8 February 2013

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

Dear Commissioner,

Thank you for the opportunity to comment on the Productivity Commission's draft report on compulsory licensing in Australia.

Medicines Australia supports the Commission's draft findings and recommendations. In particular, we agree that there should not be special mechanisms, standards or processes for challenging patents covering healthcare technologies, including medicines.

It is important that the patent system in Australia remain technology neutral, as required under the terms of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights. This means that Australian patent law should be interpreted and applied consistently, regardless of technology.

Medicines Australia believes that any changes which seek to "carve out" certain technologies for different regulatory or judicial treatment have the potential to stifle entire fields of innovation. This is particularly so for fields such as pharmaceuticals and other technologies which treat and prevent human disease, where the risks of failure are high and huge investments are required to understand and then address medical and scientific problems.

We also agree that implementing new methods of dispute resolution, including new bodies to adjudicate cases involving compulsory licenses, is unwarranted.

Several past reviews, such as the Advisory Council on Intellectual Property's (ACIP) review of post-grant enforcement strategies, have recommended the establishment of independent tribunals to issue non-binding decisions in patent-related disputes, including ones involving applications for compulsory licenses. Medicines Australia believes that there is no basis upon which pharmaceutical patents should be treated differently from any other patents in terms of avenues for reviewing compulsory license applications. These additional processes for assessing applications would not negate the need for court action in most circumstances, and would therefore create additional steps in the review processes without any significant benefits for the parties involved.

We agree that inserting an "objects clause" in the Patents Act may assist in more clearly defining the purpose of the patent system in Australia, and we note that the Australian Government has already indicated its intention to do so.

However, Medicines Australia would caution against the Commission's draft recommendation to repeal section 136 of the Patents Act, which requires the operation of Australian patent law with respect to compulsory licensing to be consistent with Australia's international obligations. The Commission's recommendation that specific elements of international treaties be incorporated directly into the Patents Act could require frequent amendments to the Act as Australia becomes party to new international treaties covering intellectual property rights. The clear advantage of the existing legislation is that it reduces the need for frequent legislative changes to account for new treaties and new interpretations of existing treaties, which helps ensure the stability and predictability of the patent system in Australia.

In addition, whilst Medicines Australia supports the recommendation for IP Australia to develop a plain English guide on the compulsory licensing provisions of the Patents Act, we believe that if draft recommendation 6.1 is implemented and new and amended provisions are included in the Competition and Consumer Act 2010 in relation to compulsory licence orders based on restrictive trade practices by the patent holder, these provisions should also be explained in the plain English guide. We further request that Medicines Australia and other stakeholders are consulted on the drafting of the plain English guide.

A strong, stable and predictable intellectual property system is critical to Australia's ability to attract investment in R&D and high-tech manufacturing. It is also critical to Australian patients being able to receive the latest treatments as quickly as possible.

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. It would also, as the Commission's draft report appears to acknowledge, 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 looks forward to an ongoing engagement with the Productivity Commission as it continues its review of compulsory licencing in Australia.

Yours sincerely

Dr Brendan Shaw
Chief Executive