OUTCOMES: BIOLOGICS

For the first time in a trade agreement, the TPP contains intellectual property rights and other specific protections for biologics, a rapidly-evolving class of medicines that treat difficult to cure diseases and illnesses, such as cancer. Importantly, this does not change Australia's existing 5 years of data protection for biologics or any other part of our health system, and will not increase the cost of medicines.

Australia is recognised internationally as a leading hub for investment in research and development (R&D). The pharmaceutical sector alone includes approximately 400 firms, including 50 global companies. The combined pharmaceuticals and medical technologies sector employs in excess of 27,000 highly-skilled workers, generates nearly $5 billion in exports each year and invests around $1 billion under the R&D Tax Incentive programme. The TPP will provide incentives for innovation, spurring new scientific and technological discoveries, and creating a more attractive trade and investment environment for the pharmaceutical sector.

What is a biologic?

A biologic is a type of highly complex medicine created by biotechnology processes. Examples include many cancer medicines, and medicines that treat chronic conditions such as rheumatoid arthritis. Biologics differ from traditional small molecule medicine (which are derived from chemical synthesis) and are more expensive to develop. The 'generic' or 'follow-on' version of a biologic is called a 'biosimilar.'

How does Australia protect biologics?

In Australia, new and inventive biologics are protected, like other medicines, via the patent system which provides 20 years of protection, with an extension of up to 5 years for delays in the approval process.

Before a medicine can be supplied in Australia it must be approved by the Therapeutic Goods Administration (TGA). As part of the approval process, the applicant seeking approval for an innovator medicine must submit the information it has generated to demonstrate the product's safety and efficacy, such as clinical trial data. Australian law provides 5 years of data protection for the innovator's information from the date of regulatory approval of the medicine by the TGA. During this period, the information cannot be used by the TGA to approve a generic version of that medicine, or a biosimilar version (when the medicine is a biologic). When the data protection expires, the TGA can approve a generic or biosimilar medicine relying on the innovator's information, so a generic or biosimilar can enter the market as soon as any relevant patent expires. This remains unchanged as a result of the TPP.

There are over 100 biologics approved in Australia that would be covered by the TPP provision. There are currently over 70 biologics listed on the PBS and 5 biosimilars.

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More information on the Trans-Pacific Partnership Agreement is available at http://dfat.gov.au/trade/agreements/tpp/

What is the TPP outcome on biologics?

The TPP recognises the importance of effective protection in the market for biologics, and that this can be achieved by different means.

The TPP has a two-track outcome on biologics protection. Parties can choose to provide effective market protection through at least 8 years of data protection. Alternatively, Parties can choose to provide effective market protection through at least 5 years of data protection, along with other measures, including existing measures in the case of Australia, and recognising market circumstances. These measures and circumstances include regulatory settings, patents, and the time it takes for follow-on medicines to become established in the market. Australia will follow the 5 year option, which reflects our current system and requires no changes. This acknowledges that different tracks can deliver comparable outcomes.

The TPP allows transition periods for countries that need to change their laws in order to comply with the TPP's provisions on biologics. As Australia does not need to do so, Australia is not among those countries listed as being in this category.

Recognising that countries have limited experience with biosimilars, which are only just coming to market, TPP Parties have also agreed to consult after ten years, or otherwise decide to review the TPP provisions on biologics, with a view to providing effective incentives for the development of biologics, as well as to facilitate timely access to medicines, including biosimilars. The consultation and review provisions do not pre-judge any outcome, but provide a useful opportunity to assess the situation at the time, which will support evidence-based policy making in an area subject to rapid scientific change.

What does this mean for Australia?

In the TPP, Australia has negotiated protections that are consistent with existing Australian law and practice. Australia is not required to change any part of its current law, including data protection for biologics, or our patent regime. There will be no adverse impact on the Pharmaceutical Benefits Scheme and no price increases for medicines.