



Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Australian regulatory guidelines for prescription medicines

Appendix 24: Information about therapeutic goods and the use of human embryos, human embryonic stem cells and materials derived therefrom

June 2004

TGA Health Safety
Regulation



About the Therapeutic Goods Administration (TGA)

- The TGA is a division of the Australian Government Department of Health and Ageing, and is responsible for regulating medicines and medical devices.
- TGA administers the Therapeutic Goods Act 1989 (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.
- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.
- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. TGA investigates reports received by it to determine any necessary regulatory action.
- To report a problem with a medicine or medical device, please see the information on the TGA website.

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Appendix 24: Information about therapeutic goods and the use of human embryos, human embryonic stem cells and materials derived therefrom

The *Therapeutic Goods Regulations 1990* require that the sponsor of therapeutic goods that are:

1. manufactured using a human embryo or human embryonic stem cell or any other material sourced from a human embryo or human embryonic stem cell; and
2. approved as registered goods on or after 1 July 2004,

must not supply the goods unless the sponsor supplies with the goods a written statement that human embryos or human embryonic stem cells or any other material sourced from a human embryo or human embryonic stem cell were used in the manufacture of the therapeutic good.

The information must be included in the Product Information (PI) and Consumer Medicine Information (CMI).

In addition, where information is provided to the Therapeutic Goods Administration (TGA) (as part of an application for registration of a prescription medicine) that refers to the use of human embryos, human embryonic stem cells (or materials sourced from human embryos or human embryonic stem cells) in research undertaken in the development of the medicine, then the draft PI and CMI provided to the TGA should provide a statement to this effect. Subject to approval of the PI by the TGA, and following registration of the medicine, the CMI is also expected to include a similar statement in line with the PI.

These requirements take effect in respect of therapeutic goods approved as registered goods on or after 1 July 2004.

Human embryo means a live embryo that has a human genome or an altered human genome and that has been developing for less than 8 weeks since the appearance of 2 pro-nuclei or the initiation of its development by other means.

Human embryonic stem cell means undifferentiated cells derived from a human embryo that have the potential to become a wide variety of specialised cell types.

Product information, in relation to therapeutic goods, has the meaning given by subsection 9D (5) of the *Therapeutic Goods Act 1989*.

For the purposes of the definition of **human embryo**, in working out the length of the period of development of a human embryo, any period when the development of the embryo is suspended is to be disregarded.

Manufacture, in relation to therapeutic goods that are not medical devices, means:

1. to produce the goods; or
2. to engage in any part of the process of producing the goods or of bringing the goods to their final state, including engaging in the processing, assembling, packaging, labelling, storage, sterilising, testing or releasing for supply of the goods or of any component or ingredient of the goods as part of that process.

Sponsors should complete the declaration in Module 1 of the Common Technical Document (CTD)¹

Historical document

¹ <http://www.tga.gov.au/industry/pm-ctd.htm>

Historical document

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Reference/Publication #