Australia - United States Free Trade Agreement

Fact Sheet 10

HEALTH

Pharmaceutical Benefits Scheme [PBS]

- Australia will make improvements to the transparency and timeliness of PBS processes and provide more opportunities for companies seeking listing of new medicines on the PBS to have input to the process.
    - Australians will gain a better understanding of decisions about adding new medicines to the PBS and will benefit from faster access to subsidies for new prescription medicines.
- Access by Australians to affordable medicines under the PBS will be maintained under the AUSFTA.
    - The Government has delivered on its commitment that the price of prescription medicines will not increase as a result of this Agreement.

Pharmaceutical Intellectual Property

- The Agreement reinforces Australia's existing framework for intellectual property protection of pharmaceuticals.
- Agreed measures include:
    - preserving existing arrangements under which generic medicines manufacturers can obtain marketing approval overseas once a patent extension has been granted for the patented product; and
    - retaining the current five years of protection for test data submitted with an application for marketing approval.
- The Therapeutic Goods Administration (TGA) marketing approval process will ensure that a generic manufacturer is not able to enter the market with a generic version of a medicine before a patent covering that product has expired.
    - in those limited cases where a generic manufacturer considers a patent to be invalid, and intends to enter the market before that patent expires, the patent owner will be notified when the generic manufacturer applies to the TGA for marketing approval of the generic version of the patented product.

Plasma Fractionation Arrangements

- Australia will review Australian blood plasma fractionation arrangements by 1 January 2007.

  - The review will be undertaken by Commonwealth, State and Territory governments and will include examining whether, in the future, suppliers of fractionation services should be selected through competitive tender processes.

- All decisions will continue to be based on delivering the safest and most clinically effective treatments for Australians.

- Australia's policy on self sufficiency in blood products will not be affected and blood plasma products for use in Australia will continue to be derived from plasma collected from Australian blood donors.

Who to contact

For further information, please contact DFAT's AUSFTA Taskforce:
Hotline: **1300 558 413** (local call rates) between 9am and 5pm (AEST) – Mon- Fri
For media enquiries please call DFAT Media Liaison Section (02) 6261 1555.
Email: us_fta@dfat.gov.au
Fax: 02 6261 3514
Visit our website: http://www.dfat.gov.au/trade/negotiations/us.html
For advice on exporting, call Austrade on 13 28 78 or visit at www.austrade.gov.au