

Joint Standing Committee on Treaties
PO Box 6021
Parliament House
Canberra ACT 2600



20 April 2018

Via email: jsct@aph.gov.au

Dear Sir/Madam,

Joint Standing Committee on Treaties Inquiry into the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (TPP-11)

Medicines Australia strongly supports the principles underpinning free trade and therefore welcomes the opportunity to make a submission to the Joint Standing Committee on Treaties Inquiry into the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (TPP-11) Agreement.

Medicines Australia is the peak industry body representing the research-based medicines industry in Australia, innovative companies that research, develop, manufacture and supply new medicines and vaccines to the Australian market. Our members are proud of the contribution they make to the health and well-being of everyday Australians, as well as to the local economy. Our industry provides high value jobs for Australians, generates close to \$4 billion in exports¹ and invests over \$1 billion in research and development every year.

To achieve this, our industry is highly reliant on a stable policy environment, which strongly supports innovation, R&D and commercial translation to at least the same levels as competitor nations. This requirement is particularly acute when it comes to intellectual property (IP) policy. A strong, effective and stable IP system is critical to fostering pharmaceutical innovation, investment, productivity and competitiveness. In this way, IP is a cornerstone of increased access to life-changing and life-saving medicines for Australian patients.

Within this context, Medicines Australia's submission (Attachment 1) strongly recommends that any further expansion of the TPP-11 should revisit the need for stronger IP provisions. In particular:

- **Strengthen regulatory data protection:** the proposed duration for regulatory data protection specified in the now suspended articles of the original agreement² is insufficient
- **Ensure a strong, enforceable patent notification scheme:** Thereby providing certainty and preventing delay in generic market entry.

¹ Medicines Australia FactsBook, 4th Edition

² Provision 18.50.1 and 18.51.1

Australia must recognise that to remain internationally competitive it must provide a stable and supportive environment that encourages investment. As the Government is seeking to cement several trade agreements with key trading partners over the next 18 months, now is the time to ensure that comparable IP protections are in place.

We would welcome the opportunity to discuss and collaborate with the Australian Government further on this issue. Please feel free to contact Elizabeth de Somer, Interim Chief Executive on (02) 6122 8525.

Kind regards

A handwritten signature in black ink, appearing to read 'E. de Somer', written in a cursive style.

Elizabeth de Somer
Interim CEO

ATTACHMENT 1

Medicines Australia Submission to the Joint Standing Committee on Treaties Inquiry into the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (TPP-11)

Medicines Australia submits that the duration specified in the articles in relation to regulatory data protection (RDP) in the original Trans Pacific Partnership Agreement (TPP), 18.50.1 and 18.51.1, was insufficient and Australia should be matching global best practice. With the suspension of these articles from the TPP-11 the Australian Government should support the stronger IP and RDP provisions in any further expansion of the TPP-11 to encourage greater consistency and transparency in both the domestic and international business environment within which innovative pharmaceutical companies make their investment decisions.

With global demand for medicines expected to double in a decade, Australia can grow its share of the international pharmaceutical research, manufacturing and export markets through increasing advanced manufacturing and enhancing R&D activity. This will help drive economic growth, secure more high-skills jobs and provide Australians with improved access to new medicines.

But the policy settings must be right. First and foremost, Australia must uphold a strong, effective and stable IP system. The innovative pharmaceutical industry relies on strong IP protection as a key incentive to invest in R&D that will lead to new medicines. Strong IP systems drive innovation and investment by providing a framework for innovators to share their discoveries and creations in exchange for a period of exclusivity. Trade agreements that do not adequately support the important role of a strong IP system undermine investment and domestic economic growth.

Regulatory Data Protection

Regulatory data protection (RDP), also referred to as data exclusivity, plays a unique but vital role in protecting intellectual property rights, as well as encouraging R&D investment and follow-on innovation in the Australian pharmaceutical industry. RDP protects against unauthorized third-party use of data submitted by the innovator for regulatory approval. This exclusivity helps recognize the extensive time, effort and cost of clinical trials required to ensure that medicines are safe and effective for patients.

RDP is particularly important for medicines that are highly specialised, have a paediatric indication or are for diseases impacting a very small patient population. RDP is increasingly important as biological medicines become more complex and uncertain in their patentability. Where the period of market exclusivity from a patent cannot be assured, which is more likely for biologics, innovators will rely more heavily on data protection to enable them to recoup up-front investment. Without these parallel systems in place, innovators will not have the incentives needed to conduct the expensive, risky

and time-consuming work to discover and bring new medicines to market and find further uses for existing medicines.

Medicines Australia has long argued that Australia's current five-year data exclusivity provision lags our global competitors and trade partners. The United States, for example, offers up to 12 years for biologics, the EU up to 11 years, and Canada and Japan both offer eight years.

Concerns that RDP adds significant costs to Australian patients when accessing PBS medicines are misleading, as it is well documented that data protection runs alongside, and generally expires before, the patent. It was acknowledged at the JSCOT hearing on the TPP in November 2016 the TPP, in its entirety, including the now suspended articles in relation to RDP that:

*"...[there would] be no changes required to the PBS system and there will be no changes required to the Therapeutic Goods Administration system and therefore no costs passed down in any way to the Australian community as a result of this negotiation... the Department of Health has advised government that it is satisfied that there will be no impact on the PBS, nor any change required to our domestic regulatory settings."*³

The Australian Government aspires to make Australia a more innovative country with an economy driven by inventive, research-driven, knowledge-based industries. Strengthening RDP protections through free trade agreements, to align with global best practice, provide the opportunity to further enhance Australia's ability to compete for foreign investments in the knowledge and innovation-intensive biomedical sector that can drive future economic growth and stimulate high paying jobs in the STEM sector.

Patent Notification

Medicines Australia acknowledges the inclusion of provisions relating to patent notification in the TPP-11 and seeks clarity how this will translate to Australia's current provisions.

It should be noted that Taiwan has recently moved to introduce a patent linkage system and China's Food and Drug Administration is also currently considering strengthening their patent notification system.

A strong IP system must be enforceable. Lack of legal certainty can lead to avoidable damaging pharmaceutical patent disputes and delay the market entry of generic medicines. Medicines Australia maintains the provisions in the Therapeutic Goods Act are not effective in facilitating patent notification of impending generic entry to patent right holder. This has led to uncertainty that could be easily avoided with more clarity around responsibility and timelines for notification to the patent owner of impending generic entry.

³ Hansard: Hearing of JSCOT, Monday, 7 November 2016