

# "Tough but fair"? The active management of the New Zealand drug benefits scheme by an independent Crown agency

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## Abstract

For just over a decade, New Zealand has relied on an independent Crown agency to manage the public drug benefits scheme. It was established after a period of industry litigation and unsustainable budgetary increases. The agency has successfully contained prices, saving the equivalent to its originally allocated budget every year, despite a 50% increase in volumes. It shares features with similar agencies elsewhere in the world, particularly in its independence and its operational methodology. Opposition from the industry and ambivalence in the medical community remain matters of concern. The fate of such agencies is inextricably linked to wider regulatory and policy settings in the health sector.

*Aust Health Rev* 2004; 28(2): 171–181

IN THE TENTH ANNIVERSARY ANNUAL REVIEW of New Zealand's Pharmaceutical Management Agency (PHARMAC), the agency's CEO, Wayne McNee, argued that "by and large there is an acceptance of the PHARMAC approach and an acknowledgement that it is applied consistently", highlighting the application of its 'tough but fair' approach in a public controversy over its handling of a funding application for Glivec (imatinib mesylate), a significant therapeutic advance for patients with chronic myeloid leukaemia (PHARMAC 2003). Yet the pharmaceutical industry, both nationally and internationally, continues to

## What is known about the topic?

New Zealand's public drug benefits scheme has been managed since 1993 by PHARMAC. This independent Crown agency has had considerable success in containing costs while providing for access to an enhanced range of drugs.

## What does this paper add?

The analysis identifies the reasons for PHARMAC's survival and success, and provides an assessment of the organisation within a wider historical and analytical context.

## What are the implications for researchers and policymakers?

The New Zealand experience must be compared to that of other jurisdictions grappling with the rising costs of prescription medicines. This case is partly explained by the unique circumstances of New Zealand, but some of the policy mechanisms discussed in this paper have broader applicability.

campaign against the organisation — arguing that New Zealand is failing to pay its share of research costs and is not receiving innovative drugs in a timely fashion — and there is a measure of ambivalence in the medical profession about its operations (for example, Martin & Begg 2000).

At PHARMAC's founding, in 1993, the New Zealand public drug benefit bill had been increasing at a rate of up to 20% per year, threatening to crowd out investment elsewhere in the health sector. Over the subsequent decade, while volumes have increased by more than half, cost increases have been contained at less than 3% per year, and 131 new medicines have been introduced (PHARMAC 2003). At the very least, then, PHARMAC has been a successful manager of a capped budget. The key to this success has been a combination of governance arrangements — independent of direct government control — and decision-making methodol-

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ogy (consistent and widely-accepted assessment techniques), features that seem to be distinctive of comparable agencies elsewhere in the world (Maor 2004). This paper seeks to provide a broader assessment of the organisation, setting a case study of its decade of operations within a wider historical and analytical context.

### **Drugs policy — compassion and commercialism**

Few of the assumptions governing conventional market models of economics apply in the health field. While this may seem self-evident in certain areas of patient care where vulnerable individuals seek assistance for conditions that hold little market sway, such as geriatrics, mental health and disability, the generalisation also applies with some force in the case of prescription medicines. Again, patients who may know little about their condition approach providers, who diagnose and prescribe treatment with therapeutic drugs, with the costs of the encounter and the script usually underwritten by a third party insurer (often the state). This is not a standard market transaction, and yet the companies that produce therapeutic drugs are among the most successful, globalised and competitive in the advanced industrial world (Davis 1997).

It is this special mixture of the compassionate and the ruthlessly commercial that is distinctive of health policy issues in this area. As elsewhere in the health sector, most societies have sought to ensure access to care for vulnerable groups and have established elaborate regulatory regimes to ensure the safety, quality, and distribution of prescription medicines. But the products themselves are the endpoint of a sophisticated scientific, manufacturing and distribution process that is set in a highly competitive trading environment where the financial stakes are high (Schweitzer 1997).

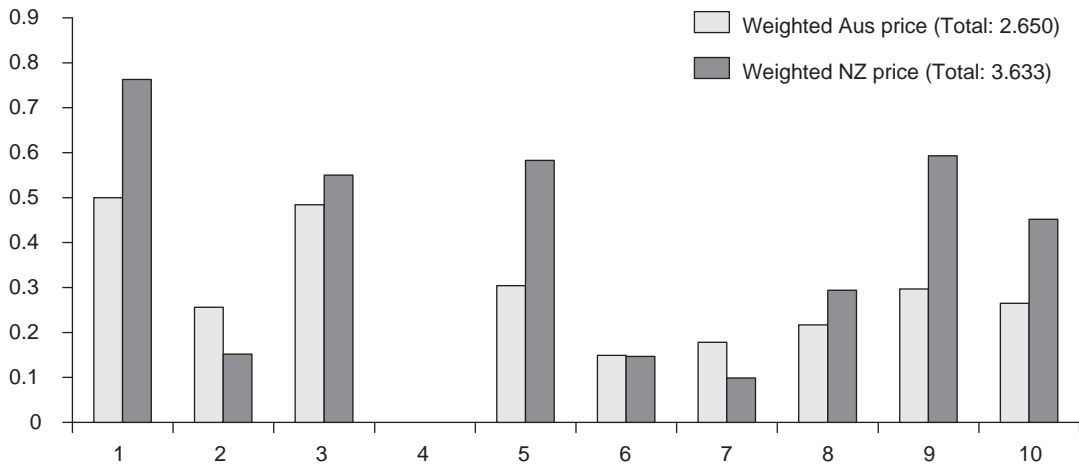
Typically, therefore, the pharmaceutical sector in the health systems of advanced industrial societies presents a dual aspect. On the one hand, societies — in the compassionate vein of the modern welfare state — seek to enhance social

solidarity and ensure access to needed treatment independent of ability to pay. This requires the expansion of the availability of medicines on the public purse. On the other hand, governments — with the hard-headed demeanour of the financier and the market regulator of last resort — struggle with the commercial imperative of companies that must satisfy their shareholders with returns on investment in pharmaceutical research and development. This requires a growing market for more, and more advanced and expensive, drugs, which imbues state-industry relations with a certain commercial wariness (Davis 1997).

In New Zealand, social policy in the 1990s took on a harder, neo-liberal edge to match the swingeing deregulatory economic policies of the 1980s (Boston, Dalziel & St. John 1999). In the health context this stimulated experimentation in the application of competitive markets (Gauld 2001). Thus, corporatised hospitals, potentially rival regional health purchasers, and the prospect of competing primary care organisations were all emergent in this period. In 1993, the four regional purchasers established a company to apply a far more commercial approach to negotiations with the pharmaceutical industry in an attempt to control the rapidly expanding budget for subsidised access to prescribed drugs (PHARMAC 2003).

This company, now a Crown Entity, has maintained and strengthened its position as the Crown's agent in negotiating reimbursement levels with the industry. It remains one of the few innovations from the health reform period of the 1990s and has expanded its role into demand management and hospital pharmaceutical purchasing. Even after ten years of operation, its principal market management tool (a combination of reference pricing, tendering and cross-product negotiations) still functions to extract remarkable savings and to foster effective price competition between pharmaceutical companies. The model is not unique to New Zealand; similar arrangements are to be found in British Columbia (Morgan, Bassett & Mintzes 2004), and a range of reference pricing arrangements is applied in a number of countries (Ioannides-

### I Comparison of Australian and New Zealand drug prices, 1985



Cooper, Lybrand & Associates 1987

Demos, Ibrahim & McNeil 2002). However, PHARMAC has a decade of consistent and cumulative experience and has established a distinct culture and *modus operandi* that are worthy of study (Bloomfield 2003).

### History and background

The cost of medicines, and the issue of ensuring affordable access, first became a matter of public policy attention in New Zealand in the 1940s. Before this period there were few demonstrably effective therapeutic drugs of wide application. With the advent of antibiotics and with the establishment of the founding pillars of the modern welfare state (and its commitment under the first Labour Government to guarantee universal access to health care), prescription medicines were caught up in the emerging financial arrangements underpinning publicly-funded health services. The New Zealand Social Security Act 1938, with its ringing commitments to rights of citizens to social and economic security, established the framework for the establishment of a set of benefits designed to defray the costs of access to health care. Alongside a subsidy to visit the family doctor and a benefit for x-rays, in 1941 the government

established an offset for the cost of prescribed medicines (Baker 1992).

In this respect, the New Zealand experience differs little from that of other welfare state systems. In all health care systems of the advanced industrial societies, prescription medicines are an important part of the standard, publicly-funded benefit package. The arrangements in New Zealand were probably more 'universalist' than most, since in many countries 'free' access to prescribed medicines was restricted to particular target groups (such as low-income earners, the retired, or people with particular diseases). From a general policy perspective, however, the expected themes emerge — increasing costs, and, to a lesser extent, safety issues. In the early days, as now, the major policy concern was the relentless growth in expenditure on prescribed medicines as a stream of new, effective and costly therapeutic drugs came onto the market (Baker 1992).

This pharmaceutical benefit system — typical of most welfare states at the time, with a Drug Tariff of guaranteed access to free medicines for citizens and prices individually negotiated by companies — was maintained until the mid-1980s. The thoroughgoing deregulation of the economy in the 1980s, including the abolition of most instances of

price control, together with major reforms of the public sector, provided the opportunity for change. There was evidence that New Zealand was paying higher prices for drugs than it needed to (see Box 1) (Cooper, Lybrand & Associates 1987), and there was pressure on health costs generally; the traditional universalist assumptions of health care provision were under question. Furthermore, the Labour government was experimenting with new forms of public enterprise and public sector management (Boston et al. 1991). It was in this context that the government established the Drug Tariff Section within the Department of Health for negotiations with the industry, and a form of reference pricing was adopted to replace individual price management (Audit Office 1992).

With a change in government in 1990, the health sector, along with the full range of social policy concern, became the focus of determined and radical state action, with the introduction of a series of structural changes. Principal among these changes was the split between the funding/purchasing and service delivery sides of the sector. At an early stage, regional public purchasers were established, with a brief to negotiate contracts with providers and generally manage the expenditure of the public purse in the health sector. As an 'uncapped' budgetary item, pharmaceuticals quickly came under scrutiny, and it was in this context that PHARMAC was established by the four regional purchasers as a jointly-owned company independent of the government.

### **PHARMAC — a new kind of state entity**

The fourth Labour government had introduced a set of far-reaching reforms in the public sector designed to separate out the specifically commercial from the more traditional public service elements of a large state sector that had accrued over a century. It then sought to expose the former to market disciplines and the latter to modern management practices. While many of the corporatised entities were subsequently sold into private ownership, the principles of separating commercial from social objectives and apply-

ing modern management practices remained. These provided the framework and context for considering how best to manage the public investment in pharmaceuticals, including relations with key sector stakeholders such as prescribers (mainly doctors, but also midwives and nurses), retail pharmacy, and the pharmaceutical industry itself.

Although established as a company jointly owned by the four regional purchasers with all the standard features of a private business entity — board of directors, shareholders, corporate mission — PHARMAC, in many respects, represented the first of a new kind of state agent: a publicly-owned commercial entity designed to work effectively in the market place but not set for privatisation, and above all required to be responsive to broader social and political goals. As with much of the rest of the structural changes of the period, a principal aim of establishing an entity of this kind was to distance operational decisions from the political arena. Inevitably, subsidy decisions, particularly those involving new drugs, drew strong public interest and the Minister of Health of the day would invariably be in the media spotlight on occasions such as this (Clark 1992). Lobbying and adept public and media campaigns were likely to have more influence on subsidy or listing decisions than any scrutiny of the research evidence. Thus, conveniently for a Minister working in a cost-constrained environment and subject to industry litigation (Maor 2004), and in the interests of fostering evidence-based decisions in a context free of excessive lobbying (Bloomfield 2003), an autonomous state entity provided crucial insulation. Besides, and just as importantly, since it was modelled on private sector lines and with an overtly commercial mission, the agency was in a much stronger position to negotiate on more equal terms with multinational pharmaceutical companies.

The important distinguishing features of this version of an autonomous state entity designed to make difficult subsidy decisions and to negotiate with powerful commercial organisations were as follows:

- A board of directors with considerable commercial expertise (for example, the chair has

usually been a prominent businessman), the members of which, while independent of overt political patronage, tend also to have the confidence of the Minister of the day.

- A clearly defined and negotiated annual budget for disbursement in the sector.
- A well-defined mission — that is, to maximise the health impact of prescribed medicines by optimising access within a given budget. In the case of PHARMAC, this also required a clause excluding consideration of a company's commercial position in New Zealand in any subsidy decisions (since deleted).
- An expert specialist advisory structure on therapeutic drugs that has the confidence of the medical community, but is also in sympathy with the broad mission of the organisation and, most importantly, stands independent of industry influence.
- A methodology as outlined in the organisation's *Operating Policies and Procedures* that provides the organisation with a relatively objective way of evaluating and justifying decisions (including reference pricing and cost utility analysis).
- Complete commercial freedom to negotiate across the sector.

While all these features may not have been in final form at the founding of PHARMAC, they have been relatively consistent organisational themes and seem to be elements contributing both to the survival of the organisation and to its apparent success in fulfilling its core mission of containing pharmaceutical subsidy costs within budget. Judging by the lobbying efforts of the industry, the most important organisational features are those ensuring independence. The industry has sought to reduce the insulation of the appointment of directors and members of advisory committees, and of subsidy decisions generally, either by having more of a say itself in such matters or by providing more openings for political influence (see Lexchin & Caygill 2000).

The strongest indications of these tendencies came with the election of the Labour-led administration in 1999. The industry selected as Chair of its association a former Minister from a previous administration who had good links with the new

government. Not only was the incoming administration committed to direct PHARMAC to list a particular drug — beta interferon — but the organisation was to be subject to a review, largely on the prompting of the industry. This combination of events, together with the promise of new enabling legislation for the health sector as a whole, represented a potentially critical challenge to the integrity of the organisation and to the culture and *modus operandi* it had built up over nearly a decade. Beta interferon was listed, but in a way that largely preserved PHARMAC's cost utility methodology. A review was carried out, but many of the recommendations could be accommodated without a major alteration to the organisation's mission and way of working. New legislation for the health sector was introduced, and it did change the constitutional status of PHARMAC, moving it substantially closer to the arena of political influence (since dismissals and appointments of Board and committee members can now be subject to Ministerial direction) (Maor 2004). To date, however, this has not resulted in any erosion of the organisation's independence or in any change in its central operations.

### **Principal tools for managing the therapeutic drugs budget**

From the earliest days of its foundation, PHARMAC has pioneered techniques for managing the government's commitment to the subsidy of medicines prescribed by doctors working outside hospital. Taken individually, these techniques were hardly novel internationally, but over time the organisation has been able to develop a highly coherent strategy tightly organised around an integrated package of management tools designed for both the supply (ie, manufacturers and retailers) and the demand (ie, prescribers and patients) sides of the market.

### **Public formulary**

A first step was to establish an arrangement equivalent to a positive list or public formulary; that is, a list of drugs that were subject to subsidy (called the Pharmaceutical Schedule, a

## 2 Market share for competing ACE inhibitor brands, 1997–1998 and 2004

	Oct-97	Oct-98	Jun-04
Captopril	25%	9%	2%
Enalapril	48%	13%	7%
Quinapril	2%	46%	39%
Cilazapril	4%	27%	41%
Other	21%	4%	9%

Source: PHARMAC, October 2004, personal communication.

more actively managed version of the existing Drug Tariff). This clearly distinguishes the gaining of a licence to market a drug in New Zealand — handled by the licensing agency in the Ministry of Health, Medsafe — from the listing for a subsidy (whether full or partial). For the first time there was a full and well documented list of subsidised drugs, a remarkable fact given the size of the budget for which the taxpayer was responsible and the potential that this provided for exerting purchasing power. Also, there was a clear signal that listing for subsidy was a further, and different, step to licensing.

### Reference pricing

Although New Zealand operated a form of reference pricing before the establishment of PHARMAC, this was not applied either systematically or as stringently as it later came to be. The principle established under PHARMAC was that the public purse would provide the same subsidy for drugs that had the same or similar effects. A programme was undertaken of systematic reviews across the drug groupings that were judged to be of equivalent therapeutic effect. In essence the organisation was, in most cases, paying for a 'class effect' — that is, a therapeutic effect thought to be associated with a particular class of drugs — rather than rewarding specific therapeutic effects within a class as claimed by different companies for their particular brand. From one perspective — the demand side (ie, the prescriber) — it is a

mechanism to encourage the use as first-line therapy of the less expensive agents that are fully reimbursed (Ioannides-Demos, Ibrahim & McNeil 2002), and thus PHARMAC attempts to have at least one fully subsidised drug in each reference-priced therapeutic grouping (Lopez-Casnovas & Puig-Junoy 2000). But, from another aspect — the supply side — this is a powerful technique for encouraging price competition among comparable drug products. In 1998, for example, a 60% reduction in the reference price for an ACE inhibitor with low market share was rewarded by an increase from 2% to 47% for the company and a saving of \$30 million a year for the drugs budget (Box 2). The impact is a sustained one, as can be seen from the data for 2004.

### Cross-product arrangements

While reference pricing could provide large savings where there were substantial price differences among otherwise equivalent brand drugs, or where a class came off patent (thus opening the market to generics), some of the most dramatic gains occurred where arrangements could be negotiated with companies across a range of products. Thus, a company wishing to achieve a favourable listing for a new product in one therapeutic grouping might be willing to drop its price for an existing product in another therapeutic grouping (thus establishing a new, and lower, reference level in that category). For example, the improvement in market share seen for two ACE inhibitors was part of the transaction which involved the listing of the same company's statin (HMG-CoA reductase inhibitor) subject to an expenditure cap (Braae, McNee & Moore 1999).

### Tenders

Where products are bulk commodity items with little therapeutic innovation, there are opportunities for putting them up for tender. The first candidate for this approach was paracetamol, in 1997. A price reduction of 44% was achieved. On retendering at a later date for a period of three years, a further price fall of 34% was

secured (Braae, McNee & Moore 1999). PHARMAC has proceeded to tender further items, and has also carried out multi-product tenders to achieve significant price reductions across a range of products.

### **Price and volume contracts**

In some cases the organisation has been able to negotiate a limited release of a new drug (say, targetted to a particular group), with the company reimbursing PHARMAC for any overshoot. In other cases negotiations have brought the price of the product down to a level where a wider group of patients can be covered for much the same cost to the taxpayer.

### **Cost-utility assessments**

The formula for reference pricing entails payment of a similar subsidy for groups of drugs with the same or similar therapeutic effects. But what happens when an entirely new drug is introduced, or a drug added to an existing group that is claimed to demonstrate an incremental advance over those currently listed in that group? Given a fixed budget, the organisation is required to assess whether the (invariably higher) price being requested for the new drug is justified by its therapeutic advance. The funding that has to be found will be at the cost of alternative investments (in new drugs). Thus, cost-utility assessments have been useful in comparing the marginal increase in cost of new drugs with any marginal gain in benefit to patients.

### **Litigation**

In the early stages of its operations PHARMAC was under almost constant legal suit from a range of companies (accounting for 18% of operating costs [Bloomfield 2003]). Before the establishment of the organisation it was the Minister for Health who was subject to litigation by companies aggrieved at listing and subsidy decisions. The level of litigation increased markedly with PHARMAC's more strategic and commercially aggressive approach to managing the pharmaceutical budget. With the organisation's success in

virtually all court actions, this level has since declined, and litigation is now less common.

### **Demand-side interventions**

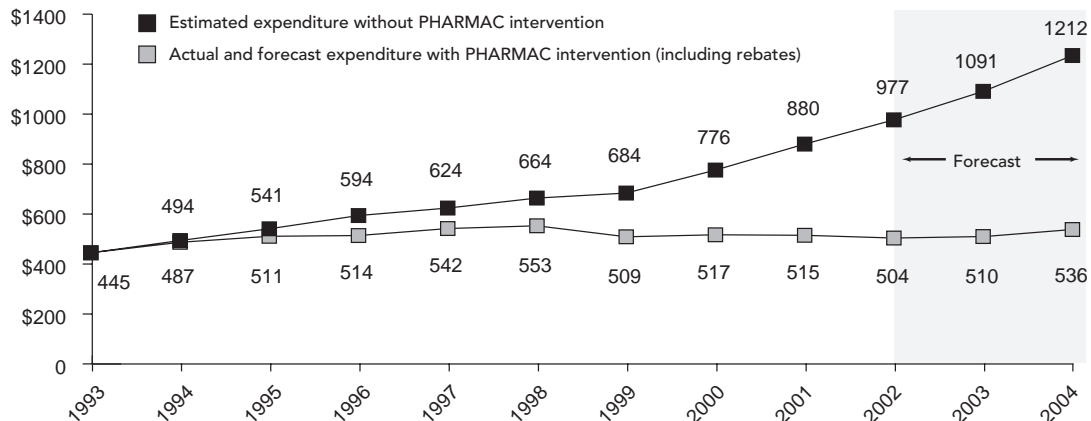
While most of the organisation's efforts have been devoted to reducing prices of existing listings and negotiating commercially on new investment bids, a growing, but less well publicised, part of PHARMAC's overall budget-management strategy has been directed at influencing the behaviour of both prescribers and patients in critical areas. For example, the organisation has worked with GPs and pharmacists to reduce antibiotic prescribing and has worked with the National Heart Foundation to promote an increase in public acceptance of statins among high-need patient groups.

### **A successful policy innovation?**

The most remarkable aspect of PHARMAC is its longevity. It is practically the only remaining brick in the edifice of the health 'reforms' of the 1990s. And this despite a concerted campaign by the industry to weaken, if not disestablish, it. Other special function agencies established in the period of reforms, such as the Public Health Commission, were absorbed back into the Ministry of Health, while others, such as the Clinical Training Agency, are a shadow of their former selves. The all-powerful Health Funding Authority was disbanded and its functions absorbed into the Ministry. But PHARMAC has survived for over a decade, with its mandate strengthened rather than diminished. Not only has the organisation successfully renewed itself, with new Board, Chair, and CEO, but it has also significantly expanded its functions, having taken on the management of the hospital pharmaceutical budget.

Behind this story of longevity lies a considerable achievement in containing the costs of the pharmaceutical budget, distancing Ministers from the controversies of funding and listing decisions, and successfully managing a range of difficult and potentially volatile stakeholder relationships. Before the establishment of PHARMAC, the pharmaceuticals budget was 'demand-driven' and

### 3 Savings achieved by price reductions: total subsidised, non-hospital-funded, drug cost in millions of dollars (excluding GST), year ending 30 June



Source: PHARMAC 2003

increasing, like its equivalents in Australia and the United States, at rates well above inflation. Since its inception, the budget has grown within inflation, while at the same time accommodating a near 50% increase in demand and an expanding range of new drugs. This statistic tends to understate the achievement. Without the price reductions negotiated by PHARMAC, largely through the judicious use of reference pricing and tendering, the budget would now, after ten years, be double its initial size (see Box 3).

The primary, and overt, *raison d'être* for PHARMAC was to manage the taxpayer commitment to prescription medicines within a defined budget. This it has achieved, taking pressure off an already constrained health budget and extracting remarkable cost-efficiencies for the public expenditure dollar. In this respect it is the one major success story of the health reforms of the 1990s. A secondary objective of the health reforms was to reduce the level of external political intervention in health decision-making. Again, PHARMAC has been largely successful here, since the Minister of the day is no longer the focus of lobbying attention every time a new drug comes on the market. An important side effect of this is that most players now appreciate that a

clear 'business' case has to be made to the organisation, in preference to the old methods of media campaigns, political wheeling and dealing, and the wining and dining of key medical opinion leaders. These old methods are certainly not absent, but there is now much wider acceptance by companies, patient lobby groups and practitioners that an evidence-based case also has to be made, in which opportunity costs and a budget constraint are directly addressed (Metcalf et al. 2003).

Related to this influence on the culture of the pharmaceutical sector has been another relatively successful feature of the organisation's operations — the encouragement of evidence-based and best practice initiatives in the prescriber community (such as the campaign to reduce antibiotic prescribing). This is an element in what PHARMAC calls its 'demand strategy' and, where it can be made to work, is important in allying the organisation with research-oriented and progressive elements in the medical community.

### Threats and weaknesses

As a Crown entity now directly answerable to the Minister for Health, PHARMAC is much more



open to political influence than it was under its previous legal mandate, where it was essentially an independent company responsible for meeting certain budget management requirements and reporting to its owners. Although the organisation has managed to maintain the independence of its Board members and expert advisors, the change in constitutional status now takes appointment a step closer to political and industry influence. As recent events in Australia have shown, the composition and culture of a key decision-making committee can be altered almost overnight by politically-induced changes in personnel (Maor 2004).

While there is no incentive for a Minister for Health to intervene in this way — it can only result in more pressure on the departmental budget and on patient charges — there is a powerful potential bureaucratic lobby of the Treasury, as well as the economic development and science ministries (as demonstrated in the European Union [Permanand & Mossialos 2004]). It is this coalition of interests that has generally determined important policy outcomes in other jurisdictions. Although New Zealand has no manufacturing interests in the sector, and while the promise of investment from multi-national companies are vague and likely to be paid for many times over out of the health budget, these blandishments are hard to resist in a country seeking options in the knowledge economy.

Aside from the lobbying power of the industry at the political and bureaucratic level, another weakness of PHARMAC's *modus operandi* has been the necessity for patients to switch brands where a significant price reduction results from the successful competitive workings of the reference pricing mechanisms. If the change is not well accepted by prescribers and if there are perceived deficits for patients, then the legitimacy of the reference pricing mechanism is temporarily weakened (McNee & Smart 1999). After some turbulence with early switches of this kind, the organisation is now much more careful about staging such changes and paying for extra visits to the doctor in order to monitor progress. A 'special authority' facility is also available, which provides exemptions in special cases.

This is an important safety valve, both for prescribers and patients, where large-scale changes of the kind described come up against individual circumstances (such as significant persisting side effects). Nevertheless, all the credible international literature evaluating the impact of reference pricing on health outcomes — which largely comes from the British Columbia experience — points to a neutral, if not benign, result. This is so whether the drug group is calcium channel blockers (Schneeweiss et al. 2003), histamine<sub>2</sub> receptor antagonists (Hazlet & Blough 2002), or angiotensin-converting enzyme inhibitors (Schneeweiss et al. 2002).

## Discussion

Independent drug reimbursement agencies, or pharmaceutical benefit managers, have been established in a number of jurisdictions. They vary in their briefs and their independence, but in each case the objective is to subject such important allocation decisions to a greater measure of scientific objectivity and budget sensitivity. Key components of such institutional packages are: relative independence from political and industry influences; ability to make decisions over central parts of the drugs reimbursement budget; and deployment of widely accepted, relatively transparent and objective tools for decision making and fund allocation (such as cost utility analysis and reference pricing). Depending on the rigour with which reference pricing is applied, considerable savings can be made through enforced price competition without apparent deleterious health effects — although how long such savings can be sustained is a matter for conjecture.

However, a strategy oriented solely to price reduction is likely to lead to diminishing returns, and thus other approaches to the management of 'demand' need to supplement supply policies. Aside from enforcing inter-supplier price competition through reference pricing, tendering and other methods, an important part of the success of independent, public drug reimbursement agencies is their commitment to evidence-based decision making. Not only does this provide a more defen-

sible rationale than simple price reduction in a scientifically nuanced and information-rich environment, but it also allies the agency with important research and practitioner sectors committed to similar values in professional practice.

One important policy question that remains is whether agencies of this kind, if they become more prevalent, can be “too successful”. If price competition is particularly harsh, will innovative pharmaceutical companies be able to reap the rewards necessary to justify investment in the essential research and development for drug advances? (Lopez-Casanovas & Puig-Junoy 2000) Without the necessary information on the cost structures of such companies, this question is impossible to address. As judged by returns on capital and stock market performance, pharmaceutical companies have consistently outperformed all other sectors. For example, at an estimated average ratio of profit to sales in the 1980s of 12.6%, Ballance et al. (1992) maintain that this is probably higher than all manufacturing activities in industrialised countries. Furthermore, there is massive public investment in the basic research that spawns potential drug breakthroughs. Pharmaceutical companies have increasingly positioned themselves as developers and marketers of intellectual property; thus they increasingly take innovations from public research institutions or small private start-up companies and progress these through development, licensing and marketing. This is a significant role, but it means that the risks of initial research failure are increasingly shifted away from the companies themselves.

It should be noted that reference pricing can only apply in circumstances where there are comparable and directly competitive drugs. For truly innovative drugs, there remains a considerable window for the exploitation of intellectual property. Indeed, reference pricing punishes those companies that have relied on replicating existing products, the so-called ‘me toos’. Arguably, in this respect useful signals are being transmitted to company strategists. Indeed, for a budget-constrained system like New Zealand’s, it is the savings made through price competition

in therapeutic groups where rivalry is considerable but innovation limited that permit investment in the genuinely new and important therapeutic breakthroughs that are likely to be offered at very high cost.

## Conclusion

The question remains — is PHARMAC *sui generis*, a beast, like the flightless and nocturnal kiwi, unique to New Zealand’s specific ‘evolutionary’ environment? Several factors have provided special conditions. The smallness of the market and the absence of a pharmaceutical manufacturing capacity weakened industry leverage. A bout of radical social and economic reform in the 1980s and 1990s provided an almost unparalleled environment for policy innovation and institutional experimentation. Yet, other jurisdictions, like British Columbia, have experimented with the model in quite different circumstances.

Setting aside the background conditions for the establishment and maintenance of such agencies — the veto power of the industry, the commitment to affordable drugs, the pressure on publicly funded health care, conducive governance arrangements and effective management — the critical operational question is this: are these organisations essentially rationing agents eking out the last public dollar for an increasingly residual and marginalised client pool; or are they, instead, necessary public regulators, certainly budget constrained but enforcing price competition in markets that are resistant, and setting and applying evidence-based standards in decision-making which would be otherwise susceptible to financial interests? These are broader questions about policy settings in the health sector and, to this extent, the fate of independent agencies of this kind is inextricably linked to the regulatory ethos and grounding values of the wider health care system.

## Acknowledgements

Thanks to Pauline Norris, Wayne McNee, Toni Ashton, Hans Lofgren, Robin Gault and Les Toop for comments on an earlier draft.

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