

1991

THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA

HOUSE OF REPRESENTATIVES

THERAPEUTIC GOODS (CHARGES) AMENDMENT BILL 1991

EXPLANATORY MEMORANDUM

(Circulated by authority of the Honourable Mr. Peter Staples MP,
Minister for Aged, Family and Health Services)



THERAPEUTIC GOODS (CHARGES) AMENDMENT BILL 1991

GENERAL OUTLINE

The purpose of this Bill is to amend the Therapeutic Goods (Charges) Act 1989 to bring it into line with changes concurrently being made to Part 3 of the Therapeutic Goods Act 1989 by the Community Services and Health Legislation Amendment Bill 1991.

Part 5 of the Community Services and Health Legislation Amendment Bill 1991 includes changes to Part 3 of the Therapeutic Goods Act 1989. One of these changes relates to the effect of the Secretary's determination to "group" certain therapeutic goods. Presently, goods so grouped may be entered in the Australian Register of Therapeutic Goods as single goods. One annual registration or listing charge applies to single products entered in the Register. Following the changes being made by the above Omnibus Bill, each group of goods grouped by the Secretary will be identified as a particular "gazetted therapeutic goods group" or "gazetted therapeutic devices group", and as such will no longer be deemed to be single products. Instead, every product within a group will be entered separately in the Register as a separate product. Amendments to the Therapeutic Goods (Charges) Act 1989 are therefore necessary to continue the present policy of applying one set of annual registration or listing charges to the same group of goods included in the Register in relation to the same person, and to reflect this intention which is carried through in the above Omnibus Bill.

Financial Impact Statement

The effect of the proposed changes will not alter existing payment arrangements for grouped therapeutic goods. However, a different prescribed charge to that applying in relation to goods that are not grouped would be possible in the future.

NOTES ON CLAUSESClause 1 - Short Title

Subclause 1(1) provides that the short title of the Act will be the Therapeutic Goods (Charges) Amendment Act 1991.

Subclause 1(2) provides that references in this Bill to the "Principal Act" will be to the Therapeutic Goods (Charges) Act 1989.

Clause 2 - Commencement

This clause provides that the Act shall commence to operate on the same day as the day Part 5 of the Community Services and Health Legislation Amendment Act 1991 commences.

Clause 3 - Charges

Paragraph (a) of this clause amends subsection 4(1) of the Principal Act to restrict the application of that subsection to goods that are not grouped therapeutic goods.

Paragraph (b) of this clause inserts new subsection 4(1A) into the Principal Act to provide that where one or more therapeutic goods, belonging to the same grouped therapeutic goods, is included in the Register under the same registration or listing number during any financial year, then the annual charge as prescribed applies, for that year, to all the goods covered by the same registration or listing number, and not to each item included within the same group.

Clause 4 - Application of Amendments

This clause provides that all the changes made by this Bill will, in the financial year in which this clause commences to operate, apply only to new registrations and listings that occur on or after the commencement date of this clause. However, in all subsequent years, the changes made by this Bill will apply to all registrations and listings that occur.

Clause 5 - Transitional

Subclause 5(1) provides that, for the purposes of this clause, the Principal Act as amended by this Bill will be referred to as the "amended Act".

Subclause 5(2) provides that, in the financial year in which this clause commences to operate or in any earlier financial year, where goods were treated as single therapeutic goods for the purposes of Part 3 of the Therapeutic Goods Act 1989, they will also be treated as such for the purposes of attracting charges under the Principal Act until the date of commencement of this clause.

Subclause 5(3) provides that, where any Regulations were made for the purposes of subsection 4(1) of the Principal Act that applied to therapeutic goods deemed to be single therapeutic goods under Part 3 of the Therapeutic Goods Act 1989, these will have effect as if they were made under new subsection 4(1A) of the amended Act and had covered the corresponding grouped therapeutic goods.

Subclause 5(4) provides that where, in the financial year in which this clause comes into operation, an annual charge becomes payable in respect of a group of goods registered or listed under the same number because they have been treated as single goods for the purposes of Part 3 of the Therapeutic Goods Act 1989, no further annual charge is to be payable in respect of the corresponding registered or listed gazetted therapeutic devices group, or gazetted therapeutic goods group, entered under the same registration or listing number under the amended Act in that same year.

