



GMiA Fact Sheet

Trans Pacific Partnership Agreement

What is the Trans Pacific Partnership (TPP)?

The TPP is a set of pluri-lateral trade negotiations between Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, the United States and Vietnam.

The Australian Government is pursuing a TPP outcome that substantially reduces barriers to trade and investment. The TPP is described as more than a traditional trade agreement; it is intended to also address behind-the-border impediments to trade and investment.

Background

The Generic Medicines Industry Association (GMiA) is the national association representing companies that manufacture, supply and export generic medicines in Australia.

The generic medicine trade associations of the countries participating in TPP negotiations represent a large majority of manufacturers providing access to affordable medicine for millions of people. These member companies are essential to the sustainability of domestic and global public health systems.

GMiA supports balanced intellectual property (IP) and comprehensively respects the IP rights associated with truly innovative medicines.

GMiA believes that while the TPP could potentially enhance trade between member countries, it is critical that measures to enforce IP rights for medicines do not themselves become barriers to legitimate trade. There must be a balance between protecting IP rights and encouraging competition to ensure access to affordable medicine.

Concerns of GMiA

GMiA is concerned that adoption of US patent and pharmaceutical laws in the smaller economies of the negotiating countries will impede the ability of these nations to deliver affordable healthcare to their populations.

GMiA has seen the “leaked” US Charter for the TPP negotiations, and is very concerned about what appears to be an attempt to “roll out” US patent and

pharmaceutical laws internationally through the TPP. The US Charter sets out (at least) the following:

- **Data exclusivity** – 5 years for products containing new chemical entities, and 3 years for subsequent products supported by new clinical information; we also understand the US is aiming to have all countries introduce a 12 year data exclusivity period for biological medicines.
- **Patent term adjustments** – these are designed to compensate patent holders for unduly lengthy review times of granting a patent by patent offices. This is typically not relevant to pharmaceuticals where lengthy development timeframes of pharmaceuticals usually result in patents being granted well before the product enters the market.
- **Prohibition on pre-grant opposition** – many countries, including Australia, provide for pre-grant opposition, which provides a cost-effective mechanism to prevent the grant of weak patents.
- **Patent linkage** – In Australia patent linkage does not result in regulatory delays. The recent introduction in Singapore of a US-type system has had a significant detrimental impact on the timely regulatory approval of generic medicines.

GMiA urges Government to protect Australian jobs & health by resisting US proposals in TPP:

The GMiA seeks to protect the high-value-add generic medicines sector in Australia, which currently delivers timely access to affordable medicines to the Australian public, substantial savings to the Pharmaceutical Benefits Scheme (PBS), thousands of highly skilled jobs and domestic manufacturing and exports of over \$500 million.

The industry cannot afford changes to the current domestic policy in the wake of US attempts to further protect pharmaceutical patents without good cause. We urge the Government:

- **NOT TO AGREE** to any IP provisions in TPP, which require changes to Australian domestic law.
- **NOT TO AGREE** to any IP provisions in TPP, which will require extended data exclusivity regimes, patent term adjustments, prohibition on pre-grant oppositions and patent linkage **at all**.



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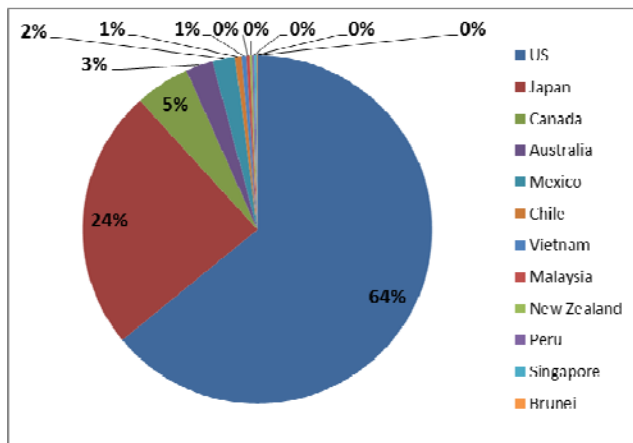
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Consequences of introducing the US patent system in Australia

- Extension of IP regimes will delay market entry of generic medicines, delaying the introduction of affordable medicines, and increasing the cost of the PBS. Remember: every time a generic medicine is dispensed, substantial savings are realised to the economy.
- Australian generic medicine manufacturers will suffer if generic medicine penetration in TPP member countries is delayed by prolonged patent monopolies, protracted data exclusivity regimes, patent term adjustments, removal of pre-grant opposition and onerous patent linkage regimes as proposed by the US.
- Market considerations in the US are different to market considerations in other negotiating countries. It is incorrect to assume that what enables and supports optimal IP protection in the US will be good for other TPP regions.
- TPP members require policy space to ensure that IP protection and timely access to medicines can be appropriately balanced domestically.

In summary, the US patent system is fit for purpose for a large economy. When the market size is large the pay-off from a single medicine is significant. The US patent system is NOT appropriate for small economies, including Australia.

Market size of negotiating countries



US New Trade Policy of 10 May 2007

The US New Trade Policy of 10 May 2007 provides a good model for international trade agreements such as TPP. GMiA supports the approach to generic medicines outlined in the US New Trade Policy

Impact on Consumers

Australians deserve access to affordable, high quality medicines regardless of their socioeconomic background or whether they live in metropolitan or rural areas.

A national survey of more than 1,000 respondents reveals that Australians are very positive about generic medicines with 89% of Australians rating generic prescription medicines as 'a product I know and trust'. Most people will trust their doctor (84%) and their pharmacist (86%) to help direct them regarding which medicine to purchase.

Implementation of the US TPP proposals will severely compromise the viability of the Australian generic medicines industry and its ability to provide these medicines to the public.

Who we are

GMiA is the national association representing companies that manufacture, supply and export generic medicines. The generic medicines sector is a high value-add sector delivering significant health and economic benefits to the Australian public.

The availability of generic medicines in this country helps to deliver:

- Timely access to affordable medicines;
- Substantial savings to the PBS;
- Thousands of highly skilled jobs; and
- Domestic manufacturing and exports of over \$300 million.

Generic medicines deliver exactly the same health benefit to all Australians as the original brand and they must meet the same strict Australian standards, including the same manufacturing requirements, as branded medicines.