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PHARMAC measures savings elsewhere to the health sector

Scott Metcalfe, Sean Dougherty, Matthew Brougham and Peter Moodie

There has been ongoing debate in the New Zealand Medical Journal regarding PHARMAC's subsidisation (or lack thereof) of prescription medicines in New Zealand.[1–6] We believe such opinions deserve a response, and believe that PHARMAC (the Pharmaceutical Management Agency of New Zealand) does systematically assess the cost-effectiveness of new proposals in ways designed to limit bias and help decision-making – where cost-effectiveness is but one criterion.

How cost-effectiveness affects the decisions PHARMAC makes

PHARMAC's core objective, as laid down by the New Zealand Public Health and Disability Act 2000, 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*" (our italics).

The normal decision-making process for a new medicine listing on the Pharmaceutical Schedule* (endnotes can be found after references at the end of this article) takes into account clinical benefit, pharmacoeconomic analysis and affordability. The usual steps include: clinical evaluation of efficacy relative to existing medicines; cost-benefit analysis; prioritisation against other new medicines; assessment against budget allocation; assessment against established criteria; consultation with the wider health sector; and final decision by the PHARMAC Board.

To support this process and meet its statutory obligations (maximising health gain within budget constraints), PHARMAC has a number of established structures, policies and procedures:

1) Formal decision criteria

PHARMAC has nine explicit published decision criteria as part of its formal Operating Policies and Procedures (OPPs),[7] described in Table 1. The PHARMAC Board uses these decision criteria each time it makes a decision. Cost-effectiveness is just one of these criteria.

2) Clinical evaluation by PTAC

The clinical evaluation role is carried out by the Pharmacology and Therapeutics Advisory Committee (PTAC). PTAC is an independent expert advisory committee to PHARMAC and is involved in PHARMAC's decision-making process. PTAC and its subcommittees provide independent and objective advice to PHARMAC, and comprise medical practitioners with broad general experience and a particular interest in medicines and their therapeutic indications. PTAC has a generalist focus, but increasingly it takes advice from known experts in their field, often via its subcommittees. PTAC members are practising clinicians, appointed by the Director-General of Health, who are specialists in their own areas and are usually drawn from the areas of general medicine, general practice, paediatrics and clinical pharmacology.

PTAC follows established processes,[8] and makes recommendations either for the attachment of high, medium, or low priorities to proposals, or that a proposal be declined or be referred back to suppliers for further information.

Table 1. PHARMAC decision criteria

No.	Criterion
1	The health needs of all eligible people within New Zealand
2	The particular health needs of Maori and Pacific peoples
3	The availability and suitability of existing medicines, therapeutic medical devices and related products
4	The clinical benefits and risks of drugs
5	The cost-effectiveness of meeting health needs by funding drugs 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 Pharmaceutical 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

PTAC uses the same decision criteria as PHARMAC when it evaluates medicines. Any recommendation by PTAC may ultimately vary from PHARMAC's view, in part because PTAC reviews Pharmaceutical Schedule applications at a different stage in the assessment process to PHARMAC; PHARMAC may have a wider range of relevant information when making decisions. Consequently, PHARMAC may attach a different listing priority or make a decision that differs from PTAC's recommendations.

One criticism of PTAC has been that its processes have not been completely transparent. However, the problem for PTAC and PHARMAC has been one of commercial sensitivity. Pharmaceutical companies have often insisted that their applications remain confidential, for both commercial reasons and to avoid any adverse public comment about their medicines. Indeed, there have been times when disclosure of PTAC minutes has been resisted by a company and they have been released only as the result of an Official Information Act request.

Following consultation, PHARMAC decided that from 1 July 2002 the minutes of PTAC meetings would be made publicly available. Once the record of a PTAC or PTAC subcommittee meeting is finalised (including review by PTAC), minutes are published on PHARMAC's web site, although PHARMAC may withhold any elements on the grounds of commercial sensitivity (guided by the principles and withholding grounds of the Official Information Act 1982).[8]

3) Systematic derivation of clinical data

PHARMAC uses cost-utility analysis, which is a form of cost-effectiveness that measures costs per quality-adjusted life year (QALY) gained. (An explanation of QALYs and how to measure them can be found on PHARMAC's website: http://www.pharmac.govt.nz/pdf/QALYExplanation.pdf) PHARMAC attempts to

conduct these analyses rigorously, with extensive data searches and analysis, peer review, consultation and sensitivity analyses.

Critical to the measurement of cost-effectiveness is the medicine's relative efficacy and side effects. In conjunction with PTAC processes, PHARMAC has systems to systematically identify and synthesise relevant clinical inputs.[9] Development of these systems happened in line with ongoing international concerns about the quality of clinical components of economic analyses,[10] and is similar to international jurisdictions.[11,12,13] PHARMAC's systems include: explicitly defining indications for treatment; defining the comparator medicines or regimes/protocols; defining disease-severity groups; explicitly stating literature search strategies; defining both explicit outcome measures and eligibility criteria for source data; assessing quality of evidence, including structured critical appraisal and place in hierarchy of evidence; assessing missing data and possible publication bias; using additional clinical opinion and clinical contacts; and review processes. The degree of rigour applied to the process relates to the level of detail required (see section 4 below).

Again, depending on the level of detail required, data used in effectiveness and cost-utility analyses are classified according to a hierarchy of evidence, using the Scottish Intercollegiate Guidelines Network (SIGN) grading system.[14,15] Clinical trials used in analyses, and guidelines used when developing access criteria, are critically appraised in a structured manner, in line with standard practice (http://www.nzgg.org.nz/tools.cfm) and using tools such as the GATE checklists developed by EPIQ (Effective Practice, Informatics & Quality Improvement) at the University of Auckland and the AGREE Tool for Critical Appraisal of Guidelines (http://www.agreecollaboration.org).

PTAC, its subcommittees, and external reviewers are used to review the clinical aspects of analyses for major investment proposals, and these analyses are then adjusted as needed.

PHARMAC expects industry to provide all relevant evidence, and will seek out evidence independently, but does also consider all evidence supplied to it. PHARMAC does accept research that is funded by the pharmaceutical industry, if remaining wary of the potential influence that funding sources might have on either the design, operation, reporting or interpretation of any clinical trial, as a possible source of bias (in common with standard international practice).[16] The funding for many clinical trials comes from pharmaceutical companies; were PHARMAC to dismiss all such funded evidence out of hand, then it would be unable to perform many evaluations at all. In short, we use this evidence, but are aware of the potential for bias.[17–23]

4) Policies and processes for economic analyses

PHARMAC also has explicit policies for assessing the comparative costs and benefits of new medicines, set out in its Prescription for Pharmacoeconomic Analysis.[24] These policies include: estimating costs not only to the Pharmaceutical Schedule, but also to other areas of the health sector, including direct costs to patients; estimating improvements in QALY gains; discounting both costs and QALY gains according to PHARMAC's current rate (10%); and using univariate and multivariate sensitivity analyses.

PHARMAC undertakes four levels of economic analysis: very rapid, preliminary, indicative, and detailed. These levels are described in Table 2. In a pragmatic public policy/purchasing environment with finite analytical capacity, there are inevitable trade-offs between precision and timeliness. The level (extent and depth) of economic analysis varies according to individual policy issues, availability of analyst resources at the time, the defensibility of any recommendations derived from the results, and the extent of information available for analysis.

Table 2. Levels of economic analysis undertaken by PHARMAC

Type	Description
Detailed	Includes a detailed and systematic identification and synthesis of effectiveness, quality of life, and cost data. Requires on average 3–6 months of full-time analyst input. Reviewed internally (PTAC for clinical assumptions, PHARMAC) and externally.
Indicative	An interim assessment using some opportunistic data, but more detailed than a preliminary analysis. These typically require 4–6 weeks of full-time analyst input. Typically reviewed internally (PTAC for clinical assumptions, PHARMAC).
Preliminary	A rapid assessment largely using opportunistic data. Likely to take 1–2 weeks' analyst input
Very Rapid	A very rapid assessment using opportunistic data, usually involving 1–2 days' full-time analyst input. Includes supplier analyses that have not yet been evaluated by PHARMAC staff.

At a minimum, less detailed analyses are explicitly described as such, permitting audiences to informally assess the robustness of analysis and the sourcing of component clinical data and assumptions. At last count, PHARMAC had completed 73 economic analyses since 1996, varying in extent and depth according to individual policy issues and analyst resource availability (16 detailed, 30 indicative, 17 preliminary, and 10 very rapid).[†]

As used to be the case with PTAC minutes, the results and component assumptions of economic analyses have not generally been widely disseminated. Commercial sensitivity is even more of an issue here, because the price offered by suppliers is so pivotal to the analyses. Further, analyses are sometimes used to estimate fair prices, using a range of notional cost/QALY values, as part of PHARMAC's negotiations with suppliers – information that is very sensitive to the supplier. Hence, explicit publication of full analyses can be problematic, apart from when such publication is no longer commercially relevant.

That said, key examples of analyses of particular interest (and that are no longer commercially sensitive) can be found on PHARMAC's web site (http://www.pharmac.govt.nz) on the resources page (pharmacoeconomics and pharmacoepidemiology) (http://www.pharmac.govt.nz/economic_analysis.asp). PHARMAC will continue to be judicious about which analyses are published in this manner.

PHARMAC reports to Parliament each year a summary of both numbers of patients receiving medicines specifically funded by new decisions in that year, and the extent of population health gains (QALY gains) expected from those investments that year.[25–29] This information is publicly available and can be found on the PHARMAC

web site publications page (http://www.pharmac.govt.nz/annual_report.asp). Data for the four years July 1998 to June 2002 can be seen in Table 3.

Table 3. Results of economic analyses and expected population health gains reported by PHARMAC's annual reports to Parliament: QALYs gained in year of decision, from key PHARMAC funding decisions from 1998/1999 to 2001/2002 (where information available)

Investment decision, where indicative cost/QALY estimates available*	No. patients in FY	Gross cost to schedule in FY ($)	Possible net costs to health sector in FY, discounted ($)	Dis-counted net health sector $/QALY in FY ($)	Net present value of total QALYs gained in FY[†]
1998/1999					
Listing of anastrozole for oncology treatment	50	15 000	13 500	8500	1.6
Listing of letrozole for breast cancer	50	15 000	15 000	8500	1.8
Listing of atypical antipsychotics for schizophrenia[‡]	5900	22 500 000	4 920 563	43 138	114.1
Listing of dorzolamide for glaucoma	200	391 000	391 000	4638	84.3
Extending access to statin drugs	2500	1 900 000	1 320 902	6559	201.4
Listing of tacrolimus for liver transplant	10	75 000			
Listing of tacrolimus for renal transplant	10	75 000	3750	2500	1.5
Listing of tolcapone for parkinsonism	270	600 000	258 000	10 084	25.6
Listing of ursodeoxycholic acid for liver disease	300	357 500			
Listing of azithromycin for chlamydia	2000	25 000			
Price increase of ceredase for Gaucher's disease	150	152 000			
Extension of access to cyclosporin for atopic dermatitis	2500	182 000			
Listing of insulin lispro for diabetes patients	60	2 000			
Listing of new HIV/ AIDS drugs nelfinavir and nevirapine		-400 000			
1999/2000					
Listing of alendronate for severe osteoporosis	341	98 333	88 418	3545	25.0
Listing of beta-interferon for multiple sclerosis	156	250 000	139 253	80 700	1.7
Listing of lamivudine for chronic Hepatitis B infection	72	11 400	3300	1500	1.2
Extending olanzapine for schizophrenia to new cases	87	172 132	91 585	27 467	0.9
Access for olanzapine for schizophrenia[§]	2282	4 494 352	-479 250	-5748	57.2
Listing of latanoprost for glaucoma	502	153 750			
2000/2001					
Listing of topiramate for epilepsy (refractory)	284	320 209	320 209	18 500	17.3
Listing of gabapentin for refractory epilepsy	42	35 870	35 870	15 000	2.4
Listing of eformoterol for asthma symptom control	2117	265 891	205 402	40 000	5.1
Listing of quetiapine for schizophrenia	208	108 419	-182 775	74 995	-2.4
Extending access to alendronate for osteoporosis to 1+# (BMD<-3.0)	502	464 246	421 457	12 426	33.9
Listing of brimonidine for refractory glaucoma	800	287 462			
Listing of abacavir for HIV/AIDS	28	48 334			
Listing of efavirenz for HIV/AIDS	79	134 465			

2001/2002					
Extending access to tranexamic acid for heavy menstrual bleeding	888	81 201	81 201 64 879	2185 141 991	37.2 0.5
Extending access to beta interferon for multiple sclerosis	122	106 469	426 976	771	553.7
Extending access to statins for cardiovascular risk (dyslipidaemia)	31 097	1 423 492	892 339	2495	357.6
Listing of leflunomide for rheumatoid arthritis	380	147 257			
Listing of budesonide with eformoterol for asthma	1237	547 927			
Extending access to Monogen for special food	13	4482			
Extending access to alendronate for severe osteoporosis	770	59			
Listing of erythropoetin beta for anaemia	205	102 184			
Listing of carvedilol for hypertension/heart failure	253	27 691			
Listing of Cosopt (combination dorzolamide & timolol) for glaucoma (refractory)	895	50 866			
Extending access to dorzolamide for glaucoma (refractory)	363	13 026			
Extending access to Timoptol XE & Timpilo for glaucoma	450	-2022			
Extending access to latanoprost for glaucoma (refractory)	641	41 385			
Listing of coal tar with salicylic acid and sulphur for	191	2067			
Extending access to quetiapine for schizophrenia	-322	-27 264			
Extending access to ranitidine for [ ]	2254	5336			
Extending access to losartan for [ ]	182	5381			
Total for investments during the FY of decision, where data available	**47 558**	**33 475 270**	**8 751 858**	**8946**	**978.3**

*indicative estimates, where the extent and depth of analysis varies according to individual policy issues and analyst resource availability (ranging from very rapid to detailed assessments); all analyses comply with PHARMAC's policies for pharmacoeconomic analyses, http://www.pharmac.govt.nz/download/pfpa.pdf

†total QALY gains in patient users over time horizon during the financial year decided, at net present value (discounting at 10%)

‡risperidone, clozapine and olanzapine

§existing patients refractory or intolerant to risperidone

PHARMAC measures 'savings' elsewhere to the health sector

There still seems to be a perception by some that PHARMAC considers only direct pharmaceutical costs when evaluating new proposals. This is incorrect. As many direct health costs as possible are included in analyses. These extend beyond just medicine costs, to include potential costs and savings (ie, costs averted) in hospitalisations and other health and disability support services, and direct costs to patients. PHARMAC consulted widely, including with the pharmaceutical industry, on this and other issues in 1999, prior to releasing the 'Prescription for Pharmacoeconomics'.[24]

For instance, the information displayed in Table 3 allows calculation of the extent of potential savings to the rest of the health sector, as a proportion of pharmaceutical spending, seen in various analyses (columns 'Possible net costs to the health sector in FY, discounted' and 'Gross cost to schedule in FY'). For instance, potential 'savings' elsewhere might have accounted for 53% of pharmaceutical spending on four key medicines newly funded or extended during 2001/02 (tranexamic acid for heavy menstrual bleeding, leflunomide for rheumatoid arthritis, statins for dyslipidaemia, beta interferon for multiple sclerosis. We intend to more fully describe such potential savings in forthcoming publications.

Given the wide consultation that PHARMAC took before deciding which costs to include in its analyses,[24] it is disappointing to keep hearing claims otherwise.

Some have suggested that "global socioeconomic costs" should be included in such evaluations.[1] PHARMAC does not include such costs, primarily because trying to quantify these figures is typically fraught, and because they can bias against certain groups. Attempts to determine the full financial implications of disease burden can produce awkward results. For example, extrapolating a recent analysis of the burden of asthma[30] to all disability-adjusted life years (DALYs) lost in New Zealand[31] would cause predicted costs to the New Zealand economy of $563 billion each year.‡ The magnitude of this figure seems overwhelming, especially when compared with the New Zealand Gross Domestic Product for 2001/02 of $120 billion.[32] The extent of the economic costs of any particular disease, although still important, can be overestimated by such methods, at the expense of other health priorities for which such analysis has yet to be undertaken. Including indirect costs, such as loss of earnings, may prejudice decisions against issues affecting the young, elderly, and other low-income groups.

Concluding remarks

One of the comments arising from the Journal's anonymous review of this viewpoint article was that it read more like an advertorial justifying PHARMAC'S current practices. As evidenced by the volume of comment in the Journal,[1–6] there is confusion about how PHARMAC undertakes assessments of new medicines. The descriptive and subjective view provided here simply aims to address some of the criticisms voiced in others' viewpoint articles.

PHARMAC was specifically set up to provide medicines from within the funding provided. This is set in legislation, and critics must realise that any increase in the total budget must come from somewhere, be it the health sector itself, other areas of government spending, or an increase in taxation. Contrary to the view that New Zealand is "going it alone", similar debates are occurring in all developed countries, including Australia, Canada, Great Britain and the USA.

If the overall budget constraint is accepted as binding, then how that budget is allocated becomes critical. It is tempting to try to find one "magic number" that will prioritise all medicines. However, any decision will be a compromise based on accessibility, relevance to the population need, effectiveness, equity, social acceptability, efficiency,[33] and level of risk and uncertainty. Many of these can only be assessed subjectively.

It is also tempting to reduce the prioritisation debate to a battle between an uncaring regulator and pressure groups (clinical, patient support groups, or suppliers). However, PHARMAC consciously seeks out the views of, and tries to work together with, the health sector to improve its decision-making processes and improve health outcomes. While PHARMAC works hard to include the views of all affected groups, it also has to work in a commercial environment, as evidenced by litigation by the pharmaceutical industry. Most of all, it is our job to worry about the health opportunities forgone from making the wrong decision.

To quote Arthur Schopenhauer, "In a constrained environment…there will be both winners and losers." There will always be a tension between those who look at the

individual and those who look at the whole of society, just as there will be a tension between those who wish to maximize profit and those charged to manage cost. For those who lose, it may be helpful to know that at least the process was fair.

Author information: Scott Metcalfe, Public Health Physician, Wellington; Sean Dougherty, Analyst Analysis and Assessment, PHARMAC, Wellington; Matthew Brougham, Manager, Analysis and Assessment, PHARMAC, Hamilton; Peter Moodie, Medical Director, PHARMAC, Wellington

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Conflicts of interest: Dr Scott Metcalfe is externally contracted to work with PHARMAC for public health advice.

Correspondence: Dr Peter Moodie, PHARMAC, PO Box 10-254, Wellington. Fax: (04) 460 4995; email: peter.moodie@pharmac.govt.nz

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Endnotes:

* Note that the process described in this paper relates to PHARMAC's assessment of community-dispensed pharmaceuticals listed on the Pharmaceutical Schedule. However, PHARMAC also has recently established a process to assess new hospital pharmaceuticals under the National Hospital Pharmaceutical Strategy. This process involves concurrent (or as near as possible) assessments by PHARMAC of pharmaceuticals assessed by DHB hospitals. Note however that national assessment by PHARMAC does not oblige DHB hospitals to fund or not fund a new pharmaceutical. The key objectives of the process are to introduce cost-utility analysis into assessments, promote dialogue and build confidence in a system aimed at ultimately achieving national consistency of access (and also reduce duplication of work). As such, the process for hospital pharmaceuticals differs in form and intent from that described in this paper for community pharmaceuticals. Further details of the New Hospital Pharmaceutical Assessment Process (and the National Hospital Pharmaceutical Strategy) are available on PHARMAC's web site at http://www.pharmac.govt.nz/hospital_strategy.asp and http://www.pharmac.govt.nz/pdf/nhps.pdf

† This figure underestimates the number of very rapid analyses, including (but not confined to) rapid assessments for Exceptional Circumstances.

‡ The 18,800 DALYS lost from asthma accounted for around 3.3% of DALYs lost in New Zealand in 1996, out of 563,000 total DALYs lost. Applying the ARFNZ report's $100,000 statistical value for a life year to these 563,000 total DALYs lost suggests that overall DALY losses cost New Zealand some $563 billion per annum.