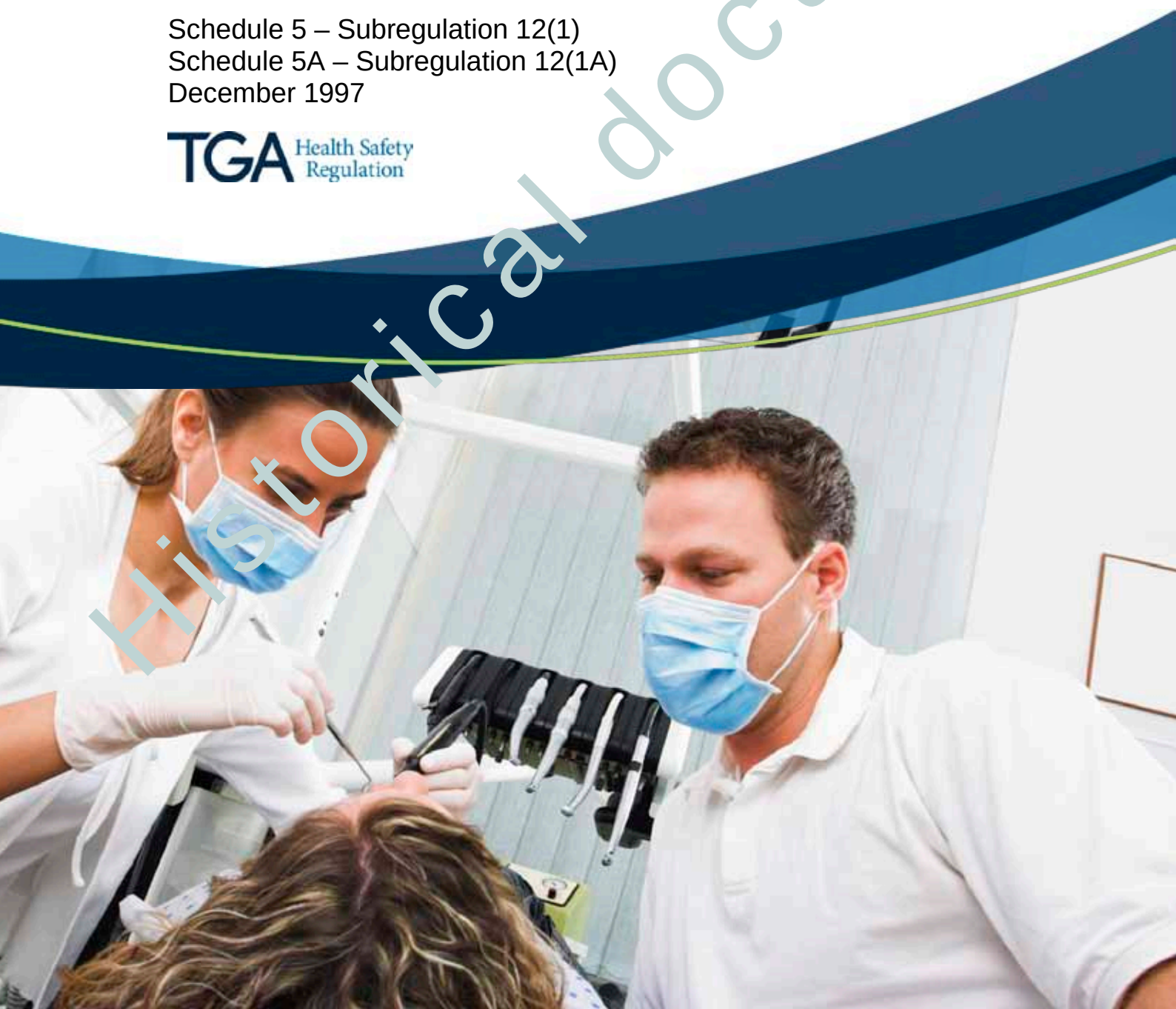
Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Therapeutic goods regulations

Exempt goods

Schedule 5 – Subregulation 12(1)
Schedule 5A – Subregulation 12(1A)
December 1997

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.

***Extract applicable to Therapeutic Devices**

Therapeutic Goods Regulations

SCHEDULE 5

Subregulation 12(1)

THERAPEUTIC GOODS EXEMPT FROM THE OPERATION OF PART 3 OF THE ACT

Item No.	Therapeutic Goods
1	therapeutic goods that are imported for use in the treatment of the importer or the importer's immediate family where: (a) the goods do not contain a substance the importation of which is prohibited under the *Customs Act 1901*; and (b) in the case of injections that contain material of human or animal origin - the goods are the subject of an approval under section 19 of the Act, or are insulin preparations; and (c) in the case of other drugs: (i) the quantity imported in one importation is not more than 3 months' supply at the maximum dose recommended by the manufacturer; and (ii) the total quantity of the drug imported for use in the treatment of the importer or the importer's immediate family in the period of 12 months ending on the day on which the latest importation occurs does not exceed 15 months' supply of the drug at the maximum dose recommended by the manufacturer; or the drugs have been approved, or are included in a class of drugs that has been approved, under regulation 5 of the Customs (Prohibited Imports) Regulations for importation into Australia; and (d) if the goods are subject to Schedule 4 or Schedule 8 to the Poisons Standard - the goods are the subject of a written authority issued by a medical practitioner registered under a law of a State or Territory, except where the goods are carried by the importer as a passenger on a ship or aeroplane
2	therapeutic goods that are exported and that: (a) are not for commercial supply; and (b) do not contain a substance the exportation of which is prohibited under the *Customs Act 1901*; and (c) are not intended for use in clinical trials on humans
3	samples of therapeutic goods imported, exported, manufactured or supplied for: (a) submission to a regulatory authority; or (b) subjection to developmental or quality control procedures; or (c) examination, demonstration or display; or (d) subjection to analysis or laboratory testing procedures; but not for supply for therapeutic use in humans
4	goods imported solely for the purpose of export that remain subject to the control of the Customs and that are not subject to manufacture in Australia
5	custom made therapeutic devices that are produced for a particular person for therapeutic application to that person, other than the following goods: (a) therapeutic devices referred to in item 3 of Part 1 of Schedule 3; (b) therapeutic devices referred to in an item in Part 2 of Schedule 3; (c) electronic devices that must be programmed for each patient using those devices
6	drugs that are dispensed, or extemporaneously compounded, for a particular person for therapeutic application to that person
7	the following therapeutic devices and parts of therapeutic devices: (a) components and parts of therapeutic devices intended for use in the manufacture, installation, repair or maintenance of devices that are not provided separately to the consumer as an accessory or consumable component, other than; (i) components for artificial limbs; or (ii) programmers for implantable electronic devices; or (iii) components of implantable devices that are assembled in the body; or (b) diagnostic goods for *in vitro* use other than: (i) goods for home use; or (ii) goods that incorporate material of human origin; or (iii) goods supplied as a pharmaceutical benefit; or (iv) containers of a kind referred to in paragraph 7(l); or (c) non-implantable, non-powered diagnostic tools that: (i) are not supplied in a sterile state; and (ii) are not intended to monitor a physiological process; and (iii) are not referred to in paragraph (b); or (d) non-powered medical or dental instruments that: (i) depend on manual dexterity for their use; and (ii) are not supplied in whole or in part in a sterile state; except endoscopes and endoscopic accessories, flexible tubes, catheters, cannulae, fluid and gas lines and other instruments that introduce fluids or gases to, or remove them from, the body; or (e) manufacturing, laboratory and dispensary equipment used in diagnosis or in the preparation of therapeutic goods except: (i) equipment specifically designed to process a patient's blood or other tissues for re-introduction to

	the patient; or (ii) a bench top or portable steriliser, not permanently connected to plumbing or electrical wiring, used to sterilise medical or dental instruments; or (f) therapeutic devices for dental use that are: (i) constructed externally to the mouth; and (ii) fitted or fixed into the mouth on a temporary or permanent basis; and (iii) intended for protection, or to correct an irregularity or deficiency; other than the following: (iv) devices of human or animal origin; (v) dental restorative materials; (vi) devices that, when used, are implanted directly into bone or soft tissue; (vii) therapeutic devices for dental use included in an item in Schedule 3 or 4; or (fa) therapeutic devices for dental use that are dental impression materials; (g) non-powered devices used in general patient care, being devices that do not constitute or contribute to a specific diagnosis, monitoring or treatment of a medical condition; or (h) furniture other than powered appliances for use in diagnosis or treatment of a medical condition; or (i) linen and bedding other than linen and bedding supplied in a sterile state; or (j) protective clothing for patients or health workers, except: (i) clothing supplied in a sterile state; or (ii) surgeon's gloves, patient examination gloves and other protective gloves for the prevention of contact with body fluids or body tissue; or (iii) patient nuclear radiation shields and radiation shielding apparel; or (k) communications equipment except telemetry equipment and other patient monitoring equipment that directly monitors a physiological process; or (l) containers other than: (i) syringes; or (ii) single use containers designed for the collection, storage and transfer of blood for diagnostic testing (other than single use containers recommended by the manufacturer to be used only in equipment measuring the physical properties of blood); or (iii) containers designed for the collection of blood for transfusion; or (iv) containers designed for the collection of blood for use in the manufacture of blood products or (v) containers designed for the storage of blood and blood components for parenteral administration; or (vi) containers, not made of glass, designed for the storage and parenteral administration of therapeutic goods (commonly referred to as "large volume parenteral infusion bags"); or (vii) bags designed for the collection of fluid drained from the body of a patient (commonly referred to as "drainage bags"); or (m) therapeutic devices: (i) imported by their users before the commencement of the Act; and (ii) that are still in use for administration to, or application in the treatment of, patients; or (n) non-sterile, non-powered therapeutic devices that are: (i) medicine droppers, measures or spoons; or (ii) non-absorbent applicators; or (iii) absorbent applicators designed for use with inhalations; or (o) non-powered orthoses or splints that do not exert traction; or (p) non-powered hot or cold packs; or (q) human tissue for implantation in the human body that is obtained, stored and supplied without any deliberate alteration to its biological or mechanical properties by institutions the procedures of which conform with principles determined under subsection 36(1) of the Act
8	(f) disinfectants, except: (i) disinfectants included in items 5 and 6 of Part 2 of Schedule 3: or (ii) disinfectants included in item 16 of Part 1 of Schedule 4; or (iii) disinfectants for use with contact lenses;

Therapeutic Goods Regulations

SCHEDULE 5A

Subregulation 12(1A)

THERAPEUTIC GOODS EXEMPT FROM THE OPERATION OF PART 3 OF THE ACT SUBJECT TO CONDITIONS

Item No.	Therapeutic goods	Conditions
1	Therapeutic goods imported into Australia that are held under the direct control of the sponsor, until the goods are: (a) the subject of a notification under item 3; or (b) approved for importation into Australia under subsection 19(1) of the Act	(a) the sponsor must: (i) keep records relating to the source and supply of the goods; and (ii) if requested by the Secretary - supply the records to the Secretary; and (b) if the goods are the subject of a notification under item 3 or an approval under subsection 19(1) of the Act - the supply of the goods must be in accordance with the notification or approval; and (c) if the goods are the subject of a notification under item 3 or an approval under subsection 19(1) of the Act and are kept in a

		warehouse in accordance with the notification or approval for a period of up to 12 months: (i) in the case of therapeutic goods other than therapeutic devices - the goods must be destroyed within 1 month of the end of that period: and (ii) in the case of therapeutic devices - the devices must be destroyed or returned to the consignor of the devices within 1 month of the end of that period
1A	Therapeutic goods imported into Australia and held under the direct control of the sponsor, until a decision is made under section 25 or 26 of the Act in relation to the goods	(a) the sponsor must: (i) keep records relating to the source of the goods; and (ii) if requested by the Secretary - supply the records to the Secretary; and (iii) have lodged an application under section 23 of the Act in relation to the goods before their importation; and (b) if the goods are not registered or listed: (i) the goods must be destroyed; or (ii) in the case of therapeutic devices - the devices must be destroyed or returned to the consignor of the devices within 1 month of the decision not to register or list the devices.
2	Item 2 omitted by No.9 1996	
3	Therapeutic goods used solely for experimental purposes in humans	(a) before starting to use the goods, the sponsor must notify the Secretary: (i) in a form approved by the Secretary; and (ii) in accordance with the requirements (if any) determined by the Secretary for the form of notification; that the sponsor intends to sponsor a clinical trial using specified goods; and (b) the notification must be accompanied by the relevant notification fee referred to in item 14 or 14A of Schedule 9; and (c) the approval of the goods for this purpose must be given by the sponsor (if the sponsor is conducting the trial), or by the body or organisation conducting the trial for the sponsor, having regard to the advice of the ethics committee that has, or will assume, responsibility for monitoring the conduct of the trial; and (d) the terms of the approval by the sponsor, body or organisation referred to in paragraph (c) must be no less restrictive than the terms advised by the ethics committee; and (e) the Secretary must not, at any time: (i) have become aware that to conduct or to continue the trial would be contrary to the public interest; and (ii) have directed that the trial not be conducted, or be stopped; and (f) the sponsor (if the sponsor is conducting the trial), or the body or organisation conducting the trial for the sponsor, must not receive, or have received, advice from the ethics committee that is inconsistent with the continuation of the trial.
4	Therapeutic goods that are imported by a member of a group of persons	(a) the group must be visiting Australia to participate in a national or an international sporting event; and (b) the goods must be for use in the treatment of a member or members of that group; and (c) the importation of the goods must not be prohibited under the Customs (Prohibited Imports) Regulations; (d) the goods must not be supplied to, or used in the treatment of, a person who is not a member of the visiting group; and (e) any portion of the goods that is unused at the end of the visit must be destroyed or removed from Australia; and (f) a member of the group must be responsible for the control and custody of the goods while the group is in Australia; and (g) the person referred to in paragraph (f) must: (i) carry a list, in English, of the quantity and nature of the therapeutic goods imported; and (ii) for each of the goods that is not a therapeutic device - include in the list the generic name and strength of the active ingredient of the goods; and (iii) keep a record of the use of the goods while the group is in Australia; and (iv) produce the list or the record for inspection at the request of a customs officer or a person who is an authorised officer for the purposes of a provision

		of Part 5 of these Regulations
5	Therapeutic goods, other than goods referred to in Item 3, that are: (a) manufactured by a person: (i) under a contract between the person and a private hospital; and (ii) in accordance with a formulation specified by the private hospital; and (iii) for use by, or in connection with, a patient of the private hospital; or (b) manufactured by a person: (i) under a contract between the person and a public hospital in a State or Territory; and (ii) in accordance with a formulation specified by the public hospital; and (iii) for use by, or in connection with, a patient of a public hospital in the same State or Territory; or (c) manufactured by a person: (i) under a contract between the person and a public institution; and (ii) in accordance with a formulation specified by the public institution; and (iii) for use by, or in connection with, a patient of the public institution	(a) there are no listed goods or registered goods that, in all relevant respects, are substantially similar to the goods; and (b) the person: (i) manufactures the goods at premises in Australia; and (ii) holds a license, required by the Act, that authorises the manufacture, or a step in the manufacture, of the goods at those premises; and (c) the person notifies the Secretary, in accordance with a form approved by the Secretary, and within 15 days of the end of a quarter, of: (i) the goods manufactured under the contract during that quarter; and (ii) the private hospital, public hospital or public institution that entered the contract
6	Anti-D immunoglobulin	(a) the product must be imported by Commonwealth Serum Laboratories Limited (“CSL”) from Orthodiagnostic System Inc (“OSI”) in the United States of America; and (b) supply of the product in Australia must be by, or on behalf of, CSL; and (c) when supplied to the patient, the product must have with it: (i) a copy of the Patient Information that includes a explanation of the conditions under which its importation was permitted; and (ii) a copy of the Product Information, applicable to the product, that is published by OSI and approved by the United States Food and Drug Administration; and (d) the patient must give to the treating medical practitioner, in writing, adequately informed consent to the administration of the product; and (e) the treating medical practitioner must retain the written consent of the patient.
7	Therapeutic goods, or parts of therapeutic goods, that form part of one of the following device kits: (a) orthopaedic fixation systems; (b) diagnostic goods for *in vitro* use that are reagents, reagent products or a combination of those products; (c) drug delivery systems in which the drug is supplied in a device that acts as a container; (d) dental restorative systems	(a) none of the goods, or any part of the goods are separately supplied in Australia; and (b) if the component and kit manufacturer are the same manufacturer and the components are not separately supplied outside the kit by the kit sponsor; and (c) if the kit sponsor or the manufacturer obtains components from other manufacturers and the kit manufacturer's license covers quality control of those components

* Please refer to the Therapeutic Goods Regulations for complete Schedules

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6232 8605
www.tga.gov.au