Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Additional Estimates 2016 - 2017, 1 March 2017

Ref No: SQ17-000388

OUTCOME: 5 - Regulation, Safety and Protection

Topic: Biosimilars

Type of Question: Written Question on Notice

Senator: Di Natale, Richard

Question:

In response to a question I placed on notice from October's Supplementary Budget Estimates, the TGA stated that: "The 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." Last month, the US Food and Drug Administration released its final nomenclature policy on the naming of biological products, which stipulates that biological products, including biosimilars, bear a non-proprietary name that includes an FDA-designated suffix1.
a) With this announcement, and following on from the release of the draft WHO naming policy in January 2015, when does the TGA expect to finalise, and release, its review of its naming policy?
b) Is the TGA able to outline in detail the consultation process it will undertake to finalise its policy?
c) The FDA clearly states that its naming convention will facilitate pharmacovigilance for originator biological products, related biological products, and biosimilar products, and facilitate accurate identification of these biological products by health care practitioners and patients.
d) Does the TGA believe that adopting the proposed a naming convention in line with the WHO and FDA's naming conventions will provide clarity, and avoid confusion, for Australian prescribers and patients by clearly distinguishing biological medicines and biosimilars?

Answer:

a) The Therapeutic Goods Administration (TGA) is currently drafting a public consultation paper addressing the naming issues associated with biosimilars. It is expected to be released in April 2017.

b) The consultation paper will be posted to the TGA website for a period of six weeks. In addition, relevant stakeholders such as professional societies, consumer groups and industry associations will be contacted to alert them to the consultation paper and to seek submissions.

c) and d)
TGA's view will be informed by the consultation process.