



**RMI SUBMISSION ON THE  
REVIEW OF THE GUIDELINES FOR THE  
PHARMACOLOGY AND THERAPEUTICS  
ADVISORY COMMITTEE (PTAC) AND ITS SUBCOMMITTEES**

The Researched Medicines Industry Association of New Zealand (RMI) is the professional and trade organisation representing companies engaged in the research, development, manufacture and marketing of prescription medicines.

The RMI/Pharmaceutical Industry Taskforce submission on the *Towards a New Zealand Medicines Strategy* Consultation (refer Appendix 1) noted that a key problem with the current system for funding medicines is the bundling of the assessment of pharmaceuticals and their benefits with procurement decisions within a single organisation, PHARMAC. This creates incentives to subordinate clinical judgement to budget imperative. The Taskforce recommended the pharmacology and therapeutics advisory committee (PTAC) become an independent body separate from PHARMAC.

Similar concerns were raised by other submitters regarding the ability of PTAC to provide PHARMAC with free and frank, objective advice in relation to medicines funding applications. In response, the Ministry of Health and PHARMAC are reviewing the Guidelines for the Pharmacology and Therapeutics Advisory Committee (PTAC) and its Subcommittees.

However, as the consultation is being conducted within the context of the current framework, the degree to which meaningful change can occur is limited.

The New Zealand Public Health and Disability Act 2000 requires that the PHARMAC Board establishes the PTAC. Thus, unless the legislation is amended to ensure that PTAC, (including its secretariat), is independent of PHARMAC, the concerns regarding the ability of PTAC to provide free and frank, objective advice will remain.

Level 1, Perpetual Trust House  
111 Customhouse Quay  
PO Box 10447  
Wellington 6143  
Telephone: 04-499 4277  
Facsimile: 04-499 4276  
[www.rmianz.co.nz](http://www.rmianz.co.nz)

PTAC currently sits within PHARMAC - it is not independent of PHARMAC. Thus PTAC will not only be perceived to be influenced by PHARMAC but also has the potential to be influenced through PHARMAC's involvement in every aspect of the PTAC process, from setting the agenda to determining what information will be published in the minutes.

PHARMAC has the greatest potential to negatively impact on the independence of PTAC's advice through the material provided by PHARMAC to PTAC members for consideration in respect of an Application, and the participation of PHARMAC staff and the PHARMAC Chair at PTAC meetings.

The consultation document invites submitters to comment of "any other issues and amendments that you consider are required to ensure optimal arrangements are in place for PTAC to provide free and frank advice to the PHARMAC Board. The RMI, therefore, takes this opportunity to strongly recommend that the New Zealand Public Health and Disability Act 2000 is urgently amended to provide separation of PTAC from PHARMAC.

Notwithstanding the limitations noted above, in the interim the RMI would like to make the following comments with regard to the proposed changes to the PTAC Guidelines/Terms of Reference:

- The RMI supports the proposal to make available some information about PTAC deferrals (but not the whole minute)
- The RMI supports the proposal to allow suitably qualified non-medical health professionals to be appointed to PTAC.

A handwritten signature in black ink, appearing to read "Ken Shirley". The signature is fluid and cursive, with a large loop at the end.

**Ken Shirley**  
Chief Executive Officer  
Researched Medicines Industry Association

20 June 2008

# Appendix 1

Extract from NZ Pharmaceutical Industry Taskforce : Submission on the *Towards a New Zealand Medicines Strategy* Consultation Document – March 2007

## 3.4 What Causes the Access Problem?

How did the New Zealand pharmaceutical reimbursement policy get to the point where policy-makers and the public are “flying blind” and there is no clarity on the degree of rationing or its consequences? In those cases where access is clearly a problem—such as in the case of statins—why does the system lack well-functioning error correction mechanism, so that instead of fixing the problem the institutional response is to deny it? Why is the credibility of the pharmaceutical reimbursement regime so much lower than the credibility of other policies, which involve rationing in New Zealand?

We think there are four underlying, institutional problems:

- **The bundling of clinical assessment and procurement decisions.** Effectively, the same organisation is responsible for undertaking an objective assessment of whether a medicine is effective and cost effective, and wheeling and dealing to get the best possible price for that medicine. This is likely to create incentives to subordinate clinical judgement to budget imperatives, and to understate the degree of rationing by claiming that unfunded medicines are not effective or cost-effective. In this environment, a negative assessment of a medicine’s cost effectiveness becomes a bargaining tool in the procurement process. The apparent gain in procurement bargaining power, however, reveals itself as lack of transparency about the degree of rationing, and makes it hard for the Government, DHBs and PHARMAC to make rational decisions about rationing (and conversely, about the required level of funding). PHARMAC’s emphasis on commercial secrecy leads it to keep its cost-utility assessments secret. This results in:
  - Perceptions that PHARMAC does not use its own published decision criteria to decide which pharmaceuticals will be funded and which will not
  - PHARMAC seldom being specific and explicit about trade-offs on which it relies to justify its decisions
- **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.
- **Lack of clear accountability.** In theory, the DHBs hold the purse strings with respect to overall funding allocated to pharmaceuticals. The relevant Ministers, in particular the Minister of Health, also play a key role in the annual budgeting process. Finally, PHARMAC makes decisions about funding priorities. In this mess of over-lapping responsibilities, it is impossible to identify who should be held accountable for any particular rationing decision. Institutional unbundling and introduction of clear performance metrics would improve accountability and sheet responsibility for decisions home to where they belong: whether to DHBs, Ministers, procurement organisations or clinical advisory bodies.
- **The bundling of commercial and public policy responsibilities.** PHARMAC performs two incompatible roles: it is a commercial organisation, whose objective is to use whatever technique possible—including confusion and limited access to information—to gain bargaining power. It is also a public body responsible for life-and-death decisions about the allocation of funds. The latter requires high levels of transparency. These responsibilities require different modes of operation and different organisational cultures.

These institutional problems, taken together, create an environment where the public and the Government can have little basis for confidence in the quality of decisions and outcomes. A comparison of the existing institutional arrangements for access to pharmaceuticals with the practice in other areas of public policy in New Zealand indicates 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:

- Government agencies are frequently called to make complex technical decisions in the presence of risks and imperfect information. The complexity involved in assessing whether a medicine is effective and cost-effective is similar to the complexity of assessing biohazards required of ERMA, or of competition and regulatory assessments required of the Commerce Commission. In general, other decision-making bodies have clear and transparent processes, involving consultation on submissions, written draft decisions, ability to comment on the draft decisions, and ability to appeal the final decision to an independent tribunal (or Court). These together add up to a more or less effective error correction mechanism. By contrast, decisions about effectiveness and cost-effectiveness of medicines are made without a formal process, without submitters being able to comment on draft decisions, and without any rights of appeal
- In general, in the New Zealand public service, every attempt is made to avoid giving organisations conflicting objectives. By contrast, PHARMAC is tasked with incompatible responsibilities
- In most other policy areas, considerable effort is made to develop and collect comprehensive performance metrics. Independent performance evaluations are commonplace. By comparison, neither PHARMAC nor DHBs nor the Ministry of Health produce consistent metrics of access to pharmaceuticals on an on-going basis. PHARMAC appears to devise its own metrics to assess its own performance. These include the notorious measure of savings achieved by PHARMAC which shows the actual expenditure path against a hypothetical (and totally unrealistic) expenditure path which would have prevailed if the prices of pharmaceuticals remained at the same level when the drug was listed (in other words, PHARMAC attributes to itself the effect of expiry of patents and resultant generic competition). We are not aware of any credible external evaluations of the quality of access to pharmaceuticals to New Zealand commissioned by the Ministry of Health.

Similarly, a comparison of New Zealand institutional arrangements for pharmaceutical reimbursement with countries such as UK and Australia reveals the same differences:

- Both UK and Australia emphasise the independence of the bodies responsible for assessing the effectiveness and cost effectiveness of medicines from the procurement process. In addition, the UK independent body (NICE) monitors actual levels of consumption of pharmaceuticals and recommends policies when it observes under or over-consumption
- Both UK and Australia emphasise the quality of decision-making process, such as open hearings, the right of reply and the right of appeal
- Both UK and Australia make decisions about the overall level of funding for pharmaceuticals having regard to the gap between the current level of funding and the funding required to provide access to the medicines which were independently assessed as efficacious and cost-effective. In Australia, approximately 10 percent of the medicines recommended by PBAC in 2000 were still awaiting listing in 2006. The Australian Government accepts the need to fund new medicines, but the rate at which funding is made available can depend on fiscal priorities.

It is essential to improve New Zealand's institutional structures for pharmaceutical funding so that they promote good decisions, and good health outcomes. The remarkable thing is that the institutional changes required are relatively modest and straightforward.

Having diagnosed the institutional problems which have led to the current mess (it is difficult to think of any other way to describe the current situation), it is easy to see what the institutional solutions would look like. The key changes needed to achieve this improved model involve:

- Separate cost effectiveness decisions from funding decisions
- Separate medical and scientific decisions from funding and procurement decisions
- Create reliable metrics and reporting requirements
- Improve decision-making processes.