

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2011-12, 15 February 2012

Question: E12-235

OUTCOME: 1: Population Health

Topic: DELEGATIONS

Written Question on Notice

Senator Xenophon asked:

Can the Secretary of the Department of Health and Ageing appoint a person other than an officer of the Therapeutic Goods Administration as a delegate for the purpose of exercising her powers under the *Therapeutic Goods Act 1989*?

Answer:

The *Therapeutic Goods Act 1989* (the Act) gives the Secretary of the Department of Health and Ageing numerous powers relating to the regulation of therapeutic goods. The Secretary is able to delegate these powers under section 57 of the Act. Only some of those powers can be delegated by the Secretary to persons other than officers occupying particular positions in the Therapeutic Goods Administration (TGA) which is part of the Department.

The persons to whom the Secretary can delegate her powers under section 57 of the Act include:

- an officer of the Department;
 - an officer of an authority of the Commonwealth that has functions in relation to therapeutic goods;
 - an APS employee in an Agency (within the meaning of the *Public Service Act 1999*) that has functions in relation to therapeutic goods;
 - a person occupying or acting in an office, or holding an appointment, that has been declared by the Therapeutic Goods Regulations 1990 (the Regulations)
 - the appointments currently declared by the Regulations for these purposes are (a) the appointment of National Manager of the TGA, and (b) the secondment of a person employed by a national therapeutic goods regulatory authority of another country to a position in the TGA (see regulation 46A of the Regulations); and
 - a person seconded to the Department from certain authorities of a state or territory, national regulatory authorities of foreign countries and international organisations, that have functions or national responsibilities relating to therapeutic goods, health or law enforcement.
- (see paragraphs 57(1)(a) to (d) of the Act).

Some of the Secretary's powers can only be delegated to persons holding or occupying particular positions. For instance:

- specified powers can only be delegated to a person who is an officer of the Department or who occupies or holds one of the declared offices or appointments under the Regulations and who is registered, or eligible for registration, in a state or internal territory, as a medical or dental practitioner or as a pharmacist (see subsection 57(2) of the Act);
- specified powers can only be delegated to a person who is an officer of the Department or who occupies or holds one of the declared offices or appointments under the Regulations and who is registered, or eligible for registration, in a state or internal territory, as a medical or dental practitioner (see subsection 57(6) of the Act);
- specified powers can only be delegated to a person who is registered in a state or internal territory, as a medical or dental practitioner, in such circumstances as are prescribed by the Regulations (see subsection 57(3) and regulation 47A of the Regulations); and
- specified powers can only be delegated to either or both of a) the National Manager of the TGA, and b) a person who holds, occupies or performs the duties of a position in the TGA prescribed by the Regulations (see subsection 57(8) and (9) of the Act)
- the positions prescribed for the purposes of subsection 57(8) are the Chief Regulatory Officer and Principal Medical Adviser in the TGA (see subregulation 46A(2) of the Regulations). No positions have been prescribed for the purposes of subsection 57(9) of the Act.

The power to make a decision to approve the registration of a prescription medicine under section 25 of the Act has only been delegated by the Secretary to officers occupying particular positions in the TGA. See the response to Question on Notice E12-236.