

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Additional Estimates 2014 - 2015, 25 February 2015

Ref No: SQ15-000061

OUTCOME: 7 - Health Infrastructure, Regulation, Safety and Quality

Topic: Trans-Pacific Partnership and Impact of Negotiations on Health

Type of Question: Written Question on Notice

Senator: Di Natale, Richard

Question:

Trans Pacific Partnership Agreement and the PBS:

The latest draft of the intellectual property (IP) chapter of the TPP indicated that proposals still being considered in the negotiations included possible extensions to the length of the data protection period (i.e. the period during which generic companies cannot use clinical trial data used by the originator to register their product with the TGA) for certain drugs. Currently in Australia, data is protected for 5 years for new products. TPP proposals include:

- i) Providing an additional 3 years for data produced to support new uses for existing products; and
- ii) A longer period (possibly 8-12 years) for biologic drugs.

Has the Department of Health provided estimates of the projected cost to the Pharmaceutical Benefits Scheme of these proposals and what is the projected short and long term cost of these? Is the Government considering accepting these proposals?

Answer:

The Department of Foreign Affairs and Trade (DFAT) has policy responsibility for free trade negotiations. The Department of Health works closely with DFAT on health policy issues related to trade negotiations.