Pharmaceutical Patents Review. Submission by Dr Mary Osborn

My recommendations are based on my recent PhD thesis(1) and from my contribution to the “Working Group on Promotion of Therapeutic Products”(2).

The aim of the Pharmaceutical Patents Review is to examine whether Australia’s patent system is effective in securing timely access to competitively priced pharmaceuticals and in supporting innovation and employment in the industry. An important part of the review examined Australian provisions for extending the terms of eligible pharmaceutical patents.

Issues I would like to highlight in my submission are:

1. Why does the government policy allow for payment of different prices for the same outcome. It would appear that Australian taxpayers are funding profits of overseas "big pharma" when most pharmaceutical companies are already making profitable margins of more than 25%”.
2. Why aren’t these profits providing incentives to the pharmaceutical industry to develop pharmaceuticals that offer new treatments.

Timely access to competitive priced pharmaceuticals.

A 2013 report produced by the Grattan Institute(3) suggested that the Commonwealth could save A$1.3 billion per year by reforming the Pharmaceutical Benefits Scheme (PBS). The report shows that if the PBS paid prices for drugs that many Australian public hospitals or New Zealand’s national pharmaceuticals purchaser pay, the government could produce a budget surplus. The reports suggests that since 2008 the price Australia pays for pharmaceuticals relative to similar developed countries has increased. Most countries have contained their pharmaceutical prices but Australia has not.

Submissions presented to the Pharmaceutical Patents Review in 2012 (4, 5) clearly articulate issues of extending patency rights with recommendations that include economic and social justice outcomes for Australians. Given the cost of pharmaceuticals and the general consensus that they will form an increasing part of health treatments, there is an urgent need for an effective system for generic approval and entry into the market. Recommendations 6 and 13 from Moir (4) explicitly address issues related to timely access to competitively priced pharmaceuticals (Recommendation 6: Amend the Patent Act 1990 to clarify that all late applications for changes to patents, whether of status or to claims, must be refused. Applicants must be advised that all deadlines are firm. All scope for late actions beyond limited grace periods should be removed from the act. Recommendation 13: Establish a task force charged with developing a system to ensure timely generic entry).

Two reports presented to the Parliamentary secretary (2, 6) informed the Delivering reforms— Implementation plan for TGA Reforms: A blueprint for TGA’s future (7) report. The TGA blueprint report outlines recommendations made by the two reports on improving transparency and marketing and promoting pharmaceutical products in Australia. In the 2013 budget funding was allocated to resource working groups to implement the recommendations. Recommendations include reporting the monetary transactions and transfers of value by individuals, identified healthcare professionals and companies in a form that is readily accessible and meaningful to the public; providing access to the information in a single, public repository that is readily searchable;
enabling the information to be audited and validated by healthcare professionals and companies, and to be supported by an educational process to assist all parties to interpret the information in context.

**Supporting innovation and employment in the pharmaceutical industry.**

Moir (5) reports that patents granted to inventions or innovations which are able to recoup their initial investment costs during their period of market exclusivity do not meet the criteria of effective policy, and that monopolies for such inventions impose costs on other innovating firms but provide no commensurate benefits. They are inefficient as they reward behaviour that would happen anyway – and the reward can impose costs on other parties, particularly other innovators.

Lopez reports that patents are ineffective in inducing additional innovation in most technologies (8). The economic literature demonstrates that only in circumstances where there is a large investment or where followers can enter the market extremely quickly is there any likelihood of a market failure. Moir (4) suggests that the ABS data from 2004-05 showed that 34 per cent of Australian firms were innovating (9). The ABS report shows that about 2,100 firms were introducing "new to the world" innovations, and about 2,800 firms "new to the Australia" innovations (respectively 8 and 10 per cent of innovating firms) and it is these firms that might be expected to own patents.

Light and Lexchin Data indicate that the “innovation crisis” in pharmaceuticals is a myth(10). The real innovation crisis, stems from current incentives that reward companies for developing large numbers of new drugs with few clinical advantages over existing ones.

**What could an extension provide**

The literature does not support an extension of patency rights. What is suggested is a change in the current model that encourages the pharmaceutical industry to focus on more cost effective, safer medicines. One initiative is to reduce the number of new drugs approved which often only includes a new title and where the drugs have little therapeutic value. Light and Lexchin(10) suggest reviving the Norwegian “medical need” clause that limits approval of new drugs to those that offered a therapeutic advantage over existing products(11). Other suggestions include directly rewarding innovation, such as through the large cash prizes envisioned in US Senate Bill 1137, rather than through the high prices generated by patent protection (12). The bill may not be politically suitable for Australia, includes the collection of US $billion per year from all federal and non-federal health reimbursement and insurance programmes, and a committee would award prizes in proportion to how well new drugs fulfilled unmet clinical needs and constituted real therapeutic gains. Without patents new drugs are immediately open to generic competition, lowering prices, while at the same time innovators are rewarded quickly to innovate again. This approach would save countries billions in healthcare costs and produce real gains in people’s health.

Duckett (13) reports that Parliament should set the budget for drugs and not make decisions about what drugs should be listed on the PBS and at what price. He suggests Australia adopts the New Zealand process in which an indexed budget determined by government sets the context, but then an independent expert board makes the priority choices (with public consultation) and negotiates prices.
Other suggestions for patency controls include reducing the price of drugs that come off-patent. The current situation where the PBS cuts manufacturers’ prices by 16% once off patent is too small compared with reductions achieved in other countries. To get to best practice quicker, prices of new generics should be at least halved immediately and then benchmarked internationally.

References