

Therapeutic Goods (Charges) Amendment Regulations 2001 (No. 1)

2001 No. 161

EXPLANATORY STATEMENT

STATUTORY RULES 2001 No. 161

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

Therapeutic Goods (Charges) Act 1989

Therapeutic Goods (Charges) Amendment Regulations 2001 (No. 1)

The object of the *Therapeutic Goods Act 1989* is to establish and maintain a national system of controls for the quality, safety, efficacy and timely availability of therapeutic goods that are used in Australia or exported from Australia. Under that Act therapeutic goods, unless they have been exempted from this requirement, are required to be registered or, listed in the Australian Register of Therapeutic Goods before they may be manufactured, supplied, imported or exported for use in humans. Manufacturers of therapeutic goods are also required to manufacture such goods under licence, unless they, or the class of goods being manufactured, have been exempted from the licensing requirements. The Therapeutic Goods Administration (the TGA) is responsible for administering the Act.

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

Subsection 4(1) of the Charges Act provides that annual charges as are prescribed are payable for maintaining registrations and listings of therapeutic goods in the Register. Subsection 4(1A) of the Act provides that where more than one therapeutic Good is "grouped", and each of the "grouped" therapeutic goods is covered by the same registration or listing number, then an annual charge as prescribed will apply for maintaining all the registered or listed goods covered under the same grouping. A single charge has been prescribed for this purpose.

Section 5 of the Charges Act enables the Governor-General to prescribe levels of charges that are payable for maintaining goods in the Register or for maintaining grouped therapeutic goods in the Register. The Section also enables the Governor-General to prescribe annual licensing charges for maintaining manufacturing licences for the manufacture of therapeutic goods. Licensing charges may be prescribed for different steps in the manufacture of therapeutic goods.

The principal purpose of the regulations is to increase all the charges that are payable by 6.6%, to enable the Therapeutic Goods Administration to continue to meet the government's requirement that the Administration operate on a full cost-recovery basis.

The 6.6% increase is made up of:

50% annual Wage Cost Index (WCI) 1.55%

50% CPI (annual adjusted) 1.75%

increased rent 3.30%

The increased rent is a result of the Government's policy of commercialisation of its special purpose and. industrial estates, which includes the TGA building in Symonston. This will lead to a significant increase in the annual rent that must be paid. The increase of \$3.317 million is to be

phased in over 3 years from 1 July 2001 at the rate of \$1.5 million in each of the first two years and the balance in the third year. An increase to both fees and charges of 3.3% is required to fully recover the \$1.5 million rental increase in the 2001/2002 financial year. The formula for the 6.6% increase was discussed with all key industry bodies. These are the Australian Self-Medication Industry, the Complementary Healthcare Council, the Medical Industry Association of Australia and the Australian Pharmaceutical Manufacturers Association. The four industry associations have agreed to the formula as the basis for the 6.6% increase to the charges payable under the Therapeutic Goods (Charges) Regulations.

The regulations will also increase the percentage level of the value of the wholesale turnover of therapeutic goods in relation to a particular sponsor for the purposes of determining whether the annual charge otherwise payable by a sponsor for maintaining a registration or listing of goods in the Register may be waived. Currently, if the annual charge payable by a sponsor for a registration or listing of goods is more than 6% of the value of the sponsor's wholesale turnover (or estimated turnover) of those goods, the sponsor need not pay the applicable annual charge for its registered or listed goods. The 6% benchmark has been increased to 6.5% to reflect the corresponding increase to the annual charges that will be payable for registrations and listings proposed by these regulations.

Details of the Regulations are set out in the Attachment.

The Regulations commence on 1 July 2001.

ATTACHMENT

Therapeutic Goods (Charges) Amendment Regulations 2001 (No. 1)

Regulation 1 states that the title of these regulations will be the *Therapeutic Goods (Charges) Amendment Regulations 2001 (No. 1)*

Regulation 2 provides that these regulations commence on 1 July 2001.

Regulation 3 provides that these regulations amend the *Therapeutic Goods (Charges) Regulations 1990* as provided in Schedule 1.

SCHEDULE - AMENDMENTS

Item 1 increases all the existing charges set out in the Therapeutic Goods (Charges) Regulations. These are charges for maintaining registrations and listings of therapeutic goods in the Australian Register of Therapeutic Goods, including groupings of therapeutic goods, and charges for maintaining licences for steps of manufacture of therapeutic goods.

Item 2 increases the percentage level of the value of the wholesale turnover of therapeutic goods in relation to a particular sponsor for the purposes of determining whether the annual charge otherwise payable by a sponsor for maintaining a registration or listing of goods in the Register may be waived. Currently, if the annual charge payable by a sponsor for a registration or listing of goods is more than 6% of the value of the sponsor's wholesale turnover (or estimated turnover) of those goods, the sponsor need not pay the applicable annual charge for its registered or listed goods. The 6% benchmark has been increased to 6.5%.