

**Researched Medicines Industry Association
Submission on PHARMAC High Cost Medicines Review**

1. Preamble

1.1 The Researched Medicines Industry Association of New Zealand (RMI) is the professional and trade organisation of New Zealand's research-based pharmaceutical industry. Its 18 member companies are engaged in the research, development, manufacture and marketing of prescription medicines and the ongoing improvement of medical and scientific knowledge about their products.

2. Background

2.1 In November 2005 PHARMAC announced in the media that it had, in March 2005, sought the advice of two experts to review its decision making processes for high cost medicines¹. The newspaper reported Wayne McNee, PHARMAC CEO, as saying that the review was initiated "because the Board was uncomfortable having to turn down treatments for small numbers of people who missed out because there was no easy alternative." McNee went on to say that "the economist had suggested other ways high cost drugs could be assessed and his advice was being peer reviewed".

2.2 It is our view that PHARMAC's announcement of this review in 2005, some eight months after it had been initiated, was deliberately timed to coincide with the announcement of the establishment of the Access to Medicines patient group coalition. As such it was designed to fend off the increasing level of public criticism during 2005 regarding the agency's failure to fund important medicines. PHARMAC could therefore say that it has engaged two independent experts to offer advice and that they were serious about addressing this issue.

2.3 Ultimately however it took PHARMAC nearly two years to complete this 'review' and appears to have essentially ignored the advice from the two experts who recommended, for example:

- That PHARMAC be more explicit about the value judgements it makes.
- That PHARMAC be more explicit and transparent about its overarching approach to deciding which pharmaceuticals to fund. A four step approach for such a declaration was proposed.

¹ "Pharmac reviews high-cost drugs" page 11 The Dominion Post 24th November 2005.

- That PHARMAC consider 'tightening up' how it expresses its decision criteria and consult more fully with stakeholders as to what the criteria should be.
- That PHARMAC consider using more formal methods for determining the relative importance of its decision criteria rather than the intuitive approach currently used.
- The possible establishment of a committee to provide advice based on an ethical framework.
- Specified appeal mechanisms

3. PHARMAC's consultation on high cost medicines undermines the credibility of the New Zealand Medicines Strategy that is in development.

- 3.1 At the end of 2005 the development of a New Zealand Medicines Strategy was announced as part of United Future's Supply and Confidence agreement with Labour. Most people, including Hon Peter Dunne², expected that the issue of high cost medicines would be a key part of the strategy development. Surprisingly however, policy development in this important area has been left to PHARMAC.
- 3.2 The Ministry of Health's consultation document "Towards a New Zealand Medicines Strategy" was released on 12th December 2006. The document offers little discussion on the issue of high cost medicines (1 page out of 99). It did not seek any comment about making decisions on high cost medicines and simply referred³ submitters to the PHARMAC consultation process that was at that time yet to be released.
- 3.3 The avoidance of any discussion on high cost medicines in the New Zealand Strategy consultation document undermines its credibility as a comprehensive policy review that will lead to appropriate and sustainable medicines policies for the future.
- 3.4 It is also inappropriate and unhelpful that PHARMAC had already formed its view prior to finally releasing the consultation paper "How should high cost medicines be funded?" on 18th December 2006 and stated its conclusion in the consultation documentation.
- 3.5 Prior experience has given the industry and other stakeholders little confidence in PHARMAC's ability or willingness to undertake meaningful consultation. For example, PHARMAC undertook consultation in 2005 on the third edition of its Operating Policy and Procedures document which sets out how PHARMAC carries out its role. The process started in April 2005 with a statement from PHARMAC that it "does not propose to make many changes..." but due to the level of response from

² Electorate brochure No 1 2006; Speech to the NZ Future Medicines Policy Summit, 29 May 2006; Speech to Self Medication Industry AGM, 27 February 2007

³ "The Ministry of Health encourages you to read Pharmac's consultation paper and provide your thoughts on this complicated issue to Pharmac. The Ministry looks forward to Pharmac's consultation paper and Pharmac's report on the feedback it receives." New Zealand Medicines Strategy consultation document Page 57

all stakeholders, including District Health Boards, seeking a range of improvements to the system the 'consultation' continued through to the end of the year. Despite the active and constructive participation of many people and organizations, PHARMAC finally announced on 21st December 2005, that it would only make some minor changes in addition to the few amendments it had originally proposed. None of the substantive issues raised during the consultation process were acted on.

- 3.6 Given this typical experience with PHARMAC consultations, and the fact that PHARMAC has already formed and conveyed its views on this matter, raises questions about whether this is indeed genuine consultation and whether it meets with the elements of legal consultation as determined by the Court of Appeal⁴ and Ministry of Health guidelines⁵ that state that the party obliged to consult must keep an open mind.
- 3.7 Such issues impact negatively on stakeholder and public participation and confidence in the process. That the Ministry of Health relies entirely on PHARMAC's analysis and advice on this issue, further undermines the Strategy development process and the final outcome of this important policy review.

4. The wrong consultation question has been asked.

- 4.1 In his covering letter on the 18th December Matthew Brougham, PHARMAC Acting Chief Executive, invited submissions on the question of how should high cost medicines be funded and this question specifically to "Do 'high cost' medicines require a different approach to considering funding than other medicines?" The letter goes on to advise that PHARMAC has reached the conclusion that there are no persuasive arguments for treating the funding of high cost medicines differently from other medicines.
- 4.2 The view that high cost medicines should be treated the same way as other medicines is certainly arguable. All medicines should be scrutinized to ensure safety, quality and efficacy and the relative cost effectiveness of all medicines being considered for public funding need to be thoroughly evaluated. Furthermore, considerations of patient need, health priorities and funding priorities should apply to all medicines irrespective of whether they are low cost therapies or high cost therapies.
- 4.3 There is however a critical flaw in this argument when considered in the New Zealand context: it assumes that the systems that are in place for the funding of 'other' medicines are not only working well but are sufficiently robust to deal with the introduction of modern and innovative new therapies.

⁴ Wellington International Airport v Air New Zealand (1993) 1 NZLR 671,675.

⁵ Consultation Guidelines for the Ministry of Health and District Health Boards relating to the provision of health and disability services. August 2002.

- 4.4 Clearly this is not the case in New Zealand. Investment in pharmaceuticals has been severely constrained over the last decade with expenditure growth held to less than 2% per annum on average. PHARMAC's ability to fund new medicines of any description is therefore greatly curtailed and we have seen an ever widening gap between the products that achieve funding in other developed countries and what is ultimately funded here.
- 4.5 The issue is therefore not about whether a different approach is required for high cost medicines but whether the current medicines funding system is working for medicines in general. Rather than question whether a different approach is required for high cost medicines the question must be "do we need a different approach to the funding of all medicines?" The answer to this question is a resounding "yes" and until we achieve good systems for the funding of medicines generally, we cannot have any confidence that PHARMAC has the ability to deal with high cost medicines.

5. Necessary reforms

- 5.1 In our view the key institutional problems with the current system of funding medicines are:
- The bundling of clinical assessment and procurement decisions—This is likely to create incentives to subordinate clinical judgement to budget imperative, and to understate the degree of rationing by claiming that unfunded medicines are not effective or cost-effective
 - The bundling of decisions about therapeutic substitution and procurement—New Zealand appears to have adopted the most radical definition of therapeutic substitutability of any OECD country. As a result, the choice available to New Zealand consumers is severely restricted
 - Poor quality of process—Existing decision-making processes have little credibility because they are non-transparent. More attention needs to be paid to openness, fairness, and high standards of consultation and review.
- 5.2 These weaknesses indicate that the public and the Government have little basis for confidence in the quality of decisions and outcomes. We have compared the existing institutional arrangements for access to pharmaceuticals in New Zealand with the international best practice, and with the practice in other areas of public policy in New Zealand. This comparison showed that the structures and processes involved in making the key decisions about the reimbursement of pharmaceuticals do not live up to the standards we expect of New Zealand government institutions.
- 5.3 To move from current practices to an improved model, we recommend:
- Separation of cost effectiveness decisions from funding decisions
 - Separation of medical and scientific decisions from funding and procurement decisions
 - Creation of reliable metrics and reporting requirements

– Improved decision-making processes.

5.4 Most importantly, funding decisions and rationing decisions need to be made openly, transparently and explicitly. Decisions as to the relative merit, including cost effectiveness, of medicines for which funding is sought must be made by an independent expert body so that an objective evaluation of the medicine, and what it can offer, is made. This independent body would also review and rank the medicines in terms of patient need, health priorities and funding priorities and determine the appropriate level of population access and any access restrictions.

5.5 The analysis of cost-effectiveness should essentially involve a process that is known internationally as “Health Technology Assessment” (HTA). This has been defined as:
*A multidisciplinary activity that systematically examines the technical performance, safety, clinical efficacy and effectiveness, cost, cost-effectiveness, organisational implications, social consequences, and legal and ethical considerations of the application of a health technology.*⁶

HTA must be carried out as objectively as possible and should adequately cover all the issues in the definition above.

5.6 In summary, key recommendations for an improved decision-making model include an agreed set of standards for conducting assessments and ranking pharmaceuticals, peer-review, transparency of process, stakeholder involvement and a process for the review of decisions.

6. Pharmaceutical funding: investing in health

6.1 Because New Zealand’s community pharmaceutical expenditure is capped, the fact that a medicine, high cost or otherwise, is evaluated as cost effective does not necessarily mean that it will be funded. As previously noted, growth in expenditure has been held to less than 2% per annum on average and after natural growth in the system (volume and mix) is accounted for, little is available for new investments. In the six years to May 2006 Australia subsidised 78 new innovative medicines. While 72 of the 78 were registered by Medsafe, only 20 of the 78 were subsidised in New Zealand⁷.

6.2 While the industry accepts that rationing is inevitable, constraining expenditure to this degree means that the budget is simply unable to accommodate many cost effective medicines. Medicines that are higher in cost, in terms of net cost to the Schedule,

⁶ EUR-ASSESS. Report from the EUR-ASSESS Project. Int J Technol Assess Health Care 1997;13(2):

⁷ Access by patients in NZ to innovative new prescription-only medicines; how have they been faring in recent times in relation to their trans-Tasman counterparts. - Report by Michael Wonder, Senior Health Economist, Novartis Australia June 2006.

struggle to achieve funding and those that have a relatively high cost per patient or per QALY are even more unlikely to achieve funding.

- 6.3 Delays in listing⁸ and restrictions on access are also used to help reduce expenditure. Timely and appropriate access to new medicines, and particularly higher cost medicines, is therefore significantly compromised.
- 6.4 The question of whether New Zealand's pharmaceutical management system is sufficiently robust to accommodate high cost medicines must therefore involve some discussion regarding the setting of the pharmaceutical budget. PHARMAC have not asked submitters for their views in this regard and the Ministry of Health's consultation on the Medicine Strategy simply proposes improved dialogue between PHARMAC and DHBs.
- 6.5 It is our view that budget setting should be transparent and involve a methodology that establishes the optimal level of investment in pharmaceuticals based on:
 - cost- effectiveness (including benefits accrued across the health system)
 - meeting patient needs and health priorities
 - equity and social objectives
 - affordability (to the taxpayer)

7. **Conclusion**

Sandra Coney, PHARMAC Consumer Advisory Committee Chairman, states, in commentary on the expert papers commissioned by PHARMAC, that "There is a strong case for making high-cost medicines more available." Unfortunately this will not occur without improved funding, supported by the institutional reforms we have proposed.

PHARMAC's "do nothing" conclusion is not a valid response and is clearly not an action supported by the two lead reports commissioned by PHARMAC and the nine peer reviews, all of which made various recommendations for improvement.

19 March 2007

⁸ Medicines funded in New Zealand take on average 14 months longer to be listed on the Schedule compared to Australia.