

Foreign Affairs, Defence and Trade Committee  
Department of the Senate  
PO Box 6100  
Parliament House  
CANBERRA ACT 2600

28 October 2016

Via email: [fadt.sen@aph.gov.au](mailto:fadt.sen@aph.gov.au)

Dear Sir/Madam,

## **Senate Standing Committee on Foreign Affairs, Defence and Trade References Inquiry into the Trans-Pacific Partnership (TPP)**

Medicines Australia welcomes the opportunity to make a submission to the Senate Standing Committee on Foreign Affairs, Defence and Trade References Inquiry into the Trans-Pacific Partnership (TPP) Agreement. We wish to comment on the impact of the TPP on Australia's economy and trade, investment and other related matters, in particular the interpretation and implementation of the data protection articles of the Agreement into Australian domestic law.

Trade agreements, such as the TPP, are important to Australia's growth and prosperity. The reduction of trade barriers facilitates harmonisation and integration between nations, especially for international regulatory and Intellectual Property (IP) systems. Ensuring that Australia's systems align with comparable jurisdictions will help to foster greater investment, leading to more opportunities for employment growth, especially as we transition from a resources dependent economy. Trade agreements are important for growing Australia's pharmaceutical industry, as well as for expanding access to medicines and vaccines across our region.

Medicines Australia is the peak industry body representing the research-based innovative pharmaceutical industry in Australia. Our members research and develop, manufacture and supply medicines and vaccines to the Australian community. Medicines Australia members represent over 80 per cent of the Australian prescription medicines market by value. Their medicines, discovered through global as well as local research and development, contribute to the prevention of disease in Australia and help keep Australians healthy and productive.

Medicines Australia emphasises the need to maintain a strong, stable and predictable IP environment, harmonised with international best practice, to encourage pharmaceutical innovation. IP is the fundamental source of protection for innovation; indeed, strong IP systems have been shown to drive innovation and investment by providing a framework for innovators to share their discoveries and creations in exchange for a period of exclusivity. IP systems recognise the balance between risk

and reward, particularly in highly novel areas. It is especially critical that local innovation is not disadvantaged in any way.

One of the key IP policy mechanisms in the pharmaceutical industry is that of regulatory data protection. Data protection is a form of intellectual property which is very limited in its application in Australia and is separate to patent protection. It is nonetheless increasingly important as biological medicines become more complex and uncertain in their patentability.

Medicines Australia has for some time explained that Australia's current five-year data exclusivity provision lags behind our global competitors and collaborators such as the United States (up to twelve years for biologics), Canada (eight years), the EU (up to eleven years), and Japan (eight years).

Australia formally signed the TPP on 4 February 2016, agreeing to implement the articles. However, it is still uncertain how the articles will be interpreted and incorporated in Australia's policy framework. Of particular interest to Medicines Australia are the articles on data protection for new pharmaceutical products – 18.50.1 and 18.51.1. We note comments made by the Australian Government that the TPP will not affect the current period of data exclusivity of five years. Lack of clarity or failure to meet the terms of the TPP will result in further uncertainty in the IP environment, and could have an impact on investment decisions and access timelines for Australian patients.

Accordingly, Medicines Australia submits that as part of the domestic implementation process, the Australian Government needs to provide insight and clarity as to whether and how articles 18.51.1 will be domestically implemented. This clarity will encourage greater consistency and transparency in both the domestic and international business environment within which innovative pharmaceutical companies make their investment decisions. We also take this opportunity to emphasise that it is misleading to suggest that data protection will add costs to patients when accessing prescription medications through the pharmacist.

We would welcome the opportunity to discuss and collaborate with the Australian Government further on this issue. Please feel free to contact me on (02) 6122 8501 or Elizabeth de Somer, Director of Policy and Research on (02) 6122 8525.

Kind regards



Milton Catelin  
**Chief Executive**