

EXPLANATORY STATEMENT

STATUTORY RULES 1985 NO. 312

ISSUED BY THE AUTHORITY OF THE MINISTER FOR HEALTH

THERAPEUTIC GOODS ACT 1966

THERAPEUTIC GOODS REGULATIONS

Section 30 of the Therapeutic Goods Act 1966 ('the Act') provides, among other things, 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.

Sub-section 5(8) of the Act provides that a reference in the Act to goods for therapeutic use does not include a reference to goods for use in, or in connection with, testing for pregnancy, contraception, prosthetics or orthotics unless the goods are declared, or are in a class of goods that are declared, by the regulations to be goods for therapeutic use to which the Act applies. Regulation 4A of the Therapeutic Goods Regulations (the Regulations) declares goods for use in, or in connection with, testing for pregnancy and contraception for the purposes of sub-section 5(8) of the Act.

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Discussions have taken place with representatives of the medical devices industry and it is agreed that the Act should now be applied to a wide range of products known as prostheses and orthoses. Prostheses are devices which make up a deficiency in the body - for example, dentures, artificial organs or limbs. Orthoses are devices which complement, supplement or replace a physiological function of the body - for example, contact lenses, hearing aids and heart pacemakers.

The Statute Law (Miscellaneous Provisions) Act (No. 2) 1984 changed the title of "Director-General of Health" to "Secretary to the Department of Health". That Act also changed the references to Director-General in the Therapeutic Goods Act to Secretary.

The Statutory Rules amend regulation 4A of the Regulations to declare, for the purposes of sub-section 5(8), goods for use in, or in connection with prosthetics or orthoses, to be goods for therapeutic use to which the Act applies.

3.

Regulations 1 and 3 of the Statutory Rules update the references in the Regulations from Director-General to Secretary.

The Statutory Rules came into operation on the date of their notification in the Commonwealth of Australia Gazette.