

**Senate Community Affairs Committee**

**ANSWERS TO ESTIMATES QUESTIONS ON NOTICE**

**HEALTH PORTFOLIO**

**Additional Estimates 2015 - 2016, 10 February 2016**

**Ref No:** SQ16-000343

**OUTCOME:** 9 - Biosecurity and Emergency Response

**Topic:** Vaccines

**Type of Question:** Written Question on Notice

**Senator:** Abetz, Eric

**Question:**

If a vaccine is approved by other international jurisdictions what are the procedures for having that vaccine approved and accepted by the Australian Government?

**Answer:**

In the context of vaccines procured for the National Medical Stockpile, products can be imported under a *Therapeutic Goods Act 1989* Exemption.

Vaccines to be supplied in Australia are generally required to be evaluated and assessed by the Therapeutic Goods Administration (TGA) to ensure they comply with appropriate standards of quality, safety and effectiveness before they can be supplied.

An applicant is able to submit as part of their data package to support the quality, safety and effectiveness of a vaccine, evaluation reports compiled by other stringent regulatory authorities. These may be used by the TGA to help inform its assessment of the product.