

Therapeutic Goods Amendment Regulations 2000 (No. 6) 2000 No. 267

EXPLANATORY STATEMENT

STATUTORY RULES 2000 No. 267

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

Therapeutic Goods Act 1989

Therapeutic Goods Amendment Regulations 2000 (No. 6)

The object of the *Therapeutic Goods Act 1989* (the Act) 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 exported from Australia. The Therapeutic Goods Administration (the TGA) is responsible for administering the Act.

The Governor-General may, under section 63 of the Act, make regulations for the purposes of the Act. In particular, the Governor-General may, under subsection 63(1) and paragraphs 63(2)(h and (3)(a), prescribe fees in respect of matters under the Act and Regulations and in relation to different steps in the manufacture of therapeutic goods. The Therapeutic Goods Regulations 1990 (the Regulations) prescribe a range of fees including licensing and inspection fees payable by manufacturers when they apply for manufacturing licences or payable for the conduct of inspections of manufacturing premises or operations as required under the Act or Regulations. Persons who manufacture therapeutic goods must have each step of manufacture licensed before they may undertake this activity, unless the therapeutic goods they are manufacturing have been exempted from the requirement to be manufactured under a licence.

The TGA is required under Government policy to operate on a total cost recovery basis. The purpose of the amending regulations is to prescribe new fees that will be payable for processing applications for licences to manufacture blood and blood components and for certifying that premises used in the manufacture of blood and component products meet with acceptable good manufacturing practices. Until July 2000, the manufacture of blood and blood components, carried out principally by the Australian Red Cross Blood Service (the ARCBS), was exempted from the requirement to be licensed. At its meeting on 22 April 1999, the Australian Health Ministers Advisory Committee agreed that the TGA would be the appropriate agency to regulate fresh blood components produced by the ARCBS and that the process of regulation should begin in 1999/2000 with a view to being substantially in place by the end of that year. Accordingly, the Therapeutic Goods Regulations were recently amended to remove the exemptions applying to the manufacture of fresh blood components.

The amending Regulations also make other minor changes to clarify the intention of existing Regulations, in particular, Item 2 of Schedule 1 makes a correction at the suggestion of the Senate Standing Committee on Relations and Ordinances.

Details of the Regulations are set out in the Attachment.

The Regulations commenced on gazettal.

ATTACHMENT

Therapeutic Goods Amendment Regulations 2000 (No. 6).

Regulation 1 states that the title of these regulations is the Therapeutic Goods Amendment Regulations 2000 (No. 6)

Regulation 2 provides that these regulations commence from the date of gazettal.

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

SCHEDULE 1 - AMENDMENTS

Item 1 inserts new regulation 43 AB, which provides the circumstances in which new fees, described in new Item 9AB of Schedule 9 of the Regulations, will not be payable by a manufacturer of blood and blood components. The new fees relate to inspection fees payable by a manufacturer of blood and blood components for the inspection and audit of manufacturing premises to establish compliance with good manufacturing practices. Inspections are generally conducted before a licence to manufacture blood and blood components is issued to a manufacturer, and while a manufacturer holds a manufacturing licence to manufacture these products. Inspections may also be conducted when an application for marketing therapeutic goods is lodged.

The circumstances in which a manufacturer will not be required to pay the inspection fees described in new Item 9AB will be where the inspection being undertaken is either the first or second inspection undertaken within a 3-year period of that inspection in relation to the same Metropolitan site where the manufacturing activities are carried out, and an annual charge applies to the licence that covers the manufacturing carried out at that metropolitan site. This exemption from the payment of certain inspection fees only applies in relation to inspections carried out in respect of a metropolitan manufacturing site covered by each licence issued to a manufacturer of blood and blood components.

Item 2 corrects an amendment made to paragraph 45(4A)(c) of the Regulations by Therapeutic Goods Amendment Regulations 2000 (No.4), Statutory Rules 2000 No. 123. This correction has been made following the suggestions of the Senate Standing Committee on Regulations and Ordinances. The effect of this correction is to clarify that the reduced amount payable by an applicant eligible for a reduction of fees in the circumstances described in that paragraph is the amount of \$5,000.

Items 3 and 4 amend regulation 45 A to make it clear that the discount in annual charges provided for in this regulation does not apply in relation to annual charges applying to licences issued for the manufacture of blood and blood components.

Item 5 includes a consequential amendment to Item 9 of Schedule 9 of the Regulations to clarify that the inspection fees set out for that Item does not apply to blood and blood components. Relevant inspection fees for these therapeutic goods are set out in new Items 9AB and 9AC.

Item 6 incorporates changes that are only intended to clarify that the fee payable for evaluating data in a plant master file relating to steps of manufacture lodged in connection with an application for marketing therapeutic goods, and in connection with an application for a manufacturing licence or for an export certificate, does not apply to the processing of data contained in either a technical master file or a plasma master file referred to in new item 9AD. Item 6 also inserts three new inspection fees.

New item 9AB requires a fee of \$500 per inspector per hour for undertaking an inspection of manufacturing premises or manufacturing operations associated with the manufacture of human blood and blood components undertaken at a metropolitan site covered by a licence.

New item 9AC requires a fee of \$355 per inspector per hour for undertaking an inspection of manufacturing premises or manufacturing operations associated with the manufacture of human blood and blood components undertaken at any site, other than the metropolitan site, covered by a licence.

New item 9AD inserts new fees, based upon the number of pages, payable in respect of an evaluation of data contained either in files known as technical master files or plasma master files, lodged in connection with an application to market therapeutic goods or an application for a manufacturing licence or in circumstances referred to in the Act or Regulations.