

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2011-12, 15 February 2012

Question: E12-236

OUTCOME: 1: Population Health

Topic: DELEGATIONS

Written Question on Notice

Senator Xenophon asked:

Once a decision has been made by the Therapeutic Goods Administration to approve a prescription medicine, what power is there to review and reconsider that decision?

Answer:

A decision made by the Secretary of the Department of Health and Ageing or her delegate under section 25 of the *Therapeutic Goods Act 1989* (the Act) is an "initial decision" within the meaning of section 60 of the Act. A person "whose interests are affected by an initial decision" can request the Minister to reconsider any initial decision. After reviewing the initial decision the Minister can confirm or revoke the initial decision, or revoke the initial decision and make a decision in substitution for the initial decision.

A decision under section 25 of the Act to approve the registration of a prescription medicine is made by the Secretary. The Secretary has delegated this power to officers of the Therapeutic Goods Administration (TGA) occupying particular positions. Only officers with the qualifications, skills and experience that are necessary to exercise that power occupy those positions and exercise that power. Moreover, when an application for the registration of a prescription medicine of a particular kind is received by the TGA, the decision whether to approve that application will be made by an officer with a delegation under section 25 of the Act with the qualifications, skills and experience to make a decision on prescription medicines of that kind.

The Minister for Health, the Hon Tanya Plibersek MP, has delegated the power under section 60 of the Act to undertake a review of initial decisions to officers occupying positions in the Department of Health and Ageing that are located in the TGA. That power has also been delegated to the person occupying the position of Chief Medical Officer in the Department. Only ministerial delegates who did not have an involvement in the relevant application or the initial decision undertake an internal review on that initial decision. The delegate will normally be located in another part of the TGA from the delegate who made the initial decision and will often occupy a more senior position than that occupied by the officer who made the initial decision.

A person dissatisfied with a decision of the Minister's delegate on an internal review under section 60 of the Act can apply to the Administrative Appeals Tribunal (AAT) for a review of the delegate's decision. The AAT is independent of the TGA and the Department. The AAT

can affirm or vary the decision of the Minister's delegate, or can set aside the delegate's decision and make a decision in substitution or remit the matter for reconsideration in accordance with its directions or recommendations.