21 January 2013

Ms Terry Moore
IP Australia
PO Box 200
WODEN ACT 2606

Dear Ms Moore

Pharmaceutical Patents Review: Background and Suggested Issues Paper

The Consumers Health Forum of Australia (CHF) welcomes the opportunity to provide a response to the Pharmaceutical Patents Review Background and Suggested Issues Paper.

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. This is a challenging area, and arguments about how patents support or inhibit access to affordable medications are not straightforward.

On the surface, it might appear that taking measures to limit periods of market exclusivity, for example by limiting the availability or length of patent extension periods, could benefit consumers by allowing faster access to generic versions of medications, with resulting price reductions for consumers and government. However, this is overly simplistic, and does not recognise the need for the originator pharmaceutical sector to have some kind of incentive to bring new medications to market. As is outlined in the Background and Suggested Issues Paper,

...bringing pharmaceuticals from research phase to market can be a particularly expensive and risky business, with only a small percentage of research resulting in a commercially successful product.

The originator pharmaceutical sector emphasises the importance of a period of market exclusivity as an incentive to bring new products to market:

It costs around A$1.4 billion to bring one new biopharmaceutical medicine to market, including the costs of failures. When developing a new medicine, a company needs to earn a commercial return within an effective patent-life of 11 or 12 years to justify the investment of that sort of money. This is one of the key factors governing the pricing of new medicines. If companies are not going to earn a sufficient return over and above the costs of development, it is unlikely they will invest in the development of those medicines.¹

It is also apparent that patents and periods of market exclusivity do not provide sufficient incentive for investment in the development of certain classes of new drugs. A lack of new antibiotic medicines has resulted from the decision of pharmaceutical companies not to invest in development of new drugs in this area, due to uncertainty about commercial return based on factors other than market exclusivity.\(^2\) Consumer interests may be better served by alternative incentives for new drug development.

The challenge for the Review Panel in forming its recommendations will be 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. Extensions of pharmaceutical patent terms, for example, result in additional costs to the Pharmaceutical Benefits Scheme (PBS); as outlined in the Paper, the introduction of extension of term provisions was estimated to result in an additional cost to the PBS of $6 million in 2001-02, rising to $160 million in 2005-06 due to delays in the introduction of generic products.

Australian consumers are already experiencing challenges in affording the cost of medications. Australian Bureau of Statistics data indicate that almost one in ten people aged 15 years and over who had been prescribed medication in the previous year have delayed getting or did not get their prescribed medication because of the cost.\(^3\) A recent Australian study found that 8.9 per cent of respondents to a telephone survey who had filled a prescription in the last three months reported an extreme or heavy financial burden from the cost of prescription medicines, and a further 19.5 per cent reported a moderate level of burden.\(^4\) Another study found that approximately one sixth of older Australians currently taking prescription medicines report that the cost causes them financial strain, and almost a quarter who have used prescribed medicines in the last five years report that the cost caused them financial strain over that period.\(^5\) Responses to this financial strain included rationing prescriptions, delaying taking prescriptions, and not filling prescriptions.\(^6\) With these statistics in mind, it is clear that containing the costs of medications will be essential to ensuring ongoing affordability for Australian consumers.

CHF urges the Review Panel to keep the interests of health consumers in mind as it develops its recommendations, and recognises that the Review Panel faces a considerable challenge in striking the appropriate balance between affordable access to medicines and the need to incentivise new drug development.

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\(^2\) Medicines Australia, Op cit.
\(^6\) Ibid.
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 contact CHF Deputy Chief Executive Officer, Anna Greenwood.

Yours sincerely

[Signature]

Carol Bennett
CHIEF EXECUTIVE OFFICER