

11th February 2005

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By facsimile: 04 4604995

Dear Steffan

RMI Submission on PHARMAC's Proposal Regarding the Funding of Pharmaceutical Cancer Treatments.

The Researched Medicines Industry Association (RMI), representing New Zealand's researched-based pharmaceutical industry, understands that it is proposed that from 1st July 2005 responsibility for the management and funding of all pharmaceutical cancer treatments will be transferred from DHBs to PHARMAC.

The RMI is concerned that the same strategies and operating procedures that have reduced access and choice of medicines in the community over the last decade will be applied to the supply of cancer treatments in our public hospitals with potentially serious consequences for cancer patients and their families.

Background

In 2001 the Minister of Health announced that PHARMAC was to be authorised to purchase hospital pharmaceuticals on behalf of DHBs. The objective was to achieve savings in hospital pharmaceutical expenditure through the application of the same cost containment strategies and systems employed by PHARMAC in managing the Community Pharmaceutical Schedule.

This assumes that New Zealand is paying too much for hospital pharmaceuticals and that it is both necessary and appropriate to reduce expenditure. Market data however confirms that New Zealand already spends significantly less on hospital pharmaceuticals than other developed countries e.g. Australia.

	New Zealand	Australia (\$NZ)
Total hospital pharmaceutical market for 2004	\$172,475,174	\$1,692,781,337
Hospital pharmaceutical spend per capita ¹ for 2004	\$42.35	\$83.55

Source: IMS Health (NZ) limited

¹ Current population estimates: 20,261,985 Australia and 4,072,500 New Zealand

Pharmaceutical Budget

The consultation document states that a national budget will be identified and managed by PHARMAC. PHARMAC's 2004/2005 Statement of Intent also states that the community pharmaceutical budget will be increased to reflect current spending on cancer treatments.

It therefore appears that the budget for cancer treatment will simply be absorbed into the total budget for community pharmaceuticals. For many years growth of this budget has been rigidly constrained to increases of less than 3% per annum through punitive supply side strategies and severe restrictions on access. In the OECD normal growth in pharmaceutical expenditure is approximately 8% per annum however PHARMAC and the DHBs have already agreed that funding increases for next year and 2007 will be limited to 0.5% and 1.9% respectively². This is despite PHARMAC's acknowledgement that natural cost growth in volume and mix runs at 9% per annum for those medicines already subsidised³. The cost of new medicines listed for subsidy is additional to this.

Based on current trends, growth in expenditure on hospital pharmaceutical cancer treatments (PCTs) will outstrip PHARMAC's growth targets. For example, expenditure on two main groups of PCT's, antineoplastics and cytostatic hormone therapies, increased by 32% from 2003 to 2004⁴. This is not dissimilar to Australia which experienced growth in expenditure on these pharmaceuticals in the order of 32% in 2003 and 23% in 2004.

Incorporating these medicines into a budget where growth is limited to less than 3% per annum will therefore mean that PHARMAC will have no choice but to employ stringent mechanisms to cut prices and restrict access as has been the case with community pharmaceuticals. Likewise the introduction of new cancer treatments will be completely dependant on the funding available within current year budget or PHARMAC's ability to strike trade-off deals with suppliers to free up the required funding.

Approvals for new listings

The proposal states that PHARMAC will assess proposals for new listings of pharmaceutical cancer treatments using established assessment processes. The proposal also states that expenditure on new PCT's will be prioritised along with other medicines that are assessed by PHARMAC.

Furthermore, PHARMAC's 2004/05 Statement of Intent confirms that new pharmaceuticals will continue to be evaluated using PHARMAC's pharmaco-economic tools. Priorities for funding will be established based on the projected cost-quality adjusted life year (QALY) ratio, with low ratio products having higher priority.

As the cost per QALY is essentially a function of the cost of treatment and the life years gained, cancer treatments by their nature will rate poorly against other medicines vying

² PHARMAC Annual Plan 2004/05: service budget performance

³ PHARMAC Annual Plan 2004/05: price, volume and mix trends

⁴ Source: IMS Health (NZ) Limited

for PHARMAC funding. New drug technologies for cancer are expensive and the life years gained, after adjusting for side-effects, can still be relatively few.

From a purely cost-benefit perspective PHARMAC's analysis may therefore more often than not conclude that the limited funds available for new medicines are better invested in other disease areas.

Restrictions on prescribing

Most, if not all, cancer treatments listed on the Schedule will require a Special Authority. This is an application process in which a prescriber requests government subsidy for a particular person⁵. It involves filling in a form with the patient's details and confirming that PHARMAC's clinical criteria have been met. The form is sent to HealthPAC in Wanganui and once approved the patient and prescriber is issued with an approval number which must appear on the prescription. Special Authority approvals are valid for specified period and if treatment needs to continue past this point a further application must be made.

There is no clinical reason for this process. It is simply a mechanism to limit utilisation and ensure that PHARMAC's restrictions on access are being adhered to.

Special Authority requirements therefore add costs and create unnecessary delays and bureaucracy in situations where timeliness can be critical to the success or otherwise of the treatment intervention. Cancer patients need to be able to commence treatment immediately and while delays due to workforce issues etc may be excusable, delays due to form filling are not. Compromising patient outcomes as a result of bureaucratic delays is simply unacceptable.

Exceptional Circumstances Scheme

Under the proposal District Health Boards will be prevented from providing access to any PCT not listed by PHARMAC. DHB clinicians can however apply for permission from the Hospital Exceptional Circumstances Panel, convened and managed by PHARMAC, to fund the pharmaceutical itself.

In order to qualify for Exceptional Circumstances approval one of the following criteria must be met:⁶

- The condition must be rare*, or
- The reaction to alternative funded treatment must be unusual*, or
- An unusual combination of circumstances must be present

* Rare and unusual are considered by PHARMAC to be in the order to less than 10 people nationally.

⁵ New Zealand Pharmaceutical Schedule

⁶ PHARMAC website www.pharmac.govt.nz

Where one of the above entry criteria is met the application is then further examined under supplementary criteria, assessing the suitability of the pharmaceutical, clinical benefit, the cost effectiveness of treatment, and the patient's ability to pay for the treatment.

Given the above criteria it will be extremely difficult for DHB physicians to be able to access PCT's that have been declined by the PHARMAC Board for listing on the Schedule or where PHARMAC has yet to make a funding decision⁷.

Even if the application is ultimately successful the length of time taken to meet the procedural requirements and have an application considered by the Panel may in itself have adverse consequences for the patient.

Supply side strategies

As with the existing Community Pharmaceutical Schedule PHARMAC will need to use a variety of 'supply side' strategies to cut prices and control volume and expenditure in order to stay within its capped budget. These strategies, which include tendering and sole supply contracts, limit clinician choice and result in frequent Schedule changes creating uncertainty and instability for patients as medications are swapped due to PHARMAC's latest deal.

Sole supply arrangements and the very small margins imposed by price-cutting have also caused problems with continuity of supply. Suppliers are often not in a position to carry extra stock, particularly of high cost low volume products, and stock levels become even more of an issue toward the end of the contract period due to the complete uncertainty as to whether the company will be successful in the next tendering round.

This level of instability and uncertainty does not have a place in any treatment regime for an individual and is even more unacceptable for those undergoing cancer treatment. At a minimum those who have commenced treatment prior to a Schedule amendment should be 'grand-parented' so that they, with the advice of their doctor, can choose to stay on their existing medication and not be forced to switch in order to retain the subsidy.

Conclusion

The New Zealand Cancer Control Strategy sets very clear objectives regarding the provision of optimal treatment for those with cancer⁸. Optimal treatment is defined as "treatment known to provide the best outcome based on current knowledge".

The strategy discusses the need for a systematic process for evaluating and introducing new drug treatments but does not advocate a prioritising system where cancer drugs compete against medicines for other conditions. Nor does it advocate rationing of cancer drugs in order to meet the constraints of a capped budget that is allocated annual increases in funding that run less than general inflation and significantly below accepted rates of health inflation.

⁷ The average delay between product registration in NZ and Schedule listing is 33 months

⁸ The New Zealand Cancer Control Strategy – Goal 3, Objective 1

The proposal therefore acts against the Government's Cancer Control Strategy and cannot be supported.

In summary the proposal only serves to achieve the following outcomes:

- Funding of cancer treatments will be prioritised against other medicines on the Community Pharmaceutical Schedule.
- Limited access and choice will form part of the cost containment measures necessary in order for PHARMAC to stay within budget.
- Delays in the introduction of new pharmaceutical cancer treatments due to funding constraints and prioritisation of medicines for other disease areas.
- Little to no access to cancer treatments not listed by PHARMAC as most patients will not meet the Exceptional Circumstances scheme criteria.
- Instability and difficulties with continuity of supply due to supply-side strategies employed by PHARMAC.
- Delays in treatment due to the administrative requirements of the system.

The RMI believes that this proposal will have detrimental effects for New Zealand patients who may be denied access to the pharmaceuticals needed to extend life and improve quality of life.

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