

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Additional Estimates 2013 - 2014, 26 February 2014

Ref No: SQ14-000162

OUTCOME: 1 – Population Health

Topic: Generic Medical Devices

Type of Question: Written Question on Notice

Senator: Nick Xenophon

Question:

Given generic medical devices are not able to guarantee identical manufacturing processes, such as using the same machinery, processes and materials, manufacturers will be unable to exactly replicate existing devices, which may result in slight differences leading to potential faults further down the track.

- a) Has the TGA developed any policies and outcomes in relation to the possibility of the manufacture of generic devices?
- b) How would the TGA ensure that generic devices met the same manufacturing standards as a 'brand name' device?
- c) What protocols does the TGA have in place to address future applications for generic medical devices?

Answer:

a) to c)

Every application to include a medical device on the Australian Register of Therapeutic Goods, whether or not it might be described as 'generic', is assessed on its own merits to ensure that the particular device is of acceptable quality, safety and performance.

Therefore there is no need for the Therapeutic Goods Administration to develop policies regarding so called 'generic' medical devices.