Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2011-2012, 19 October 2011

Question: E11-297

OUTCOME 1: Population Health

Topic: TGA REGULATION

Written Question of Notice

Senator Fierravanti-Wells asked:

What is the purpose of exempting certain individuals from TGA regulation under Schedule 8, part 3.3 of the TGA Act?

Answer:

The exemptions set out in Schedule 8 of the Therapeutic Goods Regulations 1990 recognise either:

- the low risk of the exempted activity (labelling)
- the low risk of the product in question
- the professional qualifications of the person exempted and their ability to manage public health risk
- the use of the products within a system with other regulatory controls (within a public hospital system, for example) or
- a combination of these factors.

Due to these factors, it is considered unnecessary to impose additional regulatory burden on these actions, as the public health risk is adequately controlled. For example, it is deemed inappropriate to apply a requirement on a doctor or pharmacist to hold a manufacturing licence and all that entails (audits by the TGA etc) to allow them to dispense medications into a new container and label that container, though this meets the broad definition of manufacturing under the Act.