



Australian Government

Department of Health

Therapeutic Goods Administration

Access to unapproved therapeutic goods

Personal importation

October 2004

TGA Health Safety
Regulation



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Historical document

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These guidelines

- This document updates *Access to Unapproved Therapeutic Goods via Personal Importation May 2001*

The changes to this document accommodate the introduction of Australia's new regulatory system for medical devices in October 2002. The changes to Australia's regulatory system for medical devices have been effected through amendment of the *Therapeutic Goods Act 1989* (the Act) and the *Therapeutic Goods Regulations 1990* (the Regulations), and through the creation of a separate set of regulations specifically for medical devices - *Therapeutic Goods (Medical Devices) Regulations 2002* (the Medical Device Regulations).

The range of mechanisms for access to unapproved therapeutic goods remains the same following the implementation of the new medical device regulatory system. However, with the creation of the Medical Device Regulations, there is now a more appropriate set of restrictions relating to the nature and quantity of unapproved medical devices that can be personally imported into Australia.

NOTE:

The Act has been substantially restructured and is now divided into 'chapters', rather than 'parts'. The requirement for products to be entered into the ARTG has been retained. However, whereas in the past all therapeutic goods were treated the same in terms of ARTG registration or listing requirements (previously Part 3 of the Act) and manufacturing requirements (previously Part 4 of the Act), there are now separate chapters dealing with medicines (chapter 3) and medical devices (chapter 4). These chapters contain quite distinct differences in the approach to the inclusion of these products on the ARTG. Chapter 3 also captures a third set of goods, which are now known as 'other therapeutic goods' (OTGs). These are goods previously regulated as devices but which no longer satisfy the revised definition of a medical device. These products include tampons and household and hospital grade disinfectants.



Medicines and 'other therapeutic goods' continue to be regulated as either 'registrable' or 'listable' goods, with the same TGA pre-market evaluation and manufacturer licensing requirements and procedures as previously (Sections 25, 26, 35 and 36 of the Act). The particular requirements for medical devices and the administrative processes and enforcement procedures principally aimed at ensuring those requirements are met are outlined in Chapter 4.

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At the time of introduction of the new regulatory system for devices, the legislation was framed such that, pursuant to s15A, existing mechanisms for access to unapproved medical devices provided under sections 18 and 19 of the Act continued to be operational for a period of 2 years. From October 2004, all mechanisms of access to unapproved medical devices will operate through the provisions set out in Chapter 4.

Importantly, the new framework excludes in-vitro diagnostic devices (IVDs),

devices of human origin and devices containing viable cells or tissue of animal origin. Although these products fit the definition of a medical device, they have been excluded because the Australian Government is committed to developing new regulatory frameworks for them. In the interim period these products will be regulated as per the previous system, as 'other therapeutic goods'.

- This publication describes how individuals can import unapproved therapeutic goods for personal use. It is intended for use as a source of information for medical practitioners, pharmacists and sponsoring companies when providing advice to individuals who wish to personally import unapproved therapeutic goods.
- These guidelines are one in a series of documents developed by the Therapeutic Goods Administration (TGA) about the mechanisms to obtain access to unapproved therapeutic goods in Australia. The publications in this series include:
 - *Access to Unapproved Therapeutic Goods via Personal Importation* (this publication);
 - *Access to Unapproved Therapeutic Goods - Clinical Trials in Australia*;
 - *Access to Unapproved Therapeutic Goods - Authorised Prescribers*; and
 - *Access to Unapproved Therapeutic Goods via the Special Access Scheme*.

The TGA has also developed a publication *Access to Unapproved Therapeutic Goods in Australia* which is a consolidation of all the documents in the series. This should be consulted if you are unsure which is the appropriate mechanism to use.

| Abbreviations and Acronyms | Name |
|----------------------------|---|
| ADRAC | Adverse Drug Reactions Advisory Committee |
| AGRD | Australian Guidelines for the Registration of Drugs |
| ARTG | Australian Register of Therapeutic Goods |
| C(PI) Regulations | <i>Customs (Prohibited Imports) Regulations 1956</i> |
| CTN | Clinical Trial Notification (Scheme) |
| CTX | Clinical Trial Exemption (Scheme) |
| DSEB | Drug Safety and Evaluation Branch, TGA |
| HREC | Human Research Ethics Committee |
| ICH | International Conference on Harmonisation (of Technical Requirements for Registration of Pharmaceuticals for Human Use) |
| ODBT | Office of Devices, Blood and Tissues, TGA |
| OTGs | 'other therapeutic goods' |

| Abbreviations and Acronyms | Name |
|---------------------------------|--|
| SAS | Special Access Scheme |
| TGA | Therapeutic Goods Administration |
| the Act | <i>Therapeutic Goods Act 1989</i> |
| the Customs Act | <i>Customs Act 1901</i> |
| the EPBC Act | <i>Environment Protection and Biodiversity Conservation Act 1999</i> |
| the Regulations | <i>Therapeutic Goods Regulations 1990</i> |
| the Medical Devices Regulations | <i>Therapeutic Goods (Medical Devices) Regulations 2002</i> |

Introduction

The major legislation dealing with the regulation of therapeutic goods in Australia is the *Therapeutic Goods Act 1989* (the Act) and the *Therapeutic Goods Regulations 1990* (the Regulations) and the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Medical Devices Regulations). One important outcome of this legislation is that most therapeutic goods are required to be approved and included on the Australian Register of Therapeutic Goods before they can be supplied unless there is an exemption. The legislation provides a number of mechanisms for exemption which allows access to therapeutic goods that have not been approved and included on the Australian Register of Therapeutic Goods.

The legal basis for supply of unapproved therapeutic goods

The *Therapeutic Goods Act 1989* and associated regulations establishes a uniform, national system of regulatory controls to ensure the quality, safety, efficacy and timely availability of therapeutic goods for human use. Responsibility for the regulatory controls lies with the Therapeutic Goods Administration (TGA) as the national regulatory authority for therapeutic goods.

Overall control of the supply of therapeutic goods is exerted through three main processes:

- the pre-market evaluation and approval of products intended for supply in Australia;
- the licensing of pharmaceutical manufacturers and certification of device manufacturer quality systems; and
- post market surveillance.

Under the Act, therapeutic goods for human use that are imported, manufactured in Australia, supplied by a corporation, supplied interstate or to the Commonwealth, or exported must be included in the Australian Register of Therapeutic Goods (ARTG) unless specifically exempted by the Act.

Some therapeutic goods are exempted under the Act from the requirement for inclusion in the ARTG before they can be supplied. These exemptions are set out in for medicines and 'other therapeutic goods' (OTGs) in Chapter 3 Section 18 and Section 19 and for medical devices in Chapter 4 Part 4-7. The regulations relevant to these sections are:

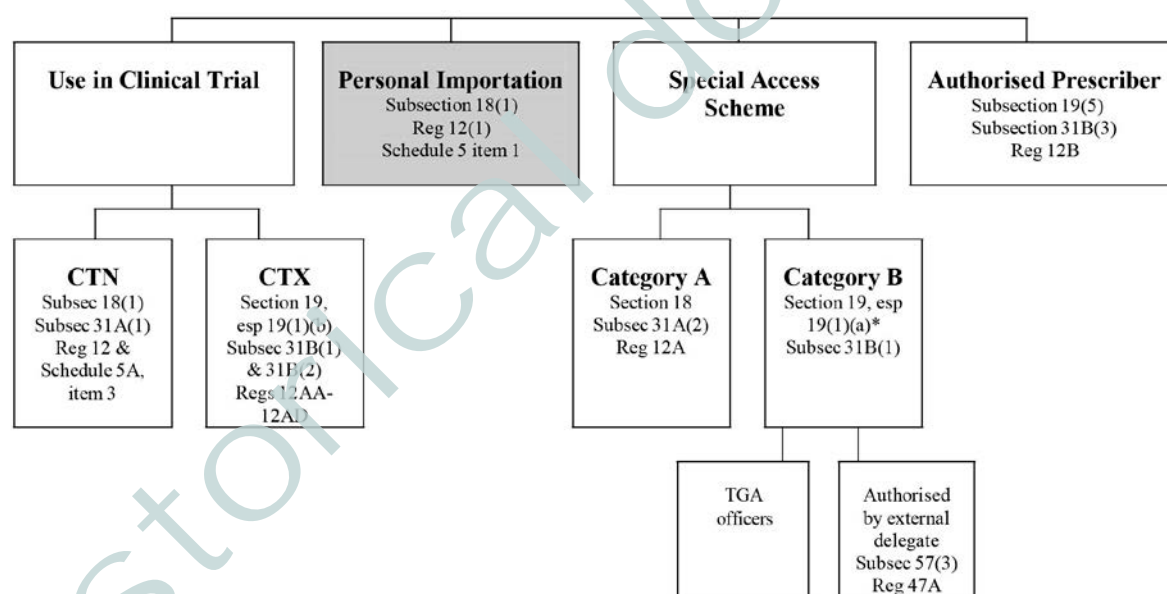
- Schedule 5 (Regulation 12(1)), Schedule 5A (Regulation 12(1A)) and Regulation 12A of the Regulations for medicines and OTGs; and
- Regulations 7.1-7.7 and Schedule 4 (Regulation 7.1) of the Medical Devices Regulations for medical devices.

The legislation provides the following mechanisms that allow individuals to gain limited access to therapeutic goods not on the ARTG:

- The Special Access Scheme (categories A and B);
- Clinical Trials (CTN and CTX schemes);
- Authorised Prescribers; and
- Importation for personal use.

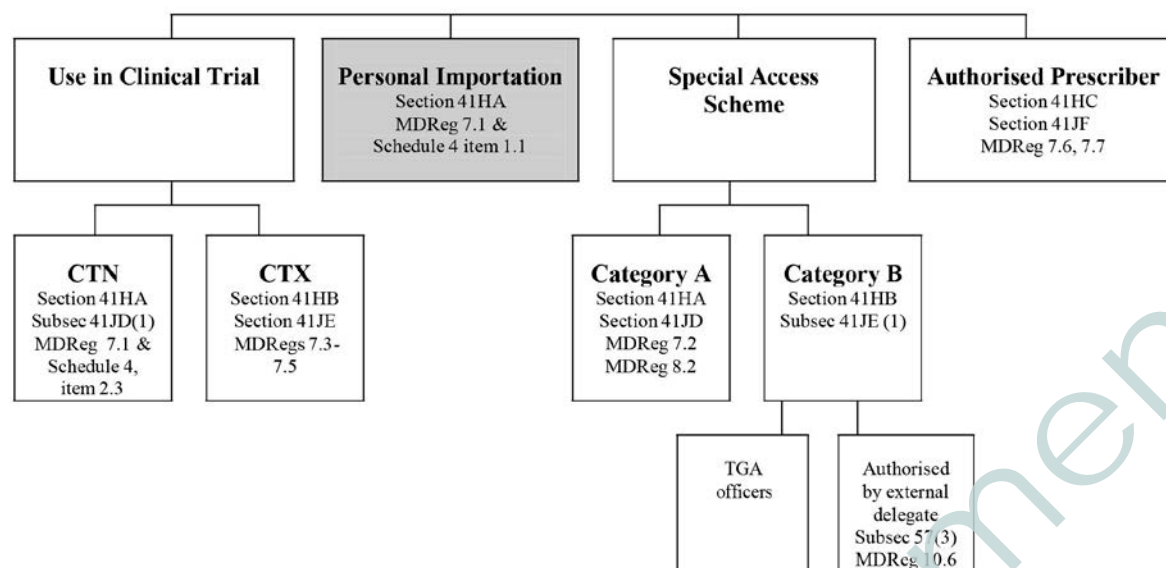
The figures below provide a graphic representation of these mechanisms and the sections of the Act and Regulations relevant to their operation. The provisions specifically relating to personal importation have been shaded.

Figure 1: Access to unapproved medicines and OTGs



* Section 19 (1)(a) allows supply for Category A and Category B patients but, in practice, category A cases are dealt with under s18 and reg12A.

Reg = *Therapeutic Goods Regulations 1990*

Figure 2: Access to unapproved medical devices

MDReg = *Therapeutic Goods (Medical Devices) Regulations 2002*

A full copy of the legislation can be found on the TGA Website at: [Legislation & legislative instruments](#)

Promotion of unapproved therapeutic goods

The promotion of unapproved therapeutic goods is an offence under subsection 22(6) of Chapter 3 (medicines) and Section 41MM of Chapter 4 (medical devices) of the Act, and carries a financial penalty. A person must not intentionally or recklessly make a claim, by any means, that the person or another person can arrange the supply of unapproved therapeutic goods.

Personal importation of unapproved therapeutic goods

What is meant by the term ‘Personal Importation’?

Personal importation occurs when:

- an individual either brings a therapeutic good into Australia on their person or arranges from within Australia for a therapeutic good to be sent to them from an overseas supplier; and
- the goods are to be used by that individual or a member of his/her immediate family and are not sold or supplied to any other person.

Legislative controls over the personal importation of therapeutic goods

The principal legislation relevant to the personal importation of therapeutic goods in Australia includes:

- the *Therapeutic Goods Act 1989*;
- the *Therapeutic Goods Regulations 1990*;
- the *Therapeutic Goods (Medical Devices) Regulations 2002*;
- the *Customs Act 1901*;
- the *Customs (Prohibited Imports) Regulations 1956* (C(Pi) Regulations); and
- State and Territory laws.

Additional legislation, which may also apply, includes:

- the *Quarantine Act 1908*; and
- the *Environment Protection and Biodiversity Conservation Act 1999*.

Individuals may import **medicines and 'other therapeutic goods'** without the goods being entered on the ARTG where:

- the goods are either for use by the importer or a member of the importer's immediate family, and
- the goods do not contain a substance which is a prohibited import under the C(Pi) Regulations, and
- the product is not an injection containing material of human or animal origin (except insulin), and
- the quantity imported does not exceed three months' supply per importation and the total quantity imported per year does not exceed 15 months' supply at the manufacturer's recommended maximum dosage; or
- importation of the goods is approved under regulation 5 of the C(Pi) Regulations or the goods are included in a gazetted class approved for importation under regulation 5; and
- in the case of prescription medicines (i.e. Schedules 4 and 8 of the Poisons Standard), the goods are the subject of a prescription issued by a State/Territory registered medical practitioner. Note: medicines carried by a passenger on a plane or ship are an exception to this requirement, however, an import licence is still required in the case of medicines in Schedule 4 of the C(Pi) Regulations if the passenger does not have a prescription.

Individuals may import **medical devices** without the goods being included in the ARTG where:

- the goods are either for use by the importer or a member of the importer's immediate family, and
- the goods do not contain a substance which is a prohibited import under the CPI Regulations, and
- the product is not manufactured using tissues, cells or substances of animal origin that have been rendered non-viable, or tissues, cells or substances of bacterial or recombinant origin, and

- the product either does not incorporate or is not intended to incorporate derivatives of human blood or blood plasma; and
- where the device is classified under the Medical Devices Regulations as low-medium risk (Class IIa) or higher, the quantity imported does not exceed the amount required to deliver three months' treatment using the device according to a treating medical practitioner's directions and the total quantity imported per year does not exceed 15 months' treatment using the device according to a treating medical practitioner's directions; and
- in the case of a medical device that is subject to Schedules 4 and 8 of the Poisons Standard, or a device that incorporates or is intended to incorporate a substance that is subject to either of those Schedules, the device is acknowledged in writing by a State/Territory registered medical practitioner to be appropriate treatment for the importer. Note: Products carried by a passenger on a plane or ship are an exception to this requirement, however, an import licence is still required in the case of medicines in Schedule 4 of the C(PI) Regulations if the passenger does not have a prescription.

Situations where personal importation is further regulated

Customs controls apply to certain therapeutic goods such as drugs of dependence, antibiotics and other substances that may be dangerous if used therapeutically. The Australian Customs Service will only allow products containing these substances to be imported if written permission for importation has been given by the TGA. ***The TGA considers the use of these products should be supervised by a medical practitioner. Thus, the TGA will not issue import permits to individuals. Instead, TGA requires applications to be made in writing by the individual's supervising physician under the Special Access Scheme – see below.***

Special approval from the TGA for the purpose of the C(PI) Regulations is required prior to importation of:

- medicines subject to control under Regulation 5 of the C(PI) Regulations and listed in Schedule 4 to those regulations. This includes medicines with the potential to cause dependence or which have a propensity for abuse, such as **narcotics, amphetamines and psychotropic substances**.

Further advice about procedures for importation should be sought from the Treaties and Monitoring Unit, TGA, telephone 02 6270 4322, fax 02 6270 4325 or mail PO Box 100 Woden ACT 2606.

- medicines subject to control under Regulation 5H of the C(PI) Regulations and listed in Schedule 8 of those Regulations. This includes **anabolic substances, androgenic steroids and treatments for alcohol and drug addiction**.

Further advice can be sought from the Experimental Drugs Section, Drug Safety and Evaluation Branch TGA, telephone 02 6232 8111, fax 02 6232 8112 or mail PO Box 100 Woden ACT.

- medicines subject to control under regulation 5G of the C(PI) Regulations and listed in Schedule 7A of those Regulations. This includes **erythropoietin, darbepoietin alfa, growth hormones and gonadotrophins**. These medicines cannot be imported for the purpose of medical treatment of athletes or persons associated with an athlete without an import permit. Other persons who are entering Australia as a passenger on a plane or ship and carrying the medicine with them are exempted from the need to obtain an import permit, provided the medicine was prescribed by a medical practitioner and the amount imported is consistent with that prescribed for the person receiving treatment.

Further advice can be sought from the Experimental Drugs Section, Drug Safety and Evaluation Branch TGA, telephone (02) 6232 8111, fax (02) 6232 8112 or mail PO Box 100 Woden ACT.

- **antibiotics**, which are subject to control under Regulation 5A of the C(P1) Regulations. Note that up to 3 months' supply of antibiotics for personal use only and in the possession of a passenger on a ship or aircraft may be imported without a permit. Otherwise a permit is required.

Further information can be sought from the Treaties and Monitoring Unit, TGA, telephone 02 6270 4322, fax 02 6270 4325 or mail PO Box 100 Woden ACT 2606;

The Customs Act requires that approval to import a prohibited good must be obtained prior to arrival of the goods in Australia. There are no powers under the Customs Act for retrospective import approval for substances already landed. People who import these medicines without TGA approval are liable to prosecution.

In addition, individuals cannot import:

- **injections that contain substances of human or animal origin** (except insulin) without a Special Access Scheme approval under Section 19 of the *Therapeutic Goods Act 1989*; or
- **the following medical devices** without a Special Access Scheme approval under Section 41HB of the *Therapeutic Goods Act 1989*:
 - devices manufactured using either tissues, cells or substances of animal origin that have been rendered non-viable, or tissues, cells or substances of bacterial or recombinant origin;
 - products either incorporating or intended to incorporate derivatives of human blood or blood plasma.

The TGA considers that these products represent a high risk from inadequately or improperly prepared materials (including a lack of sterility) and, therefore, approvals will only be granted to the supervising physician.

It is also a requirement under the Act for an individual to obtain through their supervising physician a Section 19 or Section 41HB (Special Access Scheme) approval for the **importation of single quantities in excess of 3 months' supply of a therapeutic good or more than 15 months' supply in a 12 month period.**

Further advice about procedures for importation of medicines should be sought from the Experimental Drugs Section, Drug Safety and Evaluation Branch, TGA, telephone 02 6232 8111, fax 02 6232 8112 or mail PO Box 100 Woden ACT 2606.

Information about the importation of medical devices and 'other therapeutic goods' should be sought from the Medical Devices Branch, TGA, telephone 1800 141 144, email devices@tga.gov.au or via mail PO Box 100 Woden ACT 2606.

For information about the Special Access Scheme, see the TGA publications:

- Access to Unapproved Therapeutic Goods in Australia; or
- Access to Unapproved Therapeutic Goods via the Special Access Scheme.

Responsibilities of the 'personal importer'

Individuals wishing to import unapproved products for their personal use should be aware that in many cases the quality, safety and efficacy of the goods may be unknown and they must therefore be prepared to accept any risks associated with the use of such products. If an individual suffers adverse consequences from taking such medicines, information about the goods and redress may be difficult to obtain.

It is the responsibility of individuals wishing to arrange personal importation of unapproved therapeutic goods to ensure they have complied with all relevant Commonwealth and State/or Territory laws. When seeking to arrange importation of an unapproved medicine, it is important to check whether the medicine is controlled under *Customs (Prohibited Import) Regulations 1956*, in which case special requirements for TGA approval prior to importation apply. In addition, goods imported into Australia, whether therapeutic or not, may be subject to import controls administered under the *Quarantine Act 1908* and the *Environment Protection and Biodiversity Conservation Act 1999* if the products are manufactured from animal, plant or human materials.

Prior quarantine clearance must be obtained to import any material of biological origin (human, animal, plant or bacterial). The importer should contact the Australian Quarantine & Inspection Service to see if an import permit is required. Application forms to import biological material may be obtained from the Chief Quarantine Officer in all capital cities. Applications should be sent to:

Australian Quarantine & Inspection Service (AQIS) Department of Agriculture, Fisheries and Forestry – Australia
GPO Box 858
CANBERRA ACT 2601

Ph: 02 6272 3933
Fax: 02 6272 5161
Website: <http://www.daff.gov.au>

The import or export of substances containing parts of animals and plants listed as endangered species require a permit issued under the *Environment Protection and Biodiversity Conservation Act 1999* (the EPBC Act). This can apply to many therapeutic goods, mainly of Asian origin, containing, for example, tiger bone or rhinoceros horn. For information concerning the operation of the EPBC Act, contact:

Department of the Environment and Heritage
GPO Box 787
CANBERRA ACT 2601

Ph: 02 6274 1900
Fax: 02 6274 1921
Website: <http://www.deh.gov.au/epbc/index.html>

It is also illegal to import drugs of abuse where the manufacture, possession, sale or use of the drug is prohibited by law (e.g. heroin, cannabis). These drugs are listed in Schedule 9 of the *Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP)*. The SUSDP contains the recommendations of the National Drugs and Poisons Schedule Committee, regarding the classification of drugs and poisons into Schedules for inclusion in the relevant legislation of the States and Territories. Individuals will need to check the relevant legislation of their State or Territory for a list of medicines included in this classification.

Further information

Further information about importation of therapeutic goods may be obtained by contacting the Therapeutic Goods Administration on – Information line: 1800 020 653.

Historical document

Historical document

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia

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<https://www.tga.gov.au>

Reference/Publication #