**Senate Community Affairs Committee**

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

**Supplementary Budget Estimates 2016 - 2017, 19 October 2016**

**Ref No:** SQ16-000655

**OUTCOME:** 5 - Regulation, Safety and Protection

**Topic:** TGA

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

**Senator:** Di Natale, Richard

**Question:**

Can you please update the committee on the progress of the TGA's review of its naming policy for biologics and biosimilars?
a) When do you expect to finalise the TGA's review of its naming policy and make its findings public?
b) What stakeholders are the TGA consulting as part of the review process?
c) What other areas of the Health Portfolio is the TGA consulting as part of this process?
d) A number of other regulatory bodies in Europe and the US are also reviewing their naming policies in light of the WHO's proposal. Are you engaging with your international counterparts as part of your review process?

**Answer:**

a) The Therapeutic Goods Administration's (TGA) review of our naming policy is dependent upon the World Health Organisation's (WHO) review and associated findings, and developments in nomenclature by the US Food and Drug Administration (FDA). As they have not yet announced their final nomenclature policy, there is no proposed date for finalisation at this stage.

b) Once the WHO and the US FDA have published their policies, the TGA will review and consult appropriately with stakeholders. Currently external stakeholders are involved via the TGA's Industry Working Group.

c) Once the WHO and the US FDA have published their policies, the TGA will review and consult appropriately with stakeholders. Currently internal stakeholders, Pharmaceutical Benefits Division and the Australian Digital Health Agency, are kept informed.

d) The TGA aims to be internationally aligned with other regulatory bodies with respect to therapeutic goods regulation. The TGA is represented on the International Nonproprietary Names Committee and has had input on the development of policy on the naming of all biological medicines which includes biosimilars. Representatives from regulators from the US, Europe, UK, Japan, Canada, China and Brazil also have input into this policy. In this forum, there is significant interchange of ideas and policy decisions.