TGA RESPONSE

The Therapeutic Goods Administration (the TGA) is a business unit within the Department of Health and Ageing (DoHA) responsible for evaluating the safety, quality and efficacy of medicines, medical devices and blood components available for supply in Australia and their export. The TGA is a full cost recovery agency and derives its operating income from regulatory fees and charges imposed on sponsors and manufacturers of therapeutic products.

Cost Recovery Background

To coincide with the implementation of the *Therapeutic Goods Act 1989* (the TG Act) in April 1991, Government decided the TGA would recover 50 per cent of its operating costs through fees and charges collected from the therapeutic goods industry.

Following the 1996 Election and as part of the Budget deficit reduction strategy the Government announced it would increase the level of cost recovery for TGA activities to 75 per cent to be phased in over the following three financial years, commencing 1996-1997 (58 per cent in 1996-1997, to 67 per cent in 1997-1998 and to 75 per cent in 1998-1999).

In framing the 1997-1998 Budget the Government decided to accelerate the rate of increase in the level of cost recovery from industry, moving to 75 per cent in 1997/98 and to full cost recovery in 1998-1999.

The decision covered all activities which fall within the scope of the Act including regulation of the industry, the TGA's public health responsibilities, responsibilities to consumers for information on products and TGA's support for the industry generally (i.e. facilitation of exports and international harmonisation of standards).

In December 2002 the Government released Guidelines for cost recovery by government agencies in response to the Productivity Commission's Report number 15 – Cost Recovery by Government Agencies. The Guidelines require significant cost recovery agencies to comply with cost recovery principles and undertake a review of existing cost recovery arrangements at least every five years. The TGA's cost recovery arrangements were found to be consistent with the Guidelines when reviewed in May 2005.

Cost Recovery – Current Arrangements

The TGA recovers the cost of all activities undertaken that are within the scope of the TG Act.

Fees and charges are prescribed in regulations made under the TG Act, and the *Therapeutic Goods (Charges) Act 1989* (the TG (Charges) Act).

Therapeutic Goods (Charges) Act 1989 - Overview

The object of the TG (Charges) Act is to allow the imposition of an annual charge on the registration, listing and inclusion of therapeutic goods in the Australian Register of Therapeutic Goods (the Register), and on the licensing of manufacturers of therapeutic goods. The TGA is responsible for administering the TG (Charges) Act.

Section 4 of the TG (Charges) Act provides that annual charges of such amounts as are prescribed are payable in respect of entries of therapeutic goods (including medical devices) in the Register, as well as in respect of licences that are in force at any time within a financial year. Subsection 4(1A) of the TG (Charges) Act provides that where one or more therapeutic goods are "grouped" and each of the "grouped" therapeutic goods is covered by a single 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.

Subsection 4(2) of the TG (Charges) Act provides that an annual charge of such amount as is prescribed is payable in respect of a licence that is in force at any time during a financial year.

Therapeutic Goods (Charges) Regulations 1990 (the TG (Charges) Regulations)
Subsection 5(1) of the TG (Charges) Act provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing the amounts of charges. Subsection 5(2) enables the Governor-General to prescribe different levels of charges for different classes of goods or, in the case of annual licensing charges, for different steps in the manufacture of therapeutic goods.

Annual Product Charges and Annual Licence Charges – Effective from 1 July 2008
The following annual product and licence charges are currently levied by the TGA in accordance with the TG (Charges) Regulations.

The current charges took effect on 1 July 2008.

PRESCRIPTION MEDICINES

Annual Charge	Therapeutic Goods (Charges) Regulations 1990	2008-09 Fee $
Biologics	Regulation 3(1)(b)(i) Regulation 3(1A)(b)(i)	5,250 5,250
Non-biologics	Regulation 3(1)(b)(ii), Regulation 3(1A)(b)(ii)	3,140 3,140

REGISTERED NON PRESCRIPTION MEDICINES

Annual Charge	Therapeutic Goods (Charges) Regulations 1990	2008-09 Fee $
Annual charge	Regulation 3(1)(a)(i) Regulation 3(1A)(a)(i)	1,010 1,010

LISTED NON PRESCRIPTION MEDICINES

Annual Charge	Therapeutic Goods (Charges) Regulations 1990	2008-09 Fee $
Annual charge	Regulation 3(1)(c)(i) Regulation 3(1A)(c)(i)	710 710

BLOOD, BLOOD COMPONENTS, AND HUMAN TISSUES

- Manufacturers Of Haematopoietic Progenitor Cells
- Manufacturers Of Human Tissues

Annual Charge	Therapeutic Goods (Charges) Regulations 1990	2008-09 Fee $
Primary site	Regulation 3(2)(j)(i)	111,400
Additional fixed site assoc with a primary site	Regulation 3(2)(j)(ii)	5,480
Manufacturing premises	Regulation 3(2)(ja)	4,800
Single step and single human tissue	Regulation 3(2)(k)	4,800
Two or more steps	Regulation 3(2)(l)	9,300

REGISTERED THERAPEUTIC DEVICES

Annual Charge	Therapeutic Goods (Charges) Regulations 1990	2008-09 Fee $
Annual charge - IVDs, tampons and disinfectants	Regulation 3(1)(a)(iii) Regulation 3(1A)(a)(iii)	1,240 1,240
Annual charge	Regulation 3(1)(a)(ii) Regulation 3(1A)(a)(ii)	2,170 2,170

LISTED THERAPEUTIC DEVICES

Annual Charge	Therapeutic Goods (Charges) Regulations 1990	2008-09 Fee $
Annual charge	Regulation 3(1)(c)(ii) Regulation 3(1A)(c)(ii)	1,090 1,090
Annual charge - IVDs, tampons and disinfectants	Regulation 3(1)(c)(iii) Regulation 3(1A)(c)(iii)	620 620

INCLUDED THERAPEUTIC DEVICES

Annual Charge	Therapeutic Goods (Charges) Regulations 1990	2008-09 Fee $
(a) Class AIMD medical device	Regulation 3(1B)(d)	990
(b) Class III medical device	Regulation 3(1B)(d)	990
(c) Class IIb medical device	Regulation 3(1B)(c)	760
(d) Class IIa medical device	Regulation 3(1B)(c)	760
(e) Class I medical device - sterile	Regulation 3(1B)(b)	500
(f) Class I medical device - measuring function	Regulation 3(1B)(b)	500
(g) Other Class I medical device	Regulation 3(1B)(a)	60

GOOD MANUFACTURING QUALITY (GMP)

Annual Charge	Therapeutic Goods (Charges) Regulations 1990	2008-09 Fee $
Single step/single medicine/single type of therapeutic device	Regulation 3(2)(c) Regulation 3(2)(d) Regulation 3(2)(e) Regulation 3(2)(f)	4,800 4,800 4,800 4,800
In-vitro diagnostic products	Regulation 3(2)(g)	4,800
Ingredients or components	Regulation 3(2)(c)	4,800
Herbal/homeopathic medicinal products	Regulation 3(2)(h)	4,800
Other types of therapeutic goods, including containers in which therapeutic goods are to be packed	Regulation 3(2)(a) Regulation 3(2)(b)	9,300 9,300

The full schedule of TGA fees and charges is available on the TGA Website.
http://www.tga.gov.au/fees/fees08.htm refers