

20 November 2008

**Hon Tony Ryall
Minister of Health**

OVERVIEW & KEY ISSUES

Copies to

PHARMAC Board

DHB spokesperson on pharmaceutical issues (Murray Georgel)

Director-General of Health (Stephen McKernan)

Deputy Director-General, Sector Funding and Performance (Anthony Hill)

Recommendations

It is recommended you **note** the contents of this report.

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under s9(2)(a) of the OIA]

Purpose

This is an overview of PHARMAC's operations, highlighting key issues. Three attachments are also provided (1) a set of PHARMAC Information Sheets; (2) our current Statement of Intent; and (3) our most recent Annual Report. We would be pleased to provide further information, and look forward to discussing our work with you.

Summary

- **Operating environment** – PHARMAC has achieved its statutory objective over a long period of time, including effectively managing pharmaceutical spending within budget each year. This success is despite ongoing attempts by some stakeholders – with incentives not always aligned to the public good – to undermine or fundamentally change PHARMAC.
- **Accountability** – standard reporting arrangements are in place, supplemented by issue-specific briefings. Given the nature of our work, a frequent meeting with you is likely to be useful. Our accountability to Parliament, and our 'no surprises' obligation to you, are taken very seriously.
- **Governance** – PHARMAC has strong governance procedures and a six-member decision-making Board. As all PHARMAC decisions are made by the Board (unless delegated), PHARMAC's business fundamentally revolves around a monthly Board meeting.
- **Medicines strategy** – PHARMAC believes *Medicines New Zealand* is a sensible strategy. A number of strategy actions have been completed and others are well advanced.
- **Herceptin** (12 months) – we await further advice on what, if any, role PHARMAC should play with respect to the Government's policy.
- **Budget** – the 2009/10 process has begun, culminating in you setting the budget in May/June. Spending top-ups need careful management to avoid just paying more for the same products.
- **High cost medicines** – high-priced medicines are challenging funding bodies globally. Separate funding pools have been assessed before, and PHARMAC has run its own review on funding high cost medicines, but further review in this important area is desirable.
- **Business risks** – PHARMAC has a strong focus on effective risk management, but risks – many public in nature – will always be part of our routine operating environment (e.g. upcoming brand changes – with very large savings – affecting about [redacted] people). [withheld under s9(2)(i), s9(2)(j) and/or s9(2)(b)(ii) of the OIA]

Overview of operating environment

PHARMAC is a Crown Entity, whose statutory objective is to achieve the best health outcomes from available funding. Our main role is funding medicines, but we also seek to influence medicines use and manage 'Exceptional Circumstances'.

While a government agency, PHARMAC's work has many commercial features. As a procurement body dealing with both clinical and economic considerations, we use a range of commercial strategies to get the best health outcomes from our spending. These strategies have resulted in significant price reductions in medicines, and therefore the ability to fund a wide range of new medicines (or widen access to existing medicines), which would otherwise have not been possible. PHARMAC has achieved its statutory objective over a long period of time, including effectively managing pharmaceutical spending within budget each year as required by the law.

Our focus on value-for-money and health outcomes overall (not just for specific groups) can lead to tension with some stakeholders whose incentives are not always aligned with the public good. Public disagreements and PHARMAC-criticisms are quite normal, and there have been a number of legal challenges. Spending health dollars on litigation can be perceived negatively (even when defending proceedings), but it is always with a view to getting the best health outcomes.

Despite the inherent tensions, we are working hard to improve our communication and stakeholder engagement. Our main focus is with consumer groups, medical professionals and pharmacists. Increased support from these areas could greatly assist us, and is something we need to put further work into. Effective engagement with pharmaceutical companies remains important (including with the RMI), but there is already a high level of contact.

Improving relationships does not however mean making popular decisions. What we hope to achieve is respect for (1) being impartial; (2) using a well-articulated funding process that stakeholders understand; (3) robustly assessing funding applications with a strong focus on evidence, including seeking expert advice from PTAC; and (4) consulting where appropriate.

PHARMAC believes New Zealand has a well functioning medicines system. The system has been very successful in providing access to a comprehensive range of effective and affordable medicines. PHARMAC remains focussed on business improvement, including implementing actions arising from the medicines strategy: *Medicines New Zealand*.

Accountability and governance

Our Statement of Intent (attached) defines our current commitments to Parliament. We provide monthly and quarterly reports to you as Minister, which discuss key issues and summarise our performance against SOI commitments. Our most recent Annual Report to Parliament is also attached.

Under legislation “PHARMAC” is, in practice, a reference to the PHARMAC Board – a six member Board appointed by the Minister of Health.¹ The Board comprises a wide range of expertise (including clinical, economic, and public policy), and is chaired by Richard Waddel. All PHARMAC decisions are made by or under the Board’s authority (the latter under a delegations policy). Some funding decisions, within set limits and under a certain value, are made by the Chief Executive but the rest, including all contentious decisions, are made by the Board.

Based on our experience, regular dialogue with you as Minister will be important (ideally monthly or bi-monthly). In addition to these meetings, and standing reporting requirements, a number of issue-specific briefings will be provided as part of effective implementation of our ‘no surprises’ obligation to you. We will also maintain a high level of engagement with the Ministry of Health across a wide ambit of activity. Regular contact with your office staff will also be important.

Key issues

Issue	PHARMAC comment
Herceptin	We await advice on what, if any, role PHARMAC should play with respect to the Government’s policy. If required, we can provide information on why we made our Herceptin decisions. There are related issues from funding 12 months Herceptin, such as the future of the international ‘SOLD’ trial (comparing 9 weeks v 12 months) that we are part funding. New Zealand patients have begun enrolling in the trial.
Pharmaceutical budget	The budget is set each year by you (May-June), along with two out-year ranges. The budget can also be reviewed and changed during the year. We have just commenced the 2009/10 budget process with DHBs, which will continue over the coming months. Government policy is to increase the budget. Without careful management, more money may not mean better health outcomes. There are risks from providing too much too quickly, particularly providing additional scope for companies to increase prices for existing medicines, or for PHARMAC to have to pay more than would otherwise have been the case. Given spending inertia, there are also delays in, practically speaking, generating new expenditure. PHARMAC has never operated on the basis that ‘more money is better’, as this depends on the health outcomes possible from expenditure in other health areas.



¹ **Richard Waddel** (Chair) BCom, FCA, AFInstD; **Professor Gregor Coster** (Deputy Chair) CNZM, MBChB, MSc (Hons), PhD, FRNZCGP (Dist); **Kura Denness** (Te Atiawa) MBA CA; **Dr David W Kerr** MBChB, FRNZCGP (Dist), FNZMA; **David Moore** MCom, Dip Health Econ (Tromso), CA; **Adrienne von Tunzelmann** MA (Hons), MPP.

Issue	PHARMAC comment
Upcoming brand changes	<p>Over the next few months, PHARMAC will be implementing medicine brand changes affecting about [REDACTED] New Zealanders. Patients understandably get used to a brand, so brand changes can cause complaints and, in very rare circumstances, reports of intolerance.</p> <p>These changes have been carefully considered, with savings of about \$ [REDACTED] (NPV over 3 years). The savings are freeing up significant funding to invest in other medicines. The changes also have implications through the medicine supply chain, because a reduction in the price of the medicine also leads to a reduction in the margin paid to pharmacists and wholesalers. We are working closely with DHBs and the Pharmacy Guild on implementation.</p> <p>[withheld under s9(2)(i), s9(2)(j) and/or s9(2)(b)(ii) of the OIA]</p>
Medicines New Zealand (the medicines strategy)	<p>We participated in the strategy's development, including a number of engagements with Hon Peter Dunne. The process used by Mr Dunne to develop this strategy was, in our view, very good and inclusive. While the strategy did not address all of the matters we raised, we nonetheless support the direction it has taken. A number of actions for PHARMAC were included in the strategy's action plan and have either been completed or advanced. We will continue to work with Hon Peter Dunne in accord with recent government announcements.</p> <p>The strategy stressed the need for more focus on the 'optimal use of medicines' (improving use and reducing wastage). Even the most generously funded range of medicines will fail to maximise health outcomes if medicines are not prescribed appropriately, dispensed correctly, and used by patients as intended. More emphasis in this area is still required.</p>
[REDACTED]	<p>[REDACTED]</p> <p>[withheld under s6(a) of the OIA]</p>
Current policy reviews	<p>[REDACTED] [withheld under s9(g)(i) of the OIA]</p> <p>[REDACTED] [withheld under s9(g)(i) of the OIA]</p> <p>PHARMAC recently completed a review of the PTAC Terms of Reference, another <i>Medicines New Zealand</i> action. The review confirmed that previous arrangements already enabled PTAC to provide high quality objective advice to PHARMAC, but identified opportunities for change in three main areas (1) increased publication of information; (2) increased clarity of the role, scope and functions of PTAC; and (3) increased clarity on the relationship between PHARMAC and PTAC. Taken together, these changes should lead to increased confidence in PTAC's operations and, as a result, PHARMAC's decisions.</p> <p>We are also about to review the terms of reference for our Consumer Advisory Committee.</p>

Main criticisms of PHARMAC

We are always open to improving PHARMAC's operations where changes promote the public interest. Different incentives lead some stakeholders – particularly the pharmaceutical industry – to suggest that quite significant changes to PHARMAC should be made; changes that we do not consider are desirable. The table below sets out the main criticisms of PHARMAC you are likely to hear.

Criticism	PHARMAC comment
Expenditure growth is too flat	It is not meaningful to measure pharmaceutical expenditure with reference to the CPI. Pharmaceutical prices are deflating in NZ such that, using a pharmaceutical price index, PHARMAC's real buying-power has increased threefold since 1993.

Criticism	PHARMAC comment
NZ is falling behind other countries	International comparisons are complex and inconclusive. Other countries make their choices based on a number of factors, including affordability. Comparisons based on per capita spend or OECD averages take no account of local prices for medicines. Overall, New Zealand's prices are low by international standards because our mechanisms promote a level of price competition that is not always seen in other markets. Further, most markets set prices by a regulatory means, whereas we rely on commercial procurement techniques.
Sole supply through PHARMAC's tender puts New Zealanders at unnecessary risk	Medicines go out of stock in all countries, and PHARMAC has a number of ways of managing this risk. All sole supply contracts are carefully considered, and the tender is responsible for significant savings that can be reinvested in other medicines. Direct total tender savings (cumulative) are more than \$300 million, and substantial additional savings are made from negotiating favourable terms in exchange for protection from tendering. Dual or multiple supplies generally forego savings; however, where important these approaches are used.
Generic medicines are 'cheap and nasty'	Generics are registered by Medsafe to ensure safety and quality. In some cases generic medicines may be produced using newer and superior production processes, and there are significant regulatory checks and balances around production. PHARMAC carefully considers which generic medicines to purchase through the annual sole supply tender. Brand changes can create price reductions of more than 90%, which enables funding of other medicines, management of volume growth, or provision of other health services.
PHARMAC is not transparent	There is significant information published about PHARMAC's policies, processes, analytical techniques and decisions. We are always trying to improve transparency, but there are limits given commercial sensitivities and to avoid undermining our own negotiation ability. Our website makes available significant information to interested parties and the public.
PTAC is not independent and should only focus on clinical effectiveness	Members of PTAC, our main clinical advisory committee, are independently appointed by the Director-General of Health. In PHARMAC and PTAC's own view, PTAC provides high quality free and frank advice to PHARMAC. A separate agency, or focussing PTAC on only a subset of considerations, would add costs with no benefits.
	 [withheld under s9(g)(i) of the OIA]
A new model is required: there is no more value to squeeze out	PHARMAC believes that NZ's pharmaceutical purchasing model remains fit-for-purpose. Evidence suggests that there remains significant value to be extracted through use of a range of purchasing strategies. International commentaries indicate other countries are moving toward approaches used by PHARMAC as prioritisation and value-for-money become increasingly important to governments.

Recommendations

It is recommended you **note** the contents of this briefing.



Matthew Brougham
Chief Executive