

20th May 2005

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Dear Stuart

RMI Submission – Update of PHARMAC’s Operating Policies and Procedures

The Researched Medicines Industry Association (RMI), representing New Zealand’s researched-based pharmaceutical industry, makes the following submissions regarding PHARMAC’s Operating Policy and Procedures (OPPs) and PHARMAC’s proposed changes.

1. Purpose and scope of the review

It is noted that the *Operating Policies and Procedures of the Pharmaceutical Management Agency (“PHARMAC”) Second Edition January 2001* requires that PHARMAC review the OPPs at least once in the next 5 years and that this be done in consultation with relevant groups. It is therefore disappointing that prior to consultation PHARMAC has already determined the limit of changes it is prepared to make. The Chief Executive’s covering letter states “PHARMAC does not propose to make many changes to the OPPs” and goes on to outline only two proposed amendments.

This is at odds with the Minister of Health’s public statements that the review is an opportunity to look at a number of issues including sole supply contracts and Exceptional Circumstances criteria. Neither of the changes proposed by PHARMAC address the areas the Minister has identified nor will they result in any real modification of PHARMAC operating policies and procedures. They are merely additions that serve to integrate hospital purchasing and give PHARMAC even more general scope to act.

It is also noted that there is now no reference in the draft to any requirement for future reviews.

The RMI therefore submits that regular reviews of operating policies and procedures continue to be a requirement. We also submit that the current review is lacking in scope and independence and should instead form part of a wider, independent review in order to better meet political and public expectations.

2. Purpose of Operating Policies and Procedures

PHARMAC’s press release of 11th April 2004 states that the Operating Policies and Procedures (OPPs) is the document that sets out how PHARMAC undertakes its business

of managing government expenditure on pharmaceuticals. It is therefore reasonable to expect that the OPPs will give clear guidance on the standard mechanisms and rules that will be employed by PHARMAC.

PHARMAC's operating policies and procedures as written instead serve to give PHARMAC absolute freedom to act on a case-by-case basis. As a result the reader is unlikely to be able to accurately assess how PHARMAC is likely to act in even the most fundamental of its processes.

For example, section 3 describes PHARMAC's strategies for the management of pharmaceutical expenditure but the introduction to section 3 states: "*PHARMAC is not bound to pursue any particular strategy. PHARMAC may also modify or depart from a strategy previously adopted, including not applying the strategy the same way in all situations, or may adopt new strategies...*"

This degree of latitude challenges the value and substance of PHARMAC's OPPs document. There is little point in having a statement of operating policies and procedures if the agency concerned has complete freedom to act outside it on a routine basis. Exceptions to the rules should be just that – the exception – and the statement of operating policies and procedures should reflect that.

3. PHARMAC's supply-side strategies

3.1 Reference pricing and cross deals

PHARMAC's linking of subsidy levels to the lowest off-patent molecule in a therapeutic sub-group means that innovators are denied a fair return on their investment and this in itself creates a barrier to new products entering the market. Through the reference pricing process PHARMAC may also eliminate all subsidies for other medicines in the therapeutic subgroup effectively excluding these medicines from the market and limiting patient and prescriber choice.

A key component of reference pricing is the determination of each therapeutic subgroup. PHARMAC's definition of a therapeutic subgroup is: a set of pharmaceuticals producing *similar* therapeutic effect in treating the same or *similar* conditions. It is therefore a step beyond generic substitution in that an entire class of medicines, that may have different chemical structures, are considered by PHARMAC to be equipotent and efficacious. Often this is not the case and this form of treatment selection fails to provide the range of options necessary to meet the needs of individual patients.

When considering the operation and impact of reference pricing account must be taken of other PHARMAC strategies that are applied in unison with reference pricing. When applying for a listing of a new medicine, suppliers are encouraged to offer a 'cost neutral or better' proposal. For example a successful listing of a new medicine may involve the company offering a price break on another medicine already listed on the Schedule. This second product may only have a small share of the market but the price break serves to drive down, through reference pricing, the price of the entire therapeutic subgroup.

Reference pricing also has a negative impact on continuity and stability of treatment. Reference pricing decisions can be applied as and when PHARMAC sees fit unless the listing contract with the supplier explicitly protects the product from reference pricing. Consumers therefore find that their subsidised medicine is switched for no reason other than the fact that a new deal has been struck by PHARMAC, often stemming from another therapeutic group entirely. No provision is made to 'grandparent' those patients who would prefer to stay on their current medication.

3.2 Parity Pricing

While on the surface parity pricing would seem to be simply an extension of reference pricing, parity pricing in fact goes against the accepted principles of reference pricing. Those fundamental principles are that a similar price should be paid for those medicines that have the same therapeutic purpose and effect.

In contrast, parity pricing allows PHARMAC to reduce the subsidy for a pharmaceutical in one therapeutic subgroup, thus setting the reference price for that subgroup, by setting it at the level of the subsidy for a completely separate therapeutic subgroup.

This methodology goes well beyond any clinical or pharmaco-economic rationale and is simply an additional tool that can be used PHARMAC to achieve its annual target of a 9% reduction in price of those medicines already listed on the Schedule.

3.3 Tendering and sole supply

The tendering and sole supply strategies employed by PHARMAC limit clinician choice and cause frequent Schedule changes. This creates uncertainty and instability for patients.

Continuity of supply is compromised as suppliers are not able to carry extra stock due to the very small margins imposed by the cost cutting required to win a tender or sole supply contract. As sole supply tenders are often for three years, supply can become even more tenuous toward the end of the contract period as uncertainty mounts as to whether the contract will be re-awarded or go to a cheaper supplier. Sole supply arrangements can also create major difficulties if the supplier is unable to ultimately supply as was the case with this year's influenza vaccine.

Frequently other suppliers, often the innovator, are called upon to fill the gap when supplies fail and in these situations are expected to start and stop supply within days. Companies can also be quite uncertain whether they have obtained a contract in the first place because of the lack of clearly defined response times from PHARMAC to contract submissions and tenders. A contract can be "held in abeyance" for months, or even years, making forward planning almost impossible. Companies do not know whether to run stocks down or build them up.

These 'winner-takes-all' strategies while effective in getting the best possible price also serve as a disincentive for suppliers to maintain their whole product portfolio

in New Zealand. This particularly evident with service line items and niche products.

4. Decision criteria

PHARMAC lists eight criteria for decisions about proposed amendments to the Schedule and an additional criterion of “any other criteria as PHARMAC thinks fit”.

Decision-making or evaluative factors must be transparent and include indications of weightings given to each factor or criterion. This information should be documented in the OPPs along with the rationale behind the criteria rankings.

5. Conclusion and recommendation

In summary the RMI recommends that this essentially internal review by PHARMAC be superseded by an independent review of pharmaceutical management and funding in New Zealand that includes, but is not limited to PHARMAC, its policies, operations and impacts.

Lesley Clarke
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