

## EXPLANATORY STATEMENT

### Therapeutic Goods (Charges) Act 1989

#### Therapeutic Goods (Charges) Regulations

ISSUED ON THE AUTHORITY OF THE MINISTER OF STATE FOR AGED, FAMILY AND HEALTH SERVICES

The Therapeutic Goods (Charges) Act 1989 (the Act) commenced on 1 July 1990.

Pursuant to section 3 of the Act, the Therapeutic Goods Act 1989 (the incorporated Act) is incorporated and to be read as one with the Act. Section 4 of the Act provides that annual charges are payable of such amounts as are prescribed in respect of the registration or listing of therapeutic goods and in respect of a licence in force under the incorporated Act.

Section 5 of the Act provides that the Governor-General may make Regulations prescribing the amounts of charges. The Regulations may prescribe charges relating to functions implemented by the incorporated Act.

The Regulations prescribe annual charges for the registration or listing of goods in the Australian Register of Therapeutic Goods and the annual charges for a licence to manufacture therapeutic goods under the incorporated Act. Goods of low volume and value will be exempted from the annual registration and listing charges. The charges will, however, become payable if such exemption subsequently proves to be inappropriate.

Similar Regulations were made and presented to Parliament in May 1990. The Senate disallowed those Regulations to permit, amongst other things, further consultation with all affected parties. Amendments have been included in the Regulations to reflect the outcome of this process.

As the Regulations are similar to those disallowed in May 1990, section 49 of the Acts Interpretation Act 1901 may have applied to the Regulations. That section prevents the re-making of Regulations, which are the same in substance as Regulations which have been disallowed, for a period of six months unless certain conditions are met. The period of six months has now elapsed.

S.R. 337/90