

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2011-2012, 19 October 2011

Question: E11-298

OUTCOME 1: Population Health

Topic: THERAPEUTIC GOODS ADMINISTRATION (TGA) ACT

Written Question of Notice

Senator Fierravanti-Wells asked:

Is the TGA aware that the exemption located in Schedule 8, Part 3.3 of the Act is being used by State Public Hospitals for the purposes of commercial scale diagnostic pharmaceutical manufacturing? For example, diagnostic injectables manufactured in Nuclear Medicine Department for the use in Positron Emission Tomography (PET) are exempt under the Act.

Answer:

The TGA is aware that some state public hospitals may be providing certain radioactive diagnostic injectables to other public hospitals within the same state or territory. This is envisaged under the exemption set out in Schedule 8 of the Therapeutic Goods Regulations 1990, which exempts, among other persons, radiochemists from the licensing requirements set out in Part 3-3 of the *Therapeutic Goods Act 1989* when 'the manufacture of therapeutic goods, other than biologicals, by the person when employed by a public hospital or a public institution and produced by that person for supply in hospitals or public institutions in the same State or Territory'.