Therapeutic Goods (Charges) Amendment Regulations 2000 (No. 3) 2000 No. 266

EXPLANATORY STATEMENT

STATUTORY RULES 2000 No. 266

Issued by authority of the Parliamentary Secretary to the Minister for Health and Aged Care

Therapeutic Goods (Charges) Act 1989

Therapeutic Goods (Charges) Amendment Regulations 2000 (No. 3)

The object of the *Therapeutic Goods Act 1989 is* to establish and maintain a system of controls for the quality, safety, efficacy and timely availability of therapeutic goods that are used in Australia or are exported from Australia. To this end, therapeutic goods that are manufactured in Australia or imported into Australia must meet acceptable manufacturing standards. In Australia, each step of manufacture of therapeutic goods must, unless the goods have been exempted from this requirement, be manufactured under licence.

Section 3 of the *Therapeutic Goods (Charges) Act 1989* (the Act) states that the Therapeutic Goods Act 1989 is incorporated, and is to be read as one, with the Act.

Subsection 4(2) of the Act provides that annual charges are payable for maintaining manufacturing licences during a financial year.

Section 5 of the Act provides that the Governor-General may make Regulations to prescribe the level of charges including those that are payable for maintaining manufacturing licences from year to year.

The purposes of these amendments is to prescribe an annual charge for maintaining licences now required to be taken out by manufacturers of blood and blood components. This requirement came into effect in July 2000. The charges are necessary to give effect to the Government's policy that the Therapeutic Goods Administration operate on a full cost-recovery basis. Industry has been extensively consulted on the new charges, which are linked to the recovery of operating costs.

The annual charge for maintaining a licence to manufacture blood and blood components will be $8,000 for the metropolitan or principal manufacturing site covered by a licence, and $1,950 for each additional fixed (non-mobile) site covered by the same licence. These new charges are set out in Item 2 of Schedule 1 of the amending Regulations. Item 1 of Schedule 1 makes a typographical correction.

The Regulations commenced on gazettal.