THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA

#### HOUSE OF REPRESENTATIVES

# THERAPEUTIC GOODS (CHARGES) BILL 1989

## EXPLANATORY MEMORANDUM

(<u>Circulated by authority of the Honourable Dr Neal Blewett MP</u>, <u>Minister for Community Services and Health</u>)

15473/89 Cat. No. 89 5168 3

1

# THERAPEUTIC GOODS (CHARGES) BILL 1989

# GENERAL OUTLINE

This Bill forms part of a package dealing with therapeutic goods. The background to the charges is described in the explanatory memorandum to the Therapeutic Goods Bill 1989

The Bill provides for annual charges for the registration and listing of therapeutic goods and for the licensing of manufacturers of therapeutic goods in Australia under the Therapeutic Goods Bill 1989.

## FINANCIAL IMPACT STATEMENT

Cabinet has approved a fees and charges structure that will recover from the Therapeutic Goods Industry half the costs of the therapeutics program. In 1988, the costs of the program were about \$30 million.

#### THERAPEUTIC GOODS (CHARGES) BILL 1989

#### NOTES ON CLAUSES

#### <u>Clause 1 - Short Title</u>

The short title of the Act will be the Therapeutic Goods (Charges) Act 1989.

#### Clause 2 - Commencement

à

Provides that the Act shall come into operation on 1 July 1990.

#### Clause 3 - Incorporation

Provides that the Bill is incorporated with the Therapeutic Goods Bill 1989 and is to be read in conjunction with that Bill.

#### Clause 4 - Charges

Subclause 4(1) provides for an annual charge for registered or listed goods to be prescribed in regulations. The charge applies to the whole or part of a financial year.

Subclause 4(2) provides for an annual charge for a licence to manufacture therapeutic goods in Australia. The charge applies to the whole or part of a financial year.

#### Clause 5 - Regulations

Subclause 5(1) permits the amount of the charges to be specified in regulations.

Subclause 5(2) permits different charges for different classes of goods and different steps of manufacture.

Printed by Authority by the Commonwealth Government Printer