

EXPLANATORY STATEMENT  
STATUTORY RULES 1987 No 261  
ISSUED BY AUTHORITY OF  
THE MINISTER FOR COMMUNITY SERVICES AND HEALTH  
THERAPEUTIC GOODS ACT 1966  
THERAPEUTIC GOODS REGULATIONS (AMENDMENT)

Subparagraph 30(a)(i) of the Therapeutic Goods Act 1966 ("the Act") provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing all matters which by the Act are required or permitted to be prescribed, or which are necessary or convenient to be prescribed, for carrying out or giving effect to the Act, and in particular for making provision for or in relation to the establishment of committees to advise the Minister for Community Services and Health on matters relating to the importation in Australia of therapeutic substances and on such other matters as are prescribed, and the functions and powers of those committees.

In order to assist the Minister in the administration of the Act, a new committee has been established, to be known as the Therapeutic Device Evaluation Committee ("TDEC"). The main purpose of TDEC is to deal with therapeutic devices, being goods which do not achieve their purpose as a result of chemical action, with the benefit of scientific and medical expertise. The specific functions of TDEC are -



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- . to make medical and scientific evaluations of such therapeutic devices as the Minister refers to it for evaluation;
- . to make medical and scientific evaluations of other therapeutic devices if, in the opinion of the Committee, it is desirable that it should do so;
- . to make medical and scientific evaluations of such goods for therapeutic use (not being therapeutic devices) as the Minister refers to it for evaluation;
- . to make medical and scientific evaluations of other goods for therapeutic use (not being therapeutic devices) if, in the opinion of the Committee, it is desirable that it should do so and the Committee has informed the Minister of its opinion;
- . to furnish such advice to the Minister as the Committee considers necessary relating to the importation into, the production within, and the distribution within, Australia of therapeutic devices that have been the subject of evaluations made by the Committee;
- . to furnish such advice to the Minister as the Committee considers necessary relating to the importation into, the production within, and the distribution within,

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Australia of goods for therapeutic use (not being therapeutic devices) that have been the subject of evaluations made by the Committee; and

- . to furnish advice that has been furnished to the Minister pursuant to paragraph (f) to such persons or bodies as the Minister may direct.

TDEC will consist of not less than 6 and not more than 8 persons appointed by the Minister from persons expert in one or more of the fields of anaesthetics, bioengineering, biomaterials, dentistry, epidemiology, intensive care, medicine, microbiology, ophthalmology, pharmaceuticals and surgery.

The prescription of functions empowering TDEC to deal with goods for therapeutic use (not being therapeutic devices) will permit TDEC to participate in the evaluation of goods for therapeutic use which have non-chemical features but which are not, on a legal definition, therapeutic devices. This recognises the increasing complexity of many goods for therapeutic use and permits the more efficient evaluation of such goods.

The Regulations also prescribe new functions for the Australian Drug Evaluation Committee, which is established by regulation 19 of the Therapeutic Goods Regulations. These new functions

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empower that Committee to deal with therapeutic devices. This again permits the more efficient evaluation of goods for therapeutic use which have both chemical and non-chemical features.

The Regulations make minor consequential amendments following from the establishment of TDEC. The Regulations also repeal regulation 25 of the Therapeutic Goods Regulations, which prescribes remuneration for members of committees.

Remuneration is now paid in accordance with determinations of the Remuneration Tribunal, and regulation 25 is no longer necessary.