Therapeutic Goods Amendment Regulations 2003 (No. 3) 2003 No. 257

EXPLANATORY STATEMENT
STATUTORY RULES 2003 NO. 257

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

Therapeutic Goods Act 1989

Therapeutic Goods Amendment Regulations 2003 (No. 3)

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

Section 63 of the Act provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing matters required or permitted to be prescribed by the Act or necessary or convenient to be prescribed for carrying out or giving effect to the Act. In particular, the Governor-General may, under paragraph 63(2)(e) of the Act, make regulations prescribing requirements for informational material that is included with therapeutic goods.

The purpose of the Regulations is to provide consumers with information on whether medicines have been manufactured using human embryos, human embryonic stem cells or material sourced from human embryos or human embryonic stem cells.

The Regulations require that where a medicine is manufactured using human embryos or human embryonic stem cells (or materials sourced from human embryos or human embryonic stem cells), notification to this effect must be included in the Patient Information and the Product Information documentation that accompany the supply of medicines that are, in the main, prescription medicines. The new arrangements apply from 1 July 2004.

Details of the Regulations are set out in the Attachment.

The Act specifies no conditions that need to be met before the power to make the Regulations may be exercised.

The Regulations would commence on gazettal.

ATTACHMENT

DETAILS OF THE *THERAPEUTIC GOODS AMENDMENT REGULATIONS 2003 (NO. 3)*

Regulation 1 states that the title of the Regulations would be the *Therapeutic Goods Amendment Regulations 2003 (No. 3).*

Regulation 2 provides that the Regulations would commence on gazettal.

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

SCHEDULE 1 - AMENDMENTS

Item 1 notes that in addition to the written information required to be provided with goods in accordance with regulation 9A(1), proposed regulation 9B requires that additional information must be provided in relation to certain therapeutic goods that are manufactured using a human embryo, human embryonic stem cell or any other material sourced from a human embryo or human embryonic stem cell.

Item 2 provides that a new regulation (regulation 9B) be inserted after regulation 9A. The new regulation provides that it is an offence if, on or after

July 2004, a sponsor of therapeutic goods:

- supplies goods of a kind specified in Part 1 of Schedule 10 of the Regulations (other than medical devices), but only where such goods are registered under the Act on or after 1 July 2004 - that is, the regulation would not apply to goods registered prior to 1 July 2004. Goods specified in Part 1 of Schedule 10 of the Therapeutic Goods Regulations 1990 are goods that are, in the main, registrable goods such as prescription medicines, as opposed to complementary medicines or over-the-counter medicines;

- knows that the goods were manufactured using a human embryo, human embryonic stem cell or other material sourced from a human embryo or human embryonic stem cell; and

- supplies the goods without written information stating that the goods were manufactured using a human embryo or human embryonic stem cell or other material sourced from a human embryo or human embryonic stem cell. The regulation provides that the written information in relation to the therapeutic goods must be included in the patient information document (that is required in accordance with regulation 9A) and the product information in relation to the goods.

The product information (associated with prescription medicines) essentially forms the basis for any advertising to health professionals. For example, product information is published in compendia such as *MIMS Annual* and a number of other similar medical resources available to all doctors and pharmacists. Patient information documentation is a variation on the product information that is focussed on what the consumer needs to know to use the medicine safely and effectively. Most patient information documentation is available on dispensing software used by pharmacists and more recently on prescribing software used by doctors. Some patient information is available as an insert in the medicine package and some as a printed leaflet given to the consumer by the pharmacist.

The offence will only apply to goods registered and supplied on, or after,

1 July 2004. This ensures that the new requirements will not have any retrospective effect (in terms of products already on the Australian Register of Therapeutic Goods) and that there is sufficient lead time for industry to include any relevant information in applications to the TGA for registration of medicines that have been manufactured using human embryos, human embryonic stem cells or materials sourced from human embryos or human embryonic stem cells.

The regulation establishes that the penalty for the offence is 10 penalty units and that strict liability applies to the physical elements of the offence.

The regulation also includes definitions for key terms used in the proposed regulation including human embryo, human embryonic stem cell and product information. The proposed definition of human embryo is the same as the definition used in the *Research Involving Human Embryos Act 2002.* The definition of human embryonic stem cell is based on relevant literature and in particular the definition adopted by the United States National Institute of Health. The definition of product information is the same as the definition used in subsection 9D(5) of the *Therapeutic Goods Act 1989* and means, in relation to therapeutic goods, information relating to the safe and effective use of the goods, including information regarding the usefulness and limitations of the goods.