



**Australian Government**

**Department of Health and Ageing**  
Therapeutic Goods Administration

# Excluded Goods Order No.1 of 2011

## Guideline for Items 4(o), 4(p), 4(q) and 4(r)

Version 1.1, March 2013

**TGA** Health Safety  
Regulation

## About the Therapeutic Goods Administration (TGA)

- The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health and Ageing, and is responsible for regulating medicines and medical devices.
- The 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 <[www.tga.gov.au](http://www.tga.gov.au)>.

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## Version history

Version	Description of change	Author	Effective date
V1.0	Original Publication	Office of Scientific Evaluation	03/12/12
V1.1	Minor changes regarding professional responsibilities of treating practitioners	Office of Scientific Evaluation	25/03/13

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## Purpose

The purpose of this Guideline is to outline the circumstances in which two new items included in the [Therapeutic Goods \(Excluded Goods\) Order No. 1 of 2011](#) (the Order), being certain products of human origin, would not be treated by the TGA as coming within the regulatory framework created by the the Act and Regulations. These two items are human cells and tissues (HCT) used in medical practice, and reproductive tissues for use in assisted reproductive therapy.

In addition, the Guideline explains why Items 4(o) and 4(p) in the Therapeutic Goods (Excluded Goods) Order No. 1 of 2008 (the 2008 Excluded Goods Order) which cover solid organs for transplantation and haematopoietic progenitor cells (HPC) were updated in the Order to reflect contemporary medical practice.

## Background

The Order excludes those goods that the Secretary is satisfied do not come within the definition of 'therapeutic goods' in the the Act from the operation of that Act and Regulations, so as to render them not to be subject to regulation by the TGA.

It replaces the Therapeutic Goods (Excluded Goods) Order No. 1 of 2008.

This Guideline provides information about those Items in the Order (4(o), 4(p), 4(q) and 4(r)) that are products of human origin and that are specified as 'goods that are not therapeutic goods' in Item 4.

Items 4(q) and 4(r) (new exclusions in the Order) relate to HCT obtained during medical procedures conducted as part of medical practice and tissue for use in assisted reproductive therapy respectively. Minor changes were also made in the Order to Items 4(o), transplantation of solid organs, and 4(p), use of haematopoietic progenitor cells (HPC) for haematopoietic reconstitution.

In this Guideline, there is particular attention given to Item 4(q). The effect of this is that HCT manufactured/produced for supply as therapeutic goods by, or under the supervision of, a medical practitioner for treatment of a single indication in a single course of treatment for a patient under the care of that practitioner (i.e. clinical care/ medical practice) are not regulated by the TGA.

# New Items in the Therapeutic Goods (Excluded Goods) Order No. 1 of 2011 in relation to products of human origin

## Item 4(q): Exclusion of goods manufactured and used in medical practice

The Order provides in this Item a description of HCT obtained during medical procedures that are part of medical practice and not regulated by the TGA.

This means that it is not necessary for:

- the HCT manufactured and used in the circumstances referred to in the Item to be included in the Australian Register of Therapeutic Goods; or
- the person manufacturing or producing the HCT to have a licence under Part 3-3 of the Act

Item 4(q) of the Order specifically excludes from TGA regulation HCT that are:

- i. collected from a patient who is under the clinical care and treatment of a medical practitioner registered under a law of a State or an internal Territory; and
- ii. manufactured by that medical practitioner, or by a person or persons under the professional supervision of that medical practitioner, for therapeutic application of a single indication and in a single course of treatment of that patient by the same medical practitioner, or by a person or persons under the professional supervision of the same medical practitioner.

This provision reflects the Australian Health Ministers' Conference (AHMC) agreement that single surgical procedures and medical practice should not be regulated by the TGA.

### Products (goods) covered by item 4 (q)

The Item only covers HCT that are collected from a patient and used in that same patient. That is, the products are ONLY for autologous use. An example is the use of veins from a patient's limb(s) for grafts in cardiac bypass surgery. It should be noted that only the tissue (vein in this example) itself is excluded from the definition of therapeutic goods. Equipment and materials that are used for the manufacture of the product may still be therapeutic goods to which the Act and Regulations apply and thus subject to regulation by the TGA.

### Single medical practitioner and single patient

A registered medical practitioner must have prime responsibility for the clinical care of his/her patient throughout the course of treatment in which the HCT products are used for the Item to apply. If the medical practitioner cannot assure ongoing responsibility for clinical care of that patient and oversight of the HCT, then the products will not come within the Item and thus may be subject to regulation by the TGA.

### **A single course of treatment for a single indication**

The collection of the HCT must be for a single clinical indication. The schedule for that course of treatment would be specified in accordance with the diagnosis prior to or at the time of collection of the HCT. It is possible that a course of treatment for the clinical indication may require more than one dose or administration of the HCT over a set period of time.

### **Professional supervision over the manufacture of products (goods) excluded under this Order**

Item 4(q) says that the HCT are to be 'manufactured by that medical practitioner or by a person or persons under the professional supervision of that medical practitioner'. The fact that the products being used for a patient are not directly manufactured by the treating medical practitioner does not mean that the Item does not apply.

**Professional supervision** in this context requires that the medical practitioner with primary responsibility for the clinical care of a patient is party to all manufacturing steps that are performed in a formal governance arrangement with the person or persons undertaking the manufacturing. This would include input into the protocols and quality systems used in the manufacturing process. This enables use of goods that are not directly manufactured by the treating medical practitioner.

For example, pancreatic tissue may be collected from a patient by a surgeon in collaboration with an endocrinologist, for processing of the islet cells in a laboratory. Subsequent to processing, the islet cells are infused into that same patient as an autologous transplant.

The collection, processing and infusion must however remain under the professional supervision, as described above, of the endocrinologist caring for the patient.

The Item will not apply in a situation where processing, storage or infusion/implantation of the HCT is undertaken by a person, organisation or other third party on behalf of a medical practitioner where there is no specified relationship with the agent/agency that meets the requirements for professional supervision. In such a case, the HCT is not covered by the Order and would be regulated under the Act and Regulations, and the HCT must comply with applicable therapeutic goods legislation.

### **Professional responsibilities of treating medical practitioners**

The exclusion from the operation of the Act and Regulations of HCT in the circumstances described in the Item has no effect on the professional obligations of medical practitioners to maintain satisfactory standards of practice that are appropriate to their profession. The treating medical practitioner should be mindful of adherence to professional standards when using products that have not been evaluated for safety and efficacy by the TGA. This would include consideration of whether the treatment being undertaken is necessary and safe and whether its efficacy is supported by credible clinical evidence.

Also, with use of a product that is not approved for use in Australia, patients should be provided with adequate information to enable them to give informed consent to treatment.

Professional standards include professional performance and conduct, which are governed by the Medical Board of Australia. Guidance is contained in [Good Medical Practice: A Code of Conduct for Doctors in Australia](#).

The Australian Health Practitioner Regulation Agency also has the power to prosecute for particular advertising offences which may infringe the *Health Practitioner Regulation National Law Act* (in force in each state and territory) The medical board of Australia also publishes [Guidelines for Advertising of Regulated Health Services](#).

Advertising is also regulated under the provisions of the [Competition and Consumer Act 2010](#).

### **Unapproved goods that are not excluded goods**

If the circumstances under which HCT are manufactured/produced and used mean that they would not qualify as excluded goods under the Order, compliance with TGA legislation (including provisions for the use of unapproved goods) is required. Further information on this can be found on the TGA website <[www.tga.gov.au](http://www.tga.gov.au)>.

## **Item 4(r): Exclusion of reproductive tissue**

Item 4(r) of the Order excludes 'reproductive tissue for use in assisted reproductive therapy' from the operation of the Act and Regulations. This exclusion reflects the decision of the AHMC in July 2008 that reproductive tissues should not be regulated by the TGA because use of these tissues was already coherently and consistently managed.

It should be noted that only the reproductive tissue itself is excluded from the definition of therapeutic goods. Equipment and materials that are used for the manufacture of the product may still be therapeutic goods to which the Act and Regulations apply and thus are subject to regulation by the TGA.

The comments above on the professional responsibilities of treating medical practitioners are equally applicable in relation to these goods.

# Amended items in the Therapeutic Goods (Excluded Goods) Order No. 1 of 2011 in relation to products of human origin

## **Item 4 (o): Exclusion of solid organs for direct donor-to-host transplantation**

The purpose of this Item (which was also included in the 2008 Excluded Goods Order) is to exclude organs for direct donor-to-host transplantation from the operation of the Act and Regulations. It should be noted that only the organs are excluded from the definition of therapeutic goods. The Act may still apply, for instance, to equipment and materials that are used for the manufacture of the product and may still therefore be subject to regulation by the TGA.

## **Item 4(p): Exclusion of haematopoietic progenitor cells for direct donor-to-host transplantation**

The provisions for exclusion of 'bone marrow' in the 2008 Excluded Goods Order were updated in the Order to reflect current terminology and practice in the field of HPC transplantation by replacing 'bone marrow' with HPC.

The purpose of this Item is to exclude from the operation of the Act and Regulations (and thus regulation by the TGA) HPC products for direct donor-to-host transplantation for haematopoietic reconstitution. The updated 4(p) recognises that it is HPCs extracted from bone marrow that are transplanted.

It should be noted that only the HPC are excluded from the definition of therapeutic goods. Equipment and materials that are used for the manufacture of the product may still be therapeutic goods to which the Act and Regulations apply and thus are subject to regulation by the TGA.

## **Therapeutic Goods Administration**

PO Box 100 Woden ACT 2606 Australia  
Email: [info@tga.gov.au](mailto:info@tga.gov.au) Phone: 1800 020 653 Fax: 02 6232 8605

[www.tga.gov.au](http://www.tga.gov.au)

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