment. The PHARMAC Board may take each of the criteria into account, but its minutes record only the decision and any conditions attaching to supply. The underpinning decision criteria are contained within supplementary documentation provided by PHARMAC support staff as an attachment to the official minute. This documentation includes PTAC's recommendation as well as PHARMAC's own internal assessment and,

as the case may be, other, external assessments. The nine decision criteria specifically addressed within the PHARMAC assessment in these cases are outlined in Table # 8 below.

Table # 8 PHARMAC Decisions (criteria cited)

		Criteria									
Code	Product	Nil	i	ii	iii	iv	v	vi	vii	viii	ix
PC02+	Movicol		1		1	1	1	1	1		
PC04+	Viread		1	1	1	1	1	1			
PC08+	Temodal		1	1	1	1	1	1	1	1	
PC10+	Viread		1	1	1	1	1	1			
PC08-	Emtiva		1	1	1	1	1	1			
Total		0	5	4	5	5	5	5	2	1	0

Note: only criterion **ix** was not deemed relevant to any of the specified decisions

The Board is not bound to accept PTACs assessment of the application under the decision criteria and may apply different weightings to each of the criteria from those attributed to PTAC (PTAC Guidelines, 2002). However, the documents did not provide any evidence of the criteria having been weighted. What was evident, however, is that all of the above products were listed subject to Special Authority restrictions on access, indicating at least a tacit recognition by PHARMAC of the primacy of cost-effectiveness (at the heart of criterion **v**).

What the documents do show is that PHARMAC clearly assessed each of the products against the decision criteria. And unlike PTAC, there was much less blurring of the boundaries between explicit and non-explicit application of the criteria. If PHARMAC considered a particular criterion relevant it was stated with the reasons. If PHARMAC did not consider criteria relevant, it similarly made this explicit. So, rather than the four , often overlapping, thematic groups that characterised PTAC decision-making, the PHARMAC decisions can essentially be reduced to two categories – where the decision-maker stated and applied the decision criteria; and where the decision-maker applied new factors outside the decision criteria. I will now illustrate this distinction.

Theme #1: PHARMAC state and apply criteria

This is characterised by the decision-maker both stating, and providing clear reasons as to how the stated criteria were relevant to its decision. In this we can detect congruence between reasons reported and the criteria cited. This is a common characteristic of some of the PHARMAC decisions. For example, on each occasion where Viread and Emtiva were considered, there is clear documentary evidence that PHARMAC considered all, and applied some, of the decision-criteria. In these cases, PHARMAC applied six of the nine criteria[26], the remainder being specifically reported as not relevant to the decision. For example, criterion **i** (*health needs of New Zealanders*) is clearly recognised as being a relevant consideration. The minutes note that the proposal "would enable HIV infected patients to be treated" (p.20). So too *the particular health needs of Maori and Pacific peoples* (criteria **ii**) are recognised in acknowledging that "the rate of HIV is increasing in Maori and Pacific populations mainly through sexual relations with HIV-positive immigrants" (p.20).

Clinical benefits are similarly recorded in relation to *the availability and suitability of existing medicine* (criterion **iii**):

> There are currently four classes of antiretroviral drugs funded on the Pharmaceutical Schedule: the NRTIS, NNRTIs, Protease inhibitors and an infusion inhibitor. However, new treatments are always needed to combat inevitable resistance development to existing treatments (p. 20).

Likewise, *the clinical benefits and risks* (criterion **iv**) are specifically acknowledged:

> [Viread] and [Emtiva] have been shown to have superior efficacy to Combivir (zidovudyne plus lamivudine) in HIV treatment-naïve patients. [Viread] has some advantages over the existing NRTIs on the Pharmaceutical Schedule, namely once-

[26] In contrast, PTAC recorded only criterion **iii** (*availability and suitability of existing medicines*) as having application to Viread, and also recorded only one criteria in relation to Emtiva. In the case of the latter, it recommended declining subsidy, citing criterion **iv** *(the clinical benefits and risks).* PHARMAC, however supported the application and the Board ultimately endorsed its recommendation.

> daily dosing and fewer metabolic side effects which may benefit particular patient groups (p.20).

This reasoning was reinforced:

> [Viread] may be of particular benefit in treatment-experienced patients taking the infusion inhibitor enffuvitide (Fuzeon) which must be administered with optimised background therapy (OBT) including at least one new antiretroviral drug to which the patient has never previously been exposed. In addition, Viread] is currently in development for the treatment of chronic Hepatitis B and may prove to be of particular use in HIV/Hepatitis B co-infected patients (p. 20).[27]

The relevance of *cost-effectiveness* (criterion **v**) was reported:

> Cost-utility analyses for the use of [Viread] in treatment naïve patients and as a salvage treatment in treatment-experienced patients indicate that [Viread] is relatively cost-effective ($8,000 – $21,000) compared with other pharmaceuticals that have been funded (p.20).

The *budgetary impact* , in criterion **vi** was similarly reported in great detail.

In contrast, PHARMAC identified criterion **vii** (*direct cost to health service users*) as not being relevant because "Patients' out-of-pocket expenses would remain unchanged…" (p. 21). Nor were criteria **viii** (*Government's priorities for health funding)* and **ix** (*such' other' criteria*) deemed "relevant to assessing this proposal" (p. 21).

> No weighting was attributed to any of the applied criteria. However, both products were listed subject to tight prescribing restrictions, and both were subject to a discount from the supplier. It would seem therefore that cost, and cost-containment, figured highly in the decision to subsidise both products.

[27] This latter benefit was also recognised and reported by PTAC.

Theme # 2: PHARMAC apply a factor outside criteria list (contentiousness)

Whilst PHARMAC verifiably take account of the nine criteria in the cases referred, there are also occasions where it takes into account factors outside the list. Two notable examples are Temodal and Movicol.

The Board resolved to list Temodal subject to Special Authority restrictions on prescribing. PTAC had previously come to the same conclusion but whereas PTAC cited criteria **i** (*health needs of New Zealanders*), **iii** (*clinical benefits and risks*), **vii** (*costs to health service users*) and **viii** (*Government health priorities*) as being relevant considerations, PHARMAC staff clearly considered all of the criteria and rated **i – viii** as being relevant. Only criterion **ix** (*such 'other' criteria)* was expressly deemed not relevant to the decision (p.15).

Yet, the supplementary documents also demonstrate that PHARMAC took account of factors outside the specified criteria in reaching its decision. In addition to the clinical, societal and cost considerations referenced, PHARMAC also noted "…the proposal is considered publicly *contentious* by PHARMAC's Chief Executive…" (italics mine, p. 4). This is expanded upon further:

> There has been considerable public and political interest in this issue with extensive media coverage. PHARMAC has progressed this application with some speed, and in November updated the Minister and members of Parliament in November 2005 on progress, anticipating that a funding decision would be made in early 2006 (p.7).

Therefore, the Board identified an additional factor, "contentiousness". This was given further expression with PHARMACs acknowledgement of medical interest in the issue:

> [Temodal] was the subject of a Special Series article in the New Zealand Medical Journal (NZMJ), to which PHARMAC responded including timetables. PHARMAC has since written to the Journal advising the provisional agreement and soliciting consultation feedback. (p. 7).

Theme # 3: PHARMAC apply a factor outside the criteria list (consistency)

The case of Movicol is similarly illuminating. Again the PHARMAC Board recommended listing subject to Special Authority restrictions on prescribing and restrictions on volume. PTAC had previously recommended listing citing **i** *(health needs of New Zealanders),* **iii** (*availability and suitability of existing medicines)* and **iv** *(clinical benefits and risks*). PHARMAC's assessment explicitly recognised the proposal as being "cost-effective relative to other potential investments at this time" (p.17) (criterion **v)**; extensive coverage of the *budgetary impact* (criterion **vi);** and explicit acknowledgement of the *direct cost to health service users* (criterion **vii)** reflected in the statement " This proposal would reduce the out of pocket expenses to patients who are currently purchasing Movicol privately, and who would qualify for treatment under the proposed Special Authority criteria" (p.17).

Only criteria **ii** *(health needs of Maori and Pacific peoples),* **viii** *(Government health priorities),* and **ix** *(such 'other' criteria)* were expressly held to be irrelevant. Yet PHARMAC do take account of other factors in reaching this decision.

As with Temodal, PHARMAC manifestly recognise 'contentiousness' as a factor in the decision-making process, though in this case they adjudge "the proposal is not considered legally/politically/medically or publicly *contentious* by PHARMAC's Acting Chief Executive" (italics mine, p. 6).

However, in this case they introduce yet another factor, '*consistency'*, into the mix. It is noted that; "The proposal is *consistent* with previous Board decisions on policy because it involves investing in a new pharmaceutical entity on recommendation from the Pharmacology and Therapeutics Advisory Committee." (italics mine, p.6).

Thus, to the stated criteria, PHARMAC might add *consistency* with prior decisions along with the degree to which a decision might be publicly acceptable, politically expedient, litigious or medically defensible (*contentious*).

From the foregoing, it is clear that PHARMAC is more diligent in its application of the existing criteria than its medical advisory committee, PTAC. Similarly, there is less ambiguity with PHARMAC decisions as to why particular criteria were deemed relevant. Moreover, PHARMAC were more likely to consider and apply a wider range of criteria. However, the greatest point of departure was that PHARMAC either implicitly, or explicitly, introduced new factors into the decision-making process. Whether the decision was likely to be *contentious,* or whether it was *consistent* with prior decisions were also important factors for PHARMAC to consider.

Whilst the decisions were invariably justified on the basis of therapeutic gains to those deemed likely to benefit from the particular drug, usually relative to other currently available treatments, the effect of cost, and the related budgetary implications, were also important considerations. Significantly, all of the products approved by PHARMAC were subject to restrictions on prescribing, and in all cases were subject to rebates or discounts from the suppliers. However, the relative weight of each criterion is nowhere attested, and although cost implications might be suspected as carrying more weight than therapeutic implications, this is purely a matter of conjecture.

Chapter Five – Discussion

Research into the important role undertaken by PHARMAC is sparse. This is surprising, given the impact that PHARMAC has on the health of so many people. In managing the Pharmaceutical Schedule PHARMAC is responsible for the provision of medicines which ultimately affect the health of millions of New Zealanders. Currently, it is estimated that at least 2.69 million people had their medicine subsidised (PHARMAC, Annual Review 2007). Presently, there are approximately 2600 medicines which receive Government subsidy, though not all are fully subsidised. Each year PHARMAC typically approves around 40 applications from drug companies for subsidised access to their products. Some of these are for new products, but more often they are for expanded access to existent products.

PHARMAC was established with the specific aim of improving the management of Government expenditure on pharmaceuticals (Davis, 2004). In assessing which pharmaceuticals to subsidise, PHARMAC takes into account nine decision criteria. These guiding criteria are predominantly fiscal, though two are essentially societal and another two motivated by clinical considerations. PHARMAC has wide discretion in the application of these criteria and can apply whatever weighting it considers appropriate.

In undertaking its core function, PHARMAC can draw on the expertise of various advisory bodies, foremost among them PTAC. PTAC is similarly required to take account of the guiding decision criteria.

This inductive analysis of funding decisions during the period 2000-06 aimed to extend the understanding of PHARMACs decision-making. This study utilised the official minutes of the PHARMAC Board and PTAC relating to subsidy decisions. PTAC decisions both precede and inform PHARMAC decisions. The intention of the study was to examine whether stated intentions were reflected in the recorded decisions of both agencies. Moreover, it examined the written decisions for factors outside the nine criteria. Therefore,

the twin goals of this research were to determine whether the written decisions reflected the stated criteria and whether other factors are reflected in the decisions.

Subsidy decisions which the PHARMAC Board undertakes are not in themselves simple procedures. The process of reaching a decision involves an understanding of inputs from a variety of sources. Normally the Board has to consider clinical and therapeutic advice from PTAC and other parties, as well as in-house cost-benefit assessments from PHARMAC staff or external analysts. Given the length of the evaluation process and the complexity of the evidence presented from these various sources, it is recognised that the minutes are accordingly selective.

What do the minutes convey? Typically, PTAC minutes provide a distillate of the current thinking on the clinical application of the product. They do not uniformly cite particular criteria as being relevant to their decision and often any association is implied rather than direct. In contrast, the PHARMAC Board minutes simply articulate the Board's decision and whether there are any Special Authority restrictions on prescribing. The PHARMAC Board do not produce a statement of the reasons for its decision, nor does it make direct reference to the decision criteria. Both the reasons and the relevant criteria can be discerned from the [accompanying] recommendation from PHARMAC staff.

The PHARMAC Board is required to make a decision affecting the health needs of many people from within the funding constraints imposed by Government. This puts it in an invidious position. Attempting to balance the "best possible health outcomes for New Zealanders", from "within the funding available", creates a tension. The minutes indicate how the balance is struck. PHARMAC is legally required to remain within budget and PHARMAC acknowledges this commercial imperative. Although the criteria are not explicitly accorded a weighting, examples within the minutes provided instances where cost or budgetary considerations were clearly paramount. For example, all of the cases which the Board approved for subsidy (PHARMAC01+, PHARMAC02+, PHARMAC03+ and PHARMAC04+) included favourable cost-benefit analyses from PHARMAC staff, and all were subject to restrictions on availability. Also, the proposal was subject to a rebate or discount from the supplier.

Interestingly, of the 20 recommendations affecting new products which PTAC made to PHARMAC over the extended time frame, the Board had only made decisions concerning four products. In each case the decision was to affirm subsidy. As to the remaining 16 cases, decisions remain in abeyance - in one extreme case some four years after PTAC recommended subsidy. It is not apparent whether the decisions have been to decline subsidy or merely to defer making a decision.

Arguably, the decision making process of PTAC and PHARMAC, should be informed by the criteria, though it does not follow that either body will interpret them in the same way.

The PTAC minutes reflected the medical perspective of its members. Where criteria were cited as being relevant, there was a marked propensity for the Committee to draw on the health needs of New Zealanders (criterion **i**), comparisons with other medicines (criterion **iii),** or the relative clinical benefits and risks of the product (imbued in criteria **iv**). Cost considerations were rarely cited, perhaps indicating a reluctance to be drawn into matters over which members had little apparent expertise. This reluctance was manifest in two instances where the Committee referred decisions back to PHARMAC for funding decisions (PTAC06-, PTAC07-).

However, the most significant aspect of PTAC decisions is that in a significant number of cases (five of 20) none of the criteria were cited at all. And in others, where criteria were cited it was often difficult to draw a direct association between the stated criteria and the reasons given.

This is in stark contrast to the PHARMAC minutes, where in all cases PHARMAC explicitly addressed each of the criteria. What is not known from the minutes is the individual weighting accorded each criterion. However, in all cases, regardless of whether societal or clinical issues were taken into account, cost and budgetary issues invariably trumped these considerations. The Board consciously and consistently took into account PHARMACs cost-effectiveness analysis in framing their decision. No corresponding analysis of the impact on the health needs of those affected was presented. Why cost-effectiveness or budgetary impacts are deemed more important than meeting health needs or achieving best health outcomes is not clear.

While PHARMAC explicitly assessed the relevance of each individual criterion to the decision it also took into account factors outside the stated criteria. Interestingly, factors such as contentiousness and (internal) consistency with prior decisions emerged as important considerations for the Board. Whilst there is nothing to suggest that any of these decisions were influenced by expediency, the minutes do reveal the extent to which medical dissatisfaction and public and political interest might influence the amount of time it takes for a product to be considered by the Board. Movicol, a laxative, was not held to be legally, politically, medically or publicly contentious, but Temodal, a costly cytotoxic drug used to treat newly diagnosed brain tumours, was. Because Temodal was adjudged contentiousness, the application for funding was "progressed with some speed" (p. 7). The degree to which a proposal might be contentious is not among the stated criteria, yet it is clearly an important factor for PHARMAC.

Consistency with prior decisions is another factor which the Board takes into account in its decision-making. However, they did not always apply this factor routinely. This emphasis is evident in the decision to subsidise Movicol. The Board expressly noted that this decision was consistent with previous Board policy to endorse [prior] recommendations made by PTAC. Yet, I understand the Board is not bound to heed the advice of PTAC, or any other of its advisors. In fact, in the case of Emtiva I found an example of the Board disregarding PTACs advice. In this instance PTAC recommended against subsidy, yet the Board decided to approve subsidy. Whilst there is very clear recognition of external resource constraints (within funding available), and a sensitivity to public or medical contentiousness, the degree to which self-imposed constraints such as internal consistency are applied is less clear cut, and even contradictory.

Although the Board is sensitive to controversy, it is important to note that inclusion of consumer perspectives (CAC) within the written decisions is not apparent in any of the decisions which were reviewed.

There are a number of limitations to this study. I recognise that written minutes do not and, arguably cannot, fully document the content and extent of the Committee or Board's deliberations. However, as neither PTACs meetings, nor the Board's meetings are open to

the public, the minutes are the only available means by which it is possible to assess whether, and how, the abiding decision-criteria are taken into account. The closed decision-making process directly contrasts with the situation in both the United Kingdom and Australia where applicants are able to sit in on meetings and decisions are published. In New Zealand the PHARMAC Board minutes had to be obtained under the Official Information Act.

I have also been restricted to a small number of decisions, which can only provide a snapshot of the decision-making process. Whether these cases are indicative of, or can be extended across a wider group of decisions is questionable. Nor were these examples particularly contentious. By restricting my analysis to new products, and by following a reverse chronological order, the sample did not include any of the products that have prompted substantial public or medical controversy such as Herceptin. As this research focused on the decisions and the decision-makers, and not the impact on those affected by them, future research might be profitably directed at how prescribers and patients are impacted by subsidy decisions.

Although PTAC is required to take into account cost and budgetary issues in its assessments, I found instances where it did not do so (or did not record). Also, in referring two proposals back to PHARMAC, ostensibly because of cost considerations, PTAC may have been indicating disquiet with this situation. Perhaps PTAC should not be required to focus on cost at all. Perhaps it should look solely at pharmacology and therapeutics, and leave purchasing decisions based on pharmaco-economics to PHARMAC or some other body with the requisite skills.

Conclusion

As Creswell (2003) observed, “One of the chief reasons for conducting a qualitative study is that the study is exploratory” (p. 30). In other words, not much is known about the topic being studied. In this instance, the research has some novelty in that the collective funding decisions of PHARMAC do not appear to have been studied since 2000. Much is written about PHARMAC processes (such as reference pricing) or the effects on individual

decisions by effected interest groups, but there is nothing in the literature which provides a systematic analysis of the body of decisions. The purpose of this study was to thematically analyse a sample of decisions to examine whether, and how PHARMAC and its principal advisor, PTAC, take account of stated decision-criteria. It is to be hoped that the knowledge generated by this study will serve to redress the paucity of literature on this subject and ultimately lead to greater transparency in the decision-making process.

Postscript

Medicines Strategy

On December 14, 2007 the Government released details of a policy document entitled *Medicines New Zealand,* a broad strategic document which purportedly seeks to align the medicines sector and the systems that govern the regulation, procurement, management and use of medicines[28]. This document will have a direct bearing on the way that PHARMAC operates in future. Described as an "aspirational" document, *Medicines New Zealand* seeks to provide:

- Equitable access to safe, quality medicines that are used in the most effective way possible
- Transparency
- Affordability and sustainability (Ministry of Health, 2007).

The medicines strategy is augmented by an action plan, *Actioning Medicines New Zealand* which highlights key activities and initiatives.

The current medicines system encompasses a wide range of agencies with various functions relating to access; safety and efficacy; and optimal usage. PHARMAC is primarily concerned with access, but other health agencies have different functions. For example, Medsafe and the Medicines Adverse Reactions Committee are primarily concerned with pharmacology and pharmacovigilance issues, The Best Practice Advocacy Centre and the

[28] For the purposes of *Medicines New Zealand*, medicines are held to include prescription medicines, non-prescription medicines and complementary medicines.

Safe and Quality Use of Medicines Group, with optimal usage. To integrate all of these roles within one agency would be difficult and is deemed politically undesirable (Ministry of Health, 2007 p. 4). The Government will, however, require greater collaboration between the various sectors.

Achieving the desired outcomes (quality, safety and efficacy, access, and optimal usage) will require making policy decisions across a wide range of issues. The most significant feature of the new regime regarding access to pharmaceuticals, is that ensuing policy decisions will be principles-based, including decisions around the pharmaceuticals budget. The DHBs and PHARMAC will adopt a principles-based approach to setting the pharmaceuticals budget. Six broad, and in some cases overlapping, principles are discerned (Equity, Effectiveness, Confidence, Value for money, Affordability and Transparency) Ministry of Health, 2007, p. 14).

These principles essentially reflect medical and social value judgements. Medical value judgements are concerned with interpreting the quality and the significance of the scientific evidence presented, whilst social value judgements derive from societal rather than scientific or medical considerations.

PHARMAC and the DHBs will be the first Crown agencies to adopt a principle-based approach to decision-making, though the policy is not without precedent internationally. The body responsible for appraising new drug technologies in the UK, the National Institute for Health and Clinical Excellence (NICE), has employed principle-based guidance in its decision-making since 2005. NICE committees are assisted by 13 principles, which are detailed and contrasted with the proposed PHARMAC principles below (cf. Table 4).

Table # 9. Principles Guiding PHARMAC and NICE decision-making

PHARMAC Principles	NICE Principles
Equity New Zealanders in similar need of medicines have an equitable opportunity to access equivalent medicines. Medicines and other resources are allocated in a manner that reduces inequity of outcomes. *Medicines New Zealand* acknowledges the special relationship between Maori and the Crown. Strategies to achieve equity for Maori under *Medicines New Zealand* will recognise and build on the strengths and assets of Maori.	*Principle 1* The fundamental principles that underpin the processes by which NICE guidance is developed should be maintained for current, and applied to future, forms of guidance.
Effectiveness The medicines system is effective, people-centred, evidence-based and reflects best practice to ensure safety, efficacy and timeliness. Within a population focus there is flexibility to consider individual variations.	*Principle 2* For both legal and bioethical reasons those undertaking technology appraisals and developing clinical guidelines must take account of economic considerations.
Confidence The processes within the medicines system are robust and transparent. Stakeholders (including consumers) understand and have the opportunity, as appropriate, to participate in the decision-making processes used for regulating, funding and managing medicines.	*Principle 3* NICE guidance should not support the use of interventions for which evidence of clinical effectiveness is either absent or too weak for reasonable conclusions to be reached.
Value for money The systems in the medicines sector operate efficiently and work collaboratively to secure the greatest possible value (in terms of efficacy, equity and cost) from medicines. This includes minimising compliance costs and making choices in a context of acceptance of scarcity and opportunity cost.	*Principle 4* In the economic evaluation of particular interventions, cost-utility analysis is necessary but should not be the sole basis for decisions on cost-effectiveness.
Affordability The medicines used within the health and disability support system and the structures and processes that support	*Principle 5* NICE guidance should explain, explicitly, reasons for recommending – as cost-effective

their use are affordable for individuals and the community and are met within the funding available.	– those interventions with an incremental cost-effectiveness ratio on excess of £20,000 to £30,000 per QALY
Transparency New Zealanders can be confident that the medicines system operates in a fair and reasonable manner, based on the principles set out in Medicines New Zealand. The principle of transparency is balanced against other needs, including the need to conduct commercial negotiations in order to secure the best health outcomes.	*Principle 6* NICE clinical guidance should only recommend the use of therapeutic or preventative intervention for a particular age group when there is clear evidence of differences in the clinical effectiveness of the measure in different age groups that cannot be identified by other means.
	Principle 7 In setting priorities there is no case for the Institute or its advisory bodies to distinguish between individuals on the basis of gender or sexual orientation unless these are indicators for the benefits or risks of preventative or therapeutic interventions.
	Principle 8 In developing clinical guidance for the NHS, no priority should be given based on the individuals' income, social class or position in life and individuals' social roles, at different ages, when considering cost-effectiveness. Nevertheless, in developing its approach to public health guidance, NICE wishes its advisory bodies to promote preventative measures likely to reduce those health inequalities that are associated with socio-economic status.
	Principle 9 NICE clinical guidance should only recommend the use of an intervention for a particular racial (ethnic) group if there is clear evidence of differences between racial (ethnic) groups in the clinical effectiveness of the

	intervention that cannot be identified by any other means.
	Principle 10 NICE and its advisory bodies should avoid denying care to patients with conditions that are, or may be, self-inflicted (in part or in whole). If, however, self-inflicted cause(s) of the condition influence the clinical or cost-effectiveness of the use of an intervention, it may be necessary to take this into account.
	Principle 11 Although respect for autonomy, and individual choice, are important for the NHS and its users, they should not have the consequence of promoting the use of interventions that are not clinically and/or cost-effective.
	Principle 12 It is incumbent on the Institute and its advisory bodies to respond appropriately to the comments of stakeholders and consultees and, where necessary, to amend the guidance. The board is aware, however, that there may be occasions where attempts are made (directly or indirectly) to influence the decisions of its advisory bodies that are not in the broad public interest. The board requires the Institute, and members of its advisory bodies, to resist such pressures.
	Principle 13 Priority for patients with conditions associated with social stigma should only be considered if the additional psychological burdens have not been adequately taken into account in the cost-utility analyses.

There are some parallels with the principles which underpin current NICE decision-making. For example, PHARMAC's *value for money* and *affordability* principles, are broadly commensurate with NICE's Principle # 2 which requires committees to take account of economic considerations in their appraisals, and Principle # 4 which recognises that in the economic evaluation of particular interventions, cost-utility analysis is a necessary (but not be the sole) basis for decisions on cost-effectiveness; and PHARMAC's *effectiveness* principle is in general accord with NICE's Principle # 3 which requires demonstrable evidence of clinical efficacy. The principles differ primarily in their scope, but also in their relative explicitness. In addition to the cost-effectiveness and clinical effectiveness considerations referred to, the NICE principles also reflect very explicit social value judgements which are largely absent from the PHARMAC guiding principles[29] (c.f. principles 6-11, 13).

Among the various actions designed to facilitate transparency, PHARMAC will be required to publish public summaries of decisions on subsidy applications, and to conduct a regular forum for interested 'stakeholders' (Ministry of Health, 2007, p.2)[30]. How often this forum is to be held is not spelled out in the document.

Other initiatives allow for consumer perspectives to inform PHARMAC's decision-making processes and pharmaceutical companies will be formally invited to meet with PHARMAC at the beginning of the funding application process (Ministry of Health, 2007, p. 2). Neither of these initiatives represents a radical departure from the current situation. For instance, the Consumer Advisory Committee, established in 2000, was designed to give just such a consumer perspective on the impact of PHARMAC's subsidy decision-making, and it is common practice for pharmaceutical suppliers to consult with PHARMAC officials before preparing a formal subsidy application.

With the exception of the requirement to provide public summaries of subsidy decisions, such initiatives appear to be mere tinkering. To achieve greater openness and transparency the Government could have followed the UK example, where, under NICE guidelines,

[29] The exceptions being PHARMAC's *equity* and *transparency* principles.
[30] No timeline is indicated in the document, but under NICE guidelines the final decision must be posted on their website within 5 working days.

interested parties are invited to attend decision-making meetings and comment on interim decisions (NICE, 2005)[31]. Alternatively, they could have adopted the Australian model which allows applicants the opportunity to comment on subsidy decisions while they are still in draft form (Department of Health and Ageing, 2007).

Other actions require the Ministry of Health and PHARMAC to review the PTAC appointment process to ensure that it is independent, and "to consult broadly on [proposed]changes to PTAC's Operational Guidelines to ensure that arrangements are in place so that PTAC can provide free and frank advice to the PHARMAC Board" (Ministry of Health, 2007. p. 3). Similarly, both agencies are required to review CAC's Terms of Reference to ensure that it is able to undertake its legislative role.

At a more practical level, the Medicines Strategy also requires PHARMAC to develop a mechanism that will, when decisions give rise to brand changes, enable patients to access funding for their existent medicine in defined circumstances. Furthermore, PHARMAC is required to review the Exceptional Circumstances Scheme to ensure that it fulfils its purpose; and to review Special Authority prescribing restrictions.

Both PHARMAC and NICE have adopted cost-utility analysis as the preferred approach to economic evaluation of pharmaceuticals (NICE 2005; PHARMAC, 2004, 2006). NICE views cost-utility analyses as "a necessary, but not sufficient, basis for decision-making "(2005, p. 21.); whilst PHARMAC considers cost-utility analysis "a guide to decision making, not a substitute" (2004, p. 7). The principle measure of health outcome adopted by both agencies is the QALY. This reliance on cost-utility analysis in resource allocation has proved contentious (Beauchamp & Childress, 2001; Gillon, 1994), particularly because rigid adherence to this policy could discriminate against vulnerable groups such as children, the elderly, or the terminally ill. Others are generally prepared to accept cost-utility

[31] Under NICE guidelines various groups are invited to participate in the appraisal process, among them the manufacturer(s) or sponsor(s) of the technology; national professional organisations; national patient organisations; the Department of Health; and relevant National Health Service (NHS) groups. Consultees can participate in the consultation during the draft phase and can appeal against the final decision. In addition to the invited consultees and appraisal committees, other affected groups, including competitors and the Medical Association receive details of the final decision as a matter of course, and ca make comments, though they do not have a right of appeal.

analyses if they are used to inform, rather than direct, decisions about priority setting (Beauchamp & Childress, 2001; Daniels & Sabin, 2002).

Cost-utility analysis is described by PHARMAC "as a tool for maximising health" (2004, p. 7). The goal is therefore utilitarian: it seeks to 'maximise' the greatest health benefits from the money expended. In its strictest interpretation it expounds a value judgement that seeks the most 'efficient' use of the resources available and prizes the maximisation of the overall health of the population above all else.

Although PHARMAC's approach to economic evaluation is heavily geared towards the utilitarian (efficiency) tradition, equity considerations are also acknowledged, at least implicitly, in the Agency's current decision criteria (criteria **i, ii**). Subsidy decisions can, and have been made on grounds other than maximising health, as for example when the PHARMAC Board decided age would not be a criterion for access to the statins, despite the fact that the elderly derived fewer benefits from these drugs (PHARMAC, 2004, p. 10). Equally, it is at least feasible that the Government's priorities for health funding could require PHARMAC to accord a particular intervention a higher priority for funding than it might otherwise have done (under criterion viii). The recognition of equity is, however, much more explicit under the new principle base (Principle 1).

When PHARMAC determines one intervention to be more effective than another, the Agency has to decide whether any posited increase in cost associated with the increase in efficiency represents 'value for money'. This is generally done by calculating the incremental cost-effectiveness ratio. And in this, the preferred approach is generally the cost per QALY.

NICE guidelines recognise that there is no empirical basis for assigning a particular value (or values) to the cut-off between cost-effectiveness and cost-ineffectiveness (2005, p. 22). However, the Institute generally accept, as cost-effective those interventions with an incremental cost-effectiveness ratio of less than £20,000 per QALY and that there should be increasingly strong reasons for accepting as cost-effective interventions with an incremental cost-effectiveness ratio of over £30,000 per QALY (Principal 5). In contrast, in New Zealand, if a product is calculated to cost less than $10,000 it is funded (Gillon, 2006).

It is intended that these new principles will inform, but not replace, the existing decision criteria (P. Dunne, personal communication, March 11, 2008). Whether these principles, and in particular the principle of equity, have a positive impact on PHARMACs decision-making remains to be seen.

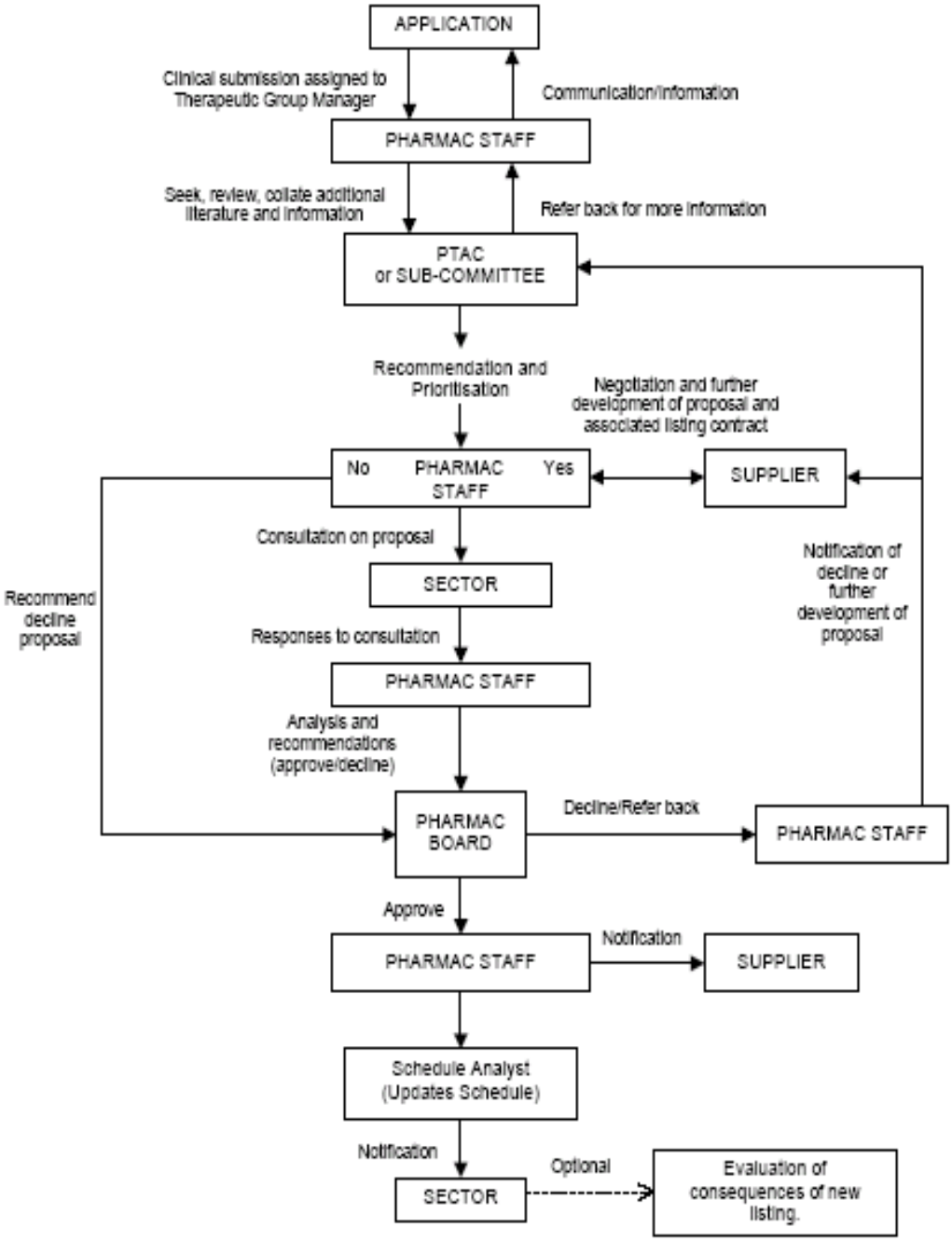
Post Postscript

Herceptin® decision

On April 3, 2008 the High Court set aside an earlier PHARMAC Board decision to decline funding for Herceptin for 12 months treatment of early stage HER2-positive breast cancer. The Court noted that PHARMAC had failed in its duty to consult and instructed PHARMAC to consult properly with the public, medical practitioners and others who have an interest in the ultimate decision (Walsh v Pharmaceutical Management Agency, 2008).

Appendix #1 Procedure for listing a pharmaceutical on the Pharmaceutical Schedule

4.5 Procedure for Listing a Pharmaceutical on the Pharmaceutical Schedule



Note: This diagram provides a simplified, indicative guide to the process that PHARMAC will usually follow when listing a community pharmaceutical on the Schedule. PHARMAC is not bound to follow the process set out in the diagram and may vary this process or adopt a different process where appropriate. Where the PHARMAC Board is referred to in the diagram, this may include PHARMAC's Chief Executive under Delegated Authority from the Board.

Appendix #2

Cancer Exceptional Circumstances (CaEC)

1. Criteria

The following criteria for approval are based on the concepts of peer- review within the DHB hospital, and ensuring equity of access to pharmaceutical cancer treatments across DHBs:

i.. Confirmation that the proposed use was evaluated and approved using established DHB review mechanisms involving experienced clinicians

ii. Confirmation that the DHB hospital providing treatment has agreed to fund the treatment;

iii. Confirmation that the condition is considered unusual (and therefore a decision to treat is unlikely to result in access inequities across DHBs)

iv. The proposed use has not been considered or is not currently under consideration by PHARMAC for funding (note a list of active applications for funding and PTAC recommendations is available on PHARMAC's website)

v. Specification of the;
   a. Product to be used
   b. Dose and treatment schedule
   c. Duration of treatment
   d. Indication
   e. Total cost

vi. The total cost is <$30,000 over a 5-year period (NPV). If the application is for a treatment of $30,000 or over it will be referred for a CUA followed by decision from PHARMAC.

The CaEC policy is administered directly by PHARMAC staff. Where applications clearly meet the criteria, approval will be communicated by PHARMAC staff to the applicant and the pharmacy. Where PHARMAC staff do not consider an application meets the criteria the application will be referred to the HEC panel for review. Every reasonable effort will be made to respond to CaEC applications within 72 hours (not including weekends and statutory holidays).

Applicants under CaEC have the right of appeal. All correspondence with the Panel must be in writing and made through the Exceptional Circumstances office. An appeal will be examined by the HEC panel. Should the Panel still decline the application, then the applicant may request a review. Contact should be made with the Medical Director, PHARMAC who will arrange for a review to be undertaken.
(PHARMAC, Information Sheet, 2007).

Appendix #3 Criteria for Community Exceptional Circumstances scheme

Community Exceptional Circumstances (CEC)
1. Entry Criteria
CEC allows for the funding of community-based treatments that are not covered under the provisions of the Pharmaceutical Schedule. A fixed budget has been set aside from the pharmaceutical budget to cover the funding of treatments for CEC. There are three entry criteria that allow for CEC funding, one of which must be met:

The condition is rare
The reaction to alternative treatment is unusual.
An unusual combination of clinical circumstances applies.

(Where rare and unusual are defined as single figures nationally)
As a guideline to assist with filling out the form there are three points that need to be considered.
i) Whilst a patient may be suffering from a rare disease/condition, the symptom requiring treatment may not be rare. For example the patient may have a rare disease. The most common manifestation of this disease is severe pain. Pain management is not a rare condition. Therefore, an application to CEC for funding of a treatment for pain management is unlikely to be successful.
ii) The general reference point for determining an "unusual reaction" is the published documentation from Medsafe (www.medsafe.govt.nz). Common reactions would generally be excluded from CEC.
iii) The criterion of "an unusual combination of clinical circumstances" allows a degree of discretion for the panel. The test applied is one of fairness to fund the pharmaceutical for one individual in one specific clinical circumstance while declining all others. The focus in on clinical, not social or economic, circumstances. The clinical circumstance must be directly related to the use of the requested medication for the particular patient.
Once the entry criteria have been met, supplementary criteria are examined as follows:
The condition is rare.
The reaction to alternative treatment is unusual.
An unusual combination of clinical circumstances applies.
(Where rare and unusual are defined as single figures nationally)
S4-3-2 #84240
2. Clinical Benefit and Suitability:
a) evidence must be included to show that the requested treatment has already shown a demonstrated and significant clinical benefit to this patient. CEC funding is not available to fund trials. OR
b) evidence must be attached to show that the requested treatment is a safe and efficacious treatment for this condition. AND
c) all applications should clearly show which alternative treatments have been trialed and the reasons why they were unsuitable. Additionally which alternative treatments were considered but deemed unsuitable for trial and why.
3. Cost Benefit:
The cost of the treatment should be acceptable when assessed on cost benefit grounds and evaluated against other health funding priorities. An application with total cost per annum in excess of $30,000 will be sent for a Cost Utility Analysis. Should the Cost per Quality Adjusted Life Year be in excess of $15,000 the final decision on funding will be made by PHARMAC.
4. Health Services Budget:
CEC funding is not available where the proposed treatment is part of a DHB or other provider contract or the responsibility of another Government funded

agency. CEC funding is not available for inpatients in DHBs or persons living in residential care facilities with drug inclusive MOH contracts. For example CEC funding is not available to fund medications administered by infusion; as these are administered under medical supervision the funding is the responsibility of the DHB.

5. Patient Income Criteria:

CEC funding is not available for financial reasons alone. Where all other criteria are met CEC funding will be granted to patients who:

a) EITHER have a community services card and are already receiving the maximum WINZ benefit available to them,

b) OR provide a declaration stating that it is otherwise unreasonable to expect them to pay. CEC is not available to fund part charges.

(PHARMAC Information Sheet, 2007)

Appendix #4 Criteria for Hospital Exceptional Circumstances scheme

Hospital Exceptional Circumstances (HEC)
HEC allows for the funding of community-based treatments for patients currently in DHB hospitals who are awaiting discharge, where there is no other provision for funding the treatment in the Pharmaceutical Schedule. Funding for HEC is from the DHB Hospital's budget. The sole criterion for accessing HEC funding is cost effectiveness. *Evidence must be provided to demonstrate that funding the pharmaceutical for a specific patient is more cost-effective for the hospital than the most likely alternative intervention or outcome.*
(PHARMAC Information Sheet, 2007)

Appendix # 5

PHARMAC Board

Chair

Richard Waddel – (Professional Director)

Board Members

Gregor Coster – (Professor, Deputy Chair, Dean of Graduate Studies, University of Auckland)

Kura Denness – (Company Director, Taranaki DHB)

David Kerr – (Company Director, General Practitioner, Christchurch)

David Moore – (Industry consultant)

Adrienne von Tunzelmann – (Public policy consultant)

Sources: PHARMAC Website, 2007. Press Release 25 September, 2007.

Appendix # 6

PHARMAC Staff Members

Acting Chief Executive

Mathew Brougham

Medical Director

Dr Peter Moodie

Corporate

Peter Alsop – (Manager, Corporate & External Affairs)

Simon England – (Communications Manager)

Melanie Pembleton Fisher – Communications Advisor & Web Administrator)

Jacquie Kean – (Legal Counsel)

Erina Rewi – (Project Manager, Maori Health and Demand Side)

Stephen Boxall – (Designer/Project Manager)

Mary-Ann Wilson – (Maori Health Analyst)

Christina Newman – (Executive Assistant)

Liz Skelley – (Finance Manager)

Lisa Adams – (Senior Receptionist)

Medical

Erin Murphy – (PTAC Secretary, Cystic Fibrosis & Gaucher Panels Co-ordinator)

Jan Quin – (Project Manager)

Dilky Rasiah (Deputy Medical Director)

Hayley Bythell – (PA to Medical Director/Team Assistant)

Jayne Watkins – (Community Exceptional Circumstances Panel Co-ordinator)

Funding & Procurement

Steffan Crausaz – (Acting Manager – Supply Side)

Sean Dougherty – (Therapeutic Group Manager)

Jackie Evans – (Therapeutic Group Manager)

Geraldine MacGibbon – (Therapeutic Group Manager)

Stephen Woodruffe – (Therapeutic Group Manager Intern)

Mike Bignall – (Tender Analyst)

Tommy Wilkinson – (Therapeutic Group Manager)

Jessica Nisbet – (Supply Side Assistant)

Andrea Dick – (Procurement Initiatives Manager)

Andrew Davies – (Procurement Initiatives Manager)

Mathew Perkins – (Procurement Initiatives Manager

Schedule & Contracts Management

Rachel Mackay – (Manager – Schedule & Contracts)

Kaye Wilson – (Schedule Analyst)

Linda Wellington – Schedule Analyst)

Trish M Mahoney – (Contract Analyst)

Christine Chapman – (Contract Analyst)

Demand Side

Marama Parore – (Acting Manager – Demand Side, Maori Health Manager)

Karen Jacobs – (Demand Side Manager)

Adam McRae – (Demand Side Manager)

Kim Ellis – (Demand Side Assistant)

Analysis & Assessment

Rico Schoeler – (Acting Manager, Analysis & Assessment)

Jason Arnold – (Forecast Analyst)

Peter Ericson – (Database Analyst)

Rachel Grocott – (Health Economist/Team Leader Assessment)

Geoff Lawn – (Analyst)

Ginny Priest – (Analyst/Health Economist)

John Geering – (IT Manager)

Dr Scott Metcalfe – (Chief Advisor –Population Medicine/Public Health Physician)

Cameron Hall – (Analyst/Health Economist)

Chris Peck – (Analyst)

Mathew Poynton – (Analyst/Health Economist).

Source: PHARMAC Website, 2007

Appendix # 7

Pharmacology and Therapeutics Advisory Committee (PTAC)

Members

Chair

Dr Carl Burgess

Deputy Chair

Dr Paul Tomlinson

Committee Members

Dr Ian Hosford, Dr Sisira Jayathissa, Dr Peter Jones, Dr Jim Lello, Dr Peter Pillans, Dr Jim Vause, Dr Tom Tompson, Dr Howard Wilson

Source: PHARMAC Website, 2007.

Appendix # 8

PTAC Sub-committees

Therapeutic categories and membership and specialty

Analgesic – Dr Howard Wilson (PTAC, GP, Chair); Dr Peter Jones (PTAC, Rheumatologis); Dr Rick Acland (Clinical Director); Dr Jonathon Adler (SMO Palliative Medicine); Dr Bruce Foggo (Palliative Medicine Consultant); Dr Lindsay Haas (Neurologist); Dr Geoff Robinson (Chief Medical Officer); Dr Jane Thomas (Paediatric Anaesthetist).

Infectious Disease – Dr Paul Tomlinson (PTAC, Paediatrician, Chair); Dr Stephen Chambers (Infectious Disease Specialist); Dr Ian Loan (General Practitioner); Dr Richard Meech (Infectious Disease Specialist); Dr Mark Thomas (Infectious Disease Specialist); Dr Howard Wilson (PTAC, GP).

Cardiac Stents – Dr Tom Thompson (PTAC, Chair, GP); Dr Mark Webster (Cardiologist); Dr Patrick Kay (Cardiologist); Dr Gerry Devlin (Clinical Direcyor); Dr Scott Harding (Cardiologist); Dr Dougal McLean (Cardiologist); Carol Foote (Nurse Manager-Cardiology); Sally Johanssen (Procurement Specialist).

Cardiovascular – Dr Sisira Jayathissa (PTAC, Physician, Chair); Dr Jim Vause (PTAC. GP); Dr Malcolm Abernathy (Cardiologist); Dr Lannes Johnson (General Practitioner); Dr Miles Williams (Cardiologist); Dr Stewart Mann (Assoc. Prof. of Cardiovascular Medicine); Dr Richard Medlicott (GP).

CATSoP – Dr Carl Burgess (PTAC, Physician, Chair); Dr Andrew Macann (Oncologist); Dr Bernie Fitzharris (Oncologist); Dr Peter Ganly (Haematologist); Dr Tim Hawkins (Haematologist), Dr Vernon Harver (Oncologist); Dr Anne O'Donnell*, Dr Lochie Teague*

Diabetes – Dr Tom Thompson (PTAC, Physician, Chair); Pat Carlton (Diabetes Nurse Specialist); Dr Tim Kenealy (GP); Dr Bruce Small (GP); Dr Paul Tomlinson (PTAC, Paediatrician); Dr Nic Crook (Diabetologist); Dr Peter Moore (Physician); Dr Jim Vause (PTAC, GP).

Hormone and Contraceptive – Dr Howard Wilson (PTAC, Chair, GP); Dr Francis McClure (General Practitioner); Dr Christine Roke (Family Planning Specialist); Dr Bruce Small (General Practitioner); Dr Michael Croxson (Endochrinologist); Dr John Hutton*.

Mental Health – Dr Ian Hosford (PTAC, Geriatrician, Chair); Dr Jim Lello (PTAC, GP); Dr Janet Holmes (General Practitioner); Dr Crawford Duncan (Psychiatrist); Dr Verity Humberstone (Psychiatrist); Dr John Werry (Psychiatrist); Dr Richard Porter (Psychiatrist).

Neurological – Dr Tom Thompson (PTAC, Physician, Chair); Dr Alistair Dunn (General Practitioner); Dr Lindsay Haas (Neurologist); Dr William Wallis (Neurologist); Peter Bergin*, Dr Sisira Jayathissa (PTAC, Physician).

Ophthalmology – Dr Tom Thompson (PTAC, Physician, Chair); Dr Allan Simpson (Ophthalmologist); Dr Neil Aburn (Ophthalmologisyt); Dr Rose Dodd (GP); Steve Guest*.

Osteoporosis – Dr Peter Jones (PTAC, Physician, Chair), Dr Anna Fenton (Endocrinologist), Dr Ian Reid (Endocrinologist); Dr Geoff Horne (Orthopaedic Surgeon); Dr Bev Lawton (GP), Liz Spellacy*.

Recombinant Factor VIII –Dr Carl Burgess (PTAC, Chair, Physician); Julia Phillips*; Mark Smith*; Paul Harper*; Peter Flanagan*.

Respiratory – Dr Jim Lello (PTAC, Chair,GP); Dr Carl Burgess (PTAC, Physician); Dr John Kolbe (Respiratory Physician); Dr Ian Shaw (Paediatrician); Dr John McLachlan (Respiratory and Sleep Pysician).

Special Foods – Dr Jim Lello (PTAC, Chair, GP); Kerry McIlroy (Dietitian); Jo Stewart (Dietitian); Dr John Wyeth (Gastroenterologist); Moira Styles (Dietitian).

Tender Medical – Dr Paul Tomlinson (PTAC, Paediatrician, Chair); Dr Jim Lello (PTAC, GP); Andrea Shirtcliffe (Pharmacist); Geoff Flavell (Pharmacist); Sarah Fitt (Hospital Pharmacist); Grant Howard (Intensive Care Specialist); David Simpson (Haematologist).

Wound Care – Dr Jim Vause (PTAC, Chair, GP); Pip Rutherford (Nurse); Emil Schmidt (Wound care Specialist); Julie Betts (Nurse Practitioner); Jo Wright (Nurse); Martin Hayles*; Kathy Wright*.

Source: PHARMAC Website, 2007

*Denotes: Designation/Specialty not given.

Appendix # 9

Consumer Advisory Committee Members

Chair

Sandra Coney – Auckland (Women's Health Action, General Consumer Health Issues).

Board Members

Matiu Dickson – Hamilton (Deputy Chair, Maori Health); Vicki Burnett – Auckland (Mental Health, Epilepsy); Sharron Cole – Wellington (Young Families, Medical Ethics); Dennis Paget – Blenheim (Health of Older People); Paul Stanley – Tauranga (Maori Men's Health, Gambling & addiction); Kuresa Tiumalu- Faleseuga – Levin (Pacific People's Health); Te Aniwa Tutara – Auckland (Maori Women's Health, Mental Health); Heather Thomson – Te Aroha (Maori Health, Isolated Rural Health Issues).

Source: PHARMAC Website, 2007

Appendix # 10

Hospitals Pharmaceuticals Advisory Committee (HPAC)

Chair

Ian Winwood – (Patient Services Manager)

Committee Members

Neil Aitcheson – (Materials Manager, Mid-Central DHB); Paul Barrett – (Pharmacy Services Manager, Canterbury DHP); Sarah Fitt – (Pharmacy Manager, Auckland DHB); Jan Goddard/Helen Cant – (Service Manager of Pharmacy, Waikato DHB); Lesley Hawke – (Service Manager of Pharmacy, Counties Manukau).

Source: PHARMAC Website, 2007

Appendix #11PTAC decisions 2002-2007

Appendix #12 PTAC decisions2006-2004 New products

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