Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2011-12, 15 February 2012

Question: E12-303

OUTCOME 1: Population Health

Topic: THERAPEUTIC GOODS ADMINISTRATION

Written Question on Notice

Senator Fierravanti-Wells asked:

Further to evidence at the Estimates hearing about the production of diagnostic pharmaceuticals, please outline the framework for TGA compliance within the state and territory legislative parameters.

Answer:

The Commonwealth does not have express power under the Constitution to make laws about therapeutic goods. The Commonwealth has power to make laws about, among other things, trading corporations, trade or commerce between Australia and a place outside Australia, among the states, between a state and a territory and between two territories. The Commonwealth also has power to make laws about pharmaceutical or repatriation benefits, and about the Commonwealth or an authority of the Commonwealth.

As the regulatory framework set out in the *Therapeutic Goods Act 1989* (the Act) and related regulations relies on these powers, it will, in general, only apply to:

- Commonwealth, state and territory entities if they engage for instance in the manufacture, supply, import or export or advertising of therapeutic goods (though if part of the "Crown", the criminal and civil penalty provisions do not apply);
- trading corporations operating within Australia if engaged in activities caught by the legislation (for example, the manufacture, importation, exportation, supply or advertising of therapeutic goods); and
- individuals but only if the regulated activity is otherwise covered by the legislation, for instance occurring in the course of interstate trade, involves the importing or exporting or therapeutic goods, or the supply of therapeutic goods attracting either pharmaceutical or repatriation benefits (thus excluding in the main, an individual manufacturing, supplying or advertising therapeutic goods solely within a state or territory).

In order to extend the Commonwealth's regulatory scheme to cover individuals who would otherwise not be covered, New South Wales, Victoria, South Australia, Tasmania and the Australian Capital Territory have adopted the Commonwealth's regulatory scheme as set out in the Act and related regulations. This includes individuals operating within the relevant state or territory, who manufacture, supply or advertise therapeutic goods solely within the state or territory.

Item 3 in Schedule 8 of the Therapeutic Goods Regulations 1990 (the Regulations) exempts radiochemists and pharmacists and biomedical engineers manufacturing therapeutic goods (other than biologicals) in a public hospital from being required to hold a manufacturing licence under the Act. However, the exemption only applies if the relevant person is employed by a public hospital or a public institution and manufactures for supply in hospitals or public institutions in the same state or territory. The exemption would also apply to individuals operating solely within the jurisdictions that have adopted the Commonwealth regulatory scheme.

For those jurisdictions that have not adopted the Commonwealth's regulatory scheme (that is, Queensland, Western Australian and the Northern Territory) the exemption would have no operation where the therapeutic goods are manufactured by individuals operating solely within the state or territory as they would be outside the coverage of the Commonwealth Act and related regulations in any event.

The exemption does not affect certain other regulatory requirements attaching to the manufactured products including that the goods meet any applicable standards. Thus, although therapeutic goods can, in the circumstances described in column 3 of item 3 in Schedule 8 of the Regulations be manufactured by radiochemists, pharmacists and biomedical engineers in a public hospital without a manufacturing licence, the goods must still comply with any applicable standard set out in a monograph in the British pharmacopoeia, the United States Pharmacopoeia or the European Pharmacopoeia. Matters that may be addressed in those monographs include purity, potency and sterility. These same requirements would apply to individuals who are not covered by the Act but are regulated by the laws in New South Wales, Victoria, South Australia, Tasmania and the Australian Capital Territory through the adoption of the Commonwealth's regulatory scheme.