Pharmaceutical Patent Review
Draft Report Response

29 April 2013
AbbVie has had the opportunity to review the draft report and recommendations released earlier this month. AbbVie would like to place on record its concern with both the recommendations contained within this report and the potential implications publication of such a report has on Australia’s reputation as a desirable location to invest in research and development work.

The review, including its recommendations, has raised significant concerns both locally and globally around the viability of such investments in Australia. In addition, should the recommendations be adopted, they have the potential to negatively impact innovation and on patients and other stakeholders that benefit from advances in pharmaceutical technologies. Consequently, we urge the review panel to reassess and reconsider both the draft report and recommendations.

To address all of the issues found within this report is challenging in the timeframe provided by the review for feedback. This submission will focus on some of the more egregious faults of the report.

**Extension of Patent Term**

Of particular concern is the review’s position on the extension of term for patents within Australia. Firstly, the report incorrectly asserts that patent term extensions provide “subsidies” to the industry. This belies a fundamental misunderstanding of this mechanism. Rather, patent term extension is an essential mechanism to compensate the patent holder for the effective patent life lost during delays at the patent office and for part of the time during the regulatory approval process.

As the draft report identifies, Australia has maintained a well-developed and consistent approach to the issue of patent term extensions for pharmaceutical products for almost 30 years. This approach has been anchored by the belief that Australia should take its place amongst innovative nations that foster research and development. The draft recommendations contained in this report are inconsistent with that policy approach and advocate instead that Australia join a race to the bottom in terms of fostering and supporting innovation.

The report also fails to provide sufficient weight to the evidence that this policy setting is delivering positive economic results for Australia. The report itself shows that over the period from 1998 to 2011, business expenditures on pharmaceutical research and development grew almost four fold. Between the years 2000 to 2012 there has been a
doubling in the export value of medicines manufactured in Australia. In the financial year 2009/10 the Australian medicines industry contributed over $4 billion in export earnings¹.

The report’s recommendations around patent term extensions appear to be based on a flawed model of economic evaluation that, at its core, displays a fundamental misunderstanding of the economic and scientific realities of research and development. The report has relied on retrospectively calculating the projected value of extension at the time of making investment decisions, the net present value (NPV), for products currently on the market and has determined that such value is relatively small at the time of initial investment. Such an approach fails to take into consideration that investment decisions are made at a point of great uncertainty and high risk of failure. Indeed, published reports indicate that for every new drug approved, in the order of 5,000 to 10,000 molecules are screened². And, for every ten new medicines marketed, only three will ever go on to recoup the research and development costs that went into making them³.

In this high risk environment investment decisions for research and development projects, by necessity, are made very early in development. Such decisions seek to determine whether any potential product can deliver a return on investment after all of the development and commercial risks have been factored in. These calculations incorporate patent term extension. Given that the success rate of developing a new compound from discovery to approval is very low, it follows that patent term extensions provide an important incentive to continue this high risk research and development expense.

It is this system of risk and reward that drives investment decisions, not only in the 30 per cent of products that successfully recoup their research and development cost but across all research and development. It is also this system which provides the financial impetus to support ongoing research and development that ultimately results in new and innovative medicines that improve patient health and wellbeing.

¹ Australian Bureau of Statistics, Catalogue 5368.0, International Trade in Goods and Services, Australia 2009-10, September 2010
**Increasing delays from registration to reimbursement**

In terms of the section commenting on determining effective patent life, the review has again shown itself to not fully understand the processes it is seeking to comment on. The application of *Pretium’s Drug Tracker*, and the conclusion drawn from its analysis do not present a complete picture of the growing delays faced by companies seeking to have their products listed on the PBS. In order to present a complete picture the review would be required to analyse this type of data using a number of filters. Appropriate filters would include the various types of Pharmaceutical Benefits Advisory Committee submissions made to capture those that were made using a cost minimisation or cost effectiveness approach and submissions seeking to list a new mechanism of action against those listing either a new chemical entity within an existing class or a generic.

To accept the current analysis within the review and to make recommendations and findings on such an approach would be to ignore the experience of pharmaceutical companies operating within Australia.

A report by the Australian Healthcare and Hospitals Association, which looked at applications for new medicines or for medicines to be used to treat new conditions approved in 2004 by the TGA, found significant delays between registration and reimbursement on the Pharmaceutical Benefits Scheme. The report found that only 43% of these products were submitted for PBS listing within two years, with an average 17-month delay from TGA approval of a product to consideration by the Pharmaceutical Benefits Advisory Committee (PBAC)\(^4\). This report is more reflective of the experience of pharmaceutical companies seeking to bring a new and innovative product to market.

**Data Exclusivity**

On the issue of data exclusivity AbbVie was again disappointed with the approach taken by the review. The panel’s view that it has not seen any evidence that lengthening the period of data protection would result in pharmaceutical products being made available in Australia lacks credibility, particularly in light of the Lucrin case study provided in the original Abbvie submission, which provides a real and acute example of why data exclusivity is so important.

On the broader issue of data protection it is essential to understand that in order to gain registration for your product extensive data must be collected for submission. This data collection carries a significant cost to innovator companies. Should a company wish to

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expand the indications that an existing marketed medicine may be used for; there is a requirement for additional studies and further submissions to both the TGA and PBAC to demonstrate its safety, efficacy and cost effectiveness within this new indication.

This requires significant additional investment, over and above the original investment to bring this product to market, and reflects an ongoing commitment to research. This approach ensures that society gains maximum advantage from product innovation as efficacy is proven in treatment of more than one condition. In order to further encourage this ongoing investment into research and innovation reward should be provided through the provision of data protection, for each new indication, for a period of time.

Such an approach would do nothing to stifle generic competition, post an innovator company being allowed to recoup the investment required to make a medicine available to treat each disease that it is registered for. Generic competition could start indication by indication reflecting the process undertaken by the originator company who first developed the product and supported the investment into the investigation of its use across multiple disease states.

**Requirement for a strong and stable intellectual property system**

AbbVie holds the view that in order to invest in research and development companies require a strong, stable and predictable intellectual property system. These fundamental tenants of investment are important because they give the pharmaceutical industry the ability to concentrate on addressing today’s health issues - from life-threatening illness to addressing chronic conditions. By actively supporting this environment Governments, around the globe, have assisted in changing the lives of millions of patients and in improving not only the length but also the quality of our lives. The recommendations included in this report seek to undermine each of these fundamental tenants, which have until now been a hallmark of Australia’s policy setting around pharmaceutical patents.

Moreover, the recommendations appear to be based on fundamental misunderstandings of how intellectual property provides incentives for investment and innovation. For example, the discussion on follow-on patents is made in the context of “extend[ing] the duration of patent protection” (or what is referred to as “evergreening”).

The patenting of new inventions that build upon prior innovation does not extend prior patents under current Australian law or the law of other major patent systems. Moreover, there is no consideration of the benefits of “follow-on” innovation, which includes significant technological advances that require considerable investment and bring enormous public health benefits.
Examples of innovation that is provided protection through follow-on patents can include the creation of heat-stable formulations to permit greater use in low-resource settings to new formulations that reduce toxicity or promote patient adherence, or other advances that improve the safety, quality and efficacy of medicines. The report as written, gives no value to the changes these innovations provide to either patients or society as a whole.

Having reviewed Medicine Australia’s supplementary submission, AbbVie endorses their position and urges the review panel to reassess both the draft report and its recommendations.

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