Time to gear up for the generic v brand-name drugs showdown

Sydney Morning Herald
February 7, 2005

Officials dealing with the trade deal must not sideline public input, writes Tom Faunce.

Last year, the Canadian health minister was applauded by a coalition of pensioners, workers and retirees for passing legislation restricting the "evergreening" of supposedly innovative drug patents.

"Evergreening", the tactical extension of monopoly rights over "innovative" medicines that have large sales, costs millions of dollars each year.

The Australian Government has made similar efforts, through legislative amendment and policies such as the 12.5 per cent automatic discount once a brand-name patent expires.

These efforts will soon be tested as US drug companies claim that generic or copy drugs nominated to be included in the Pharmaceutical Benefits Scheme infringe their "innovative" drug patents, thereby breaching the Australia-US Free Trade Agreement.

The arm-twisting between Australia and the US over pharmaceuticals, and their prices, will be carried out in private, through select committees on pharmaceutical policy set up under the trade agreement.

The US is likely to be well advanced in its nominees for these committees. Hopefully, the Australian Government is taking its appointments equally seriously.

Under the agreement, a medicines working group is to be established with membership restricted to federal government officials of both countries. This committee is limited to discussing transparency issues under the Pharmaceutical Benefits Scheme, including the nature of the "independent review process" of PBS decisions.

It is permitted to weigh the relative public health importance of pharmaceutical research and development against cheaper, quality generic medicines. But this committee cannot define "innovation" in pharmaceuticals, or consider how to make drugs available in a more "timely" or "expeditious" fashion.

This task has been left to talks between Australia's Therapeutic Goods Administration and the US Food and Drug Administration.

Defining just what is "innovation" in medicines is fundamental, and on it may hang decisions to spend hundreds of millions of dollars on drugs whose comparative therapeutic significance has yet to be proven.

In the US, drug companies can claim that medicines are innovative if they perform better than a placebo, that is, a tablet with no pharmacological effect, or have minor molecular variations without necessarily adding value to community health.

Yet, under the trade agreement, drug innovation is linked with the concepts of "affordability" and "objectively demonstrated therapeutic significance" - concepts which may require comparison with existing therapies.

Concern over drug innovation has been spurred by the recent Vioxx and Celebrex debacles. These drugs, though possessing minor variations over competitors, were aggressively marketed as "innovative".

The former federal health minister Michael Wooldridge mentioned Celebrex's "dramatically lower side effects" when including it in the PBS, a listing that cost taxpayers $140 million over the following nine months alone. More was spent on advertising these "me-too" drugs than on their research and development yet manufacturers continued to promote them long after they were known to cause fatal heart attacks.

Their claim to be innovative appears to have been too readily accepted by government officials; public safety suffered as a result.

Perhaps most important for Australian drug policy is the joint committee which is to "supervise" the implementation of the trade deal. It will comprise government officials of both parties and be chaired by the US Trade Representative and the Australian Minister for Trade.

This committee may delegate its functions to other committees, including the medicines working group. It may interpret any ambiguities in the agreement, including the definition of pharmaceutical innovation.

This committee may, but is not required to, seek advice from non-governmental persons or groups. If the Australian officials aren't careful, this could result in the input of Australian community groups with a stake in seeing a continuing important role for cheap, quality generic medicines under the PBS being sidelined. These include organisations of pensioners and retirees similar to those who fought brand-name drug patent "evergreening" in Canada and the US.

In the final exchange of letters for the free trade agreement, the US reserved its right to challenge Australian amendments protecting the role of generic drugs under the PBS. If a dispute arises, the US can threaten dispute resolution proceedings, including seeking damages and retaliation in trade areas such as agriculture or manufacturing, if its "legitimate expectations", such as those about drugs, are not achieved.

With what is at stake, it is crucial that Australian officials on these committees be experienced and dedicated to implementing PBS policy. If the Australian Government succeeds in achieving a balance between our emphasis on generic and the US focus on innovative medicines, if it succeeds in demanding research about "objective therapeutic significance" to back up claims of drug innovation, it will have defused a future political issue and gone a long way to assuring a healthier future for our ageing population.

Dr Tom Faunce is a senior lecturer in the medical school and lecturer in the law faculty at the ANU.