28 September 2012

Ms Alison McClelland
Commissioner
Productivity Commission
Locked Bag 2, Collins Street East
MELBOURNE VIC 8003

Dear Commissioner,

Thank you for the opportunity to contribute to the Productivity Commission's review of compulsory licensing provisions in Australia.

Medicines Australia represents the research-based medicines industry in Australia, which brings new medicines, vaccines and health services to the Australian market. In 2011-12, our industry generated more than $4 billion in exports and for the third consecutive year, invested over $1 billion in research and development (R&D).

Because compulsory license provisions are meant to relieve situations of rare and excessive hardship, it is not surprising that the invocation of this safety mechanism has been infrequent. That infrequency is not evidence that these licenses are difficult to get, but rather reflective of the relative rarity of extraordinary circumstances meriting them. They are not a mechanism for users and unlicensed manufacturers to avoid paying for access to innovative technologies.

The fact that no compulsory licenses have ever been granted in Australia for pharmaceutical products proves that there are other, much more effective, means available to all members of the Australian community to resolve patent related disputes.

Medicines Australia strongly believes that if Australian patent law were changed to make it easier for third parties to acquire innovative technologies through compulsory licensing -- or for compulsory licenses to be granted in Australia as a matter of routine -- it would seriously undermine the usefulness and effectiveness of the Australian patent system. Moreover, it would negate the very purpose of compulsory licensing provisions in Australian patent law, which is to provide an option of last resort to parties to resolve those issues which could not be resolved through normal commercial negotiations.

Medicines Australia understands that this review by the Productivity Commission has been initiated, in part, as a result of ongoing concerns among some members of the Australian community about the impact of patents on the ability of Australian scientists to conduct medical research and the ability of Australian patients to access innovative medicines at affordable prices. Patentability criteria and research-use exemptions were harmonised with global standards in the recent reforms to the Patent Act through the *Raising the Bar Bill*.

There can be no access to medicines which are not invented. We believe current patent and compulsory licence arrangements strike the appropriate balance between

creating incentives for innovators and ensuring access to new products for consumers.

However, making it easier to obtain a compulsory license in Australia could undermine these purposes. In fact, weakening the Australian patent system in this way would seriously harm Australia's ability to attract global investment in R&D and lead to uncertainty around the long-term enforceability of patents on many current and future medicines by creating greater uncertainty. Both would have serious and negative consequences for patient access to medicines in Australia.

Changing the law in this area would pre-empt the positive impact of the recently introduced research-use exemption in the *Raising the Bar Bill*, which makes it absolutely clear that Australian scientists are free to conduct research on patented inventions (so long as it for the purpose of investigating the patented invention and not their intention to infringe valid patents by selling these inventions without the inventors' permission).

On the issue of gene patents, Medicines Australia's strongly believes that the compulsory licensing provisions should remain technology-neutral consistent with other provisions in the Patents Act. It is also unclear to Medicines Australia how changes to compulsory licensing would address some parties concerns about the granting of gene patents. A compulsory license can only be granted where a patent exists. Those parties who raised concerns about gene patents were seeking to make this technology unable to be patented – an approach which has not been supported by any of the three inquiries which have examined this issue. In every report, these inquiries found there were no grounds for amending Australia's patent law to exclude genetic or biological materials from patentable subject matter.

The process of bringing new technologies to the market involves high degrees of risk. Only a small portion of promising research yields safe and effective products, of which only a fraction are profitable enough to generate necessary investment returns. On average, the cost of bringing a new medicine to market is approximately $1.5 billion (including the cost of "failed research projects"), and it can take between 12 and 15 years to complete the process.

By guaranteeing a clearly defined period of market exclusivity, patents (and other forms of intellectual property rights such as data exclusivity) act to mitigate the commercial risks of bringing new medicines to market, making it significantly more likely for private enterprises to continue to investment in R&D for new medicines.

The Australian Medicines Industry remains committed to improving Australian patients' access to new health technologies and ensuring that Australian scientists are free to conduct research on patented inventions.

Accordingly, there is a strong and enduring rationale for making sure that no new laws are implemented that would, in any way, undermine the ability of patent owners to defend their legitimate rights. Patents allow companies to invest in R&D, with the expectation that they will have a fair opportunity to recoup this investment before others, who did not bear the initial risk, are permitted to profit from new and improved products.

Medicines Australia looks forward to an ongoing engagement with the Productivity Commission as it conducts this review and we will respond to the draft report in due course.

Yours sincerely

Dr Brendan Shaw
Chief Executive