23 April 2013

Ms Terry Moore
IP Australia
PO Box 200
WODEN  ACT  2606

Dear Ms Moore

Pharmaceutical Patents Review: Draft Report

The Consumers Health Forum of Australia (CHF) welcomes the opportunity to provide a response to the Draft Report of the Pharmaceutical Patents Review.

CHF is the national peak body representing the interests of Australian healthcare consumers. CHF works to achieve safe, quality, timely healthcare for all Australians, supported by accessible health information and systems.

CHF and its members have a strong interest in how pharmaceutical patents can work to benefit consumers, and CHF provided a submission on the Review’s Background and Suggested Issues Paper in January 2013.

As we noted in our original submission, the challenge for the Review Panel is to strike a balance between the level of incentive that is needed to encourage originator pharmaceutical companies to bring new medicines to the Australian market and the need for access to medicines that are affordable, both for Australian consumers and the Australian Government. It appears that the Panel has recognised the importance of this balance; for example in statements such as:

> [...] the challenge is to optimise policy so as to encourage innovation that would not otherwise have taken place but to do so only to the point at which such benefits continue to outweigh the costs of such measures to consumers, in higher prices, and to innovation more generally, by obstructing ‘follow on’ innovation.\(^1\)

The emphasis on the public benefit is also welcome. As noted in the Paper,

> Evidence supports the view that the originator industry is facing a challenging period. That, however, does not of itself justify patent extensions which must be in Australia’s wider interests.\(^2\)

\[^2\] Ibid.
CHF supports draft recommendation 3.1, which recognises the need for balance in pharmaceutical patents:

_The Government should expeditiously seek a situation where Australia has strong yet parsimonious IP rights – that is, rights that are strongly enforced and that provide the incentive necessary to underpin an appropriate level of investment in innovation but that are not defined so broadly as to impose costs on innovation or other activity without commensurate benefits._

This balance is also recognised in draft recommendation 10.2, which CHF also supports:

_When drafting the objects clause to be inserted in the Patents Act, as agreed to in the Government’s response to the Senate Community Affairs Committee’s Gene Patents report, the Government should take into account that the purpose of the legislation is to:_

- further Australia’s national interest and enhance the well-being of Australians, including by providing reasonable access to healthcare; and
- provide strong, targeted IP protection – but only up to the point at which the costs (to consumers and the impediment of ‘follow on innovation’) are no greater than the benefits of incentivising innovation that would otherwise not occur.

Striking this balance is particularly important in relation to the extension of patent terms. Patent extensions come at a substantial cost to Government and the community at large — as cited in the Draft Report, these costs were $160 million in 2005-06 and are estimated to be $200 million for 2012-13. Limiting extensions of patent term could potentially result in hundreds of millions of dollars in savings, with substantial savings possible from even a small limitation in extension of term according to the Draft Report.

CHF has reviewed the evidence as presented in the Draft Report in relation to whether limitations on extension of patent term should be removed or the maximum length of extensions increased to ensure 15 years of effective patent life. We support the analysis in the Draft Report:

_Available estimates in the literature suggest that the cost of pharmaceutical R&D is increasing. However, no evidence was provided that the industry as a whole is suffering from inadequate profitability and that longer periods of patent protection are needed. Therefore, there does not appear to be an argument for increasing the length of extensions of term on the basis of a change in the average exclusive market period available._

As outlined in the Draft Report, the effectiveness of extensions of patent term as an incentive for pharmaceutical research and development (R&D) in Australia is debatable:

_It is not clear ... how the [extension of term] provisions achieve this objective, nor has the case been made in submissions to the review that they do in fact meet this objective._

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CHF supports draft recommendation 5, option 5.1, which would replace the current model of using the patents system to subsidise pharmaceutical R&D indirectly and replace this with a direct subsidy. This would involve reductions in extensions of patent terms and use of part of the associated savings to fund R&D directly. CHF particularly supports the concept that some of this funding could be used to incentivise R&D in areas in which patent provisions provide inadequate incentives, including for example the development of new antibiotics and medications to treat rare diseases.

We are less certain of the benefits of draft recommendation 5, option 5.2, which would involve patents receiving an extension of term in Australia will not expire later than the equivalent patents in major trading partners, particularly if this is intended as an alternative to option 5.1. While both options appear to support a public benefit by limiting extensions of patent terms and thus enabling faster access to generic versions of medications, option 5.2 does not provide an incentive for R&D in less profitable areas of pharmaceutical development.

Based on the rationale set out in the Draft Report, CHF is supportive of draft recommendation 6.1, that the Government should maintain the current approach that allows extensions for drugs and formulations but not for methods of use and manufacture.

Thresholds for patentability, and particularly whether patent standards are too low, have been extensively discussed in relation to pharmaceutical patenting. CHF is aware of the amendments in the Intellectual Property Laws Amendment (Raising the Bar) Act 2012 that aim to raise the thresholds for granting patents in Australia. We agree with the assessment in the Draft Report that it is premature to make further changes relating to patentability thresholds to prevent inappropriate follow-on patents when changes introduced in the Raising the Bar Act have only recently taken effect. CHF supports draft recommendation 7.1 that calls for a review of the effectiveness of the Act, but questions whether the recommended timeframe (not later than three years from the commencement of the Act) will be sufficient to identify a shift in patenting practice.

CHF notes the suggestion that the Pharmaceutical Benefits Advisory Committee (PBAC) should have regard to the current patent landscape surrounding a pharmaceutical when forming its recommendations regarding PBS listing. CHF recognises that this could fit within the PBAC’s current cost effectiveness considerations. **We would be concerned if considerations of the patent landscape were expected to take priority over improved benefit or efficiency** in the PBAC’s deliberations, and take some reassurance from the statement in the Draft Report that

> This is, of course, based on the assumption that there are no improved therapeutic outcomes being provided by the new drug and where cost minimisation and provision of alternatives, for the purpose of providing choice, are the only considerations.\(^5\)

CHF agrees that it makes sense for the Government to take a more active role in managing the costs of the PBS where a patent relating to a PBS-listed pharmaceutical is successfully challenged in the courts as recommended in draft recommendation 8.1, as there will be substantial cost benefits to Government and taxpayers in the event of a successful challenge.

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We are uncertain about whether all the suggested mechanisms for Government involvement in challenges to patents would work in practice, and will be interested in comments made in other submissions responding to the Draft Report in relation to these mechanisms.

CHF also supports in principle the concept of a Pharmaceutical System Coordinating Committee (PSCC) that will consider the success and effectiveness of the patent, marketing approval and PBS systems, particularly where these interact, as recommended in Draft Recommendation 10.1. We note, however, that the proposed membership is limited to Government agencies. We argue that the proposed membership should be expanded to include key stakeholders, including those representing the interests of healthcare consumers, or that the Terms of References for the PSCC would require it to consult with stakeholders on a regular basis and report on the outcomes of these consultations.

CHF appreciates the opportunity to provide a submission in response to the Paper, and looks forward to the next stage of the Review. If you would like to discuss the issues raised in more detail, please do not hesitate to contact me.

Yours sincerely

Carol Bennett
CHIEF EXECUTIVE OFFICER