Submission to the Pharmaceutical Patents Review

Purpose

The purpose of this brief submission is to respond to issues canvassed in the Background and Suggested Issues Paper (November 2012) circulated as part of the Australian Government’s Pharmaceutical Patents Review. The brief comments by the Pharmaceutical Society of Australia (PSA) are limited to the issue of ‘evergreening’ of pharmaceutical patents.

About PSA

PSA is the peak national professional pharmacy organisation representing Australia’s pharmacists working in all sectors and locations. There are approximately 26,700 registered pharmacists, of which approximately 80% work in the community sector.

PSA’s core functions include: providing high quality continuing professional development, education and practice support to pharmacists; developing and advocating standards and guidelines to inform and enhance pharmacists’ practice; and representing pharmacists’ role as frontline health professionals.

Comments on the Review’s Background and Suggested Issues Paper

The Background and Suggested Issues Paper circulated as part of the Pharmaceutical Patents Review identifies a number of concerns in relation to various forms of evergreening of pharmaceutical patents, which primarily relate to the effect of evergreening in delaying the entry of generic medicines into the market. The impact of such delayed entry on competition and increased costs to the Pharmaceutical Benefits Scheme (PBS) and State Government health budgets have been the subject of public comment in a variety of forums.

1 Based on Pharmacy Board of Australia data released in September 2012.
PSA wishes to canvass an additional concern about the impacts of evergreening on pharmacists and consumers, principally around the uncertainty and confusion that can be created and the potential for suboptimal use of medicines. This is particularly relevant in those cases where regulatory approval is obtained for alternative formulations of a medicine which is essentially the same therapeutic substance.

In such cases there is often no additional therapeutic benefit delivered, however the alternative formulation will commonly feature changes which can have substantial impact on consumers taking those medicines. These are changes to, for example, the labelled strength of the medicine, the physical appearance of tablets or capsules (e.g. size, shape or colour) or the external labelling or packaging of the product. Such changes may seem somewhat innocuous, however the potential for confusion by consumers is actually extremely high. Potential flow-on effects can include consumers inadvertently doubling up on their medicine and experiencing an adverse event or outcome. To prevent these types of scenarios, additional (unremunerated) demands are being placed upon pharmacists to explain the changes and implications to consumers. Additionally, pharmacists are required to carry stock of both the existing and alternative formulations during the transitional period which can be a considerable burden on stock management, storage and handling.

By way of an example of this situation, several commentators have noted the adverse impact on pharmacists and consumers of the regulatory approval of an alternative formulation of perindopril in 2006, with one commentator concerned that:

“The new formulation offers no additional therapeutic benefit, however, some problems with the changeover may arise. Compliance may be compromised by patient uncertainty about their therapy if prescribed and dispensed tablets in a ‘higher’ strength with different packaging without adequate counselling about the changes to the product. Busy general practitioners and pharmacists will be left with this burden of additional explanation.”

In the case of perindopril in 2006, PSA received reports from member pharmacists about cases of consumer confusion with the changeover to the new formulation including an incident of medication misadventure in a hospital setting. The perindopril scenario was even more complex because the use of a different perindopril salt in the new formulation resulted in a change in the ‘strength’ of the product and different dosages were necessary to achieve an equivalent clinical

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5 Tassone A. How green is my patent? i2P 2006; 50,
effect. A further complication was that multiple strengths already existed and combination products (perindopril plus another substance) were also available.

In addition, the impact of evergreening on pharmacists in relation to their role and responsibilities under the PBS Brand Substitution requirements was judged to be of such concern that legal advice was sought by the pharmacy profession’s main professional indemnity insurer in 2006. A subsequent article reported that the legal advice indicated that:

“...pharmacists who do substitute the originator brand unwittingly while complying with all other conditions will not have committed an offence.”

While this advice provides some degree of comfort, it nevertheless highlights the impact on pharmacists that can occur as a result of the evergreening of pharmaceutical patents.

A direct and significant concern for consumers is the availability of, and access to, affordable medicines. Evergreening can delay the entry of generic medicines into the Australian market as well as any listing on the PBS. It is therefore of interest to pharmacists and consumers to ensure that evergreening does not undermine the purpose and ability of the PBS to deliver affordable medicines to Australian consumers.

Concluding Comments

PSA believes that the downstream impacts on consumers, pharmacists and other health professionals must be considered as part of any decision by regulators or the judiciary that may have the effect of evergreening a pharmaceutical patent. Ideally, the results of such consideration would be communicated via a Regulatory Impact Statement or similar mechanism.

PSA would be pleased to participate in any such assessment process that might emerge as a result of the Pharmaceutical Patents Review.

Submitted by

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