Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Changes or variations to therapeutic devices in the ARTG

Is notification or prior approval from the TGA required?

February 1998

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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CHANGES OR VARIATIONS TO THERAPEUTIC DEVICES IN THE ARTG
Is notification or prior approval required?

This document summarises the requirements for sponsors to notify or seek approval of changes to registered and listed therapeutic devices or groups of devices. Therapeutic goods are registered or listed subject to the condition that no changes are to be made to the data on which the decision to register/list was made.

Changes are of two types:

(i) **variations to product information in relation to registered or listed therapeutic devices.** This information relates to the quality, safety and effective use of the goods, including information regarding the usefulness and limitations of the goods;

(ii) **additions of products to grouped registrations or listings.** In some instances a notification (**N**) may lead to a request for further information. All changes must be made in accordance with statutory standards and requirements.

Fees for Variations

All variations requiring notification or approval attract a processing fee and if approval is required for registered devices an evaluation fee is also payable. Reference should be made to Appendix *Fees & Charges* for Therapeutic Devices for details.

Explanation of table and codes used

Registered Therapeutic devices:	Refers to goods required to be registered. Refer to Schedule 3 of the *Therapeutic Goods Regulations.*
Listed therapeutic devices Extra Conditions:	Refers to goods required to be listed where extra requirements apply, such as compilance with GMP, Therapeutic Goods Orders or Test Certificates. Refer to Schedule 6 of the *Therapeutic Goods Regulations* or Appendix *Therapeutic Goods Orders / Standards.*
Listed therapeutic devices Standard Conditions:	Refers to goods required to be listed other than those referred to under 'extra conditions'.

A	denotes Approval required by the relevant unit of the CAB prior to the change being made.
N	denotes Notification required by the relevant unit of the CAB as soon as practicable and not later than three months after implementation of the changes.
R	denotes Notification required directly to the ARTG as soon as practicable and not later than three months after implementation of the change. No fee required for change in sponsor address or contact person.
*****	denotes the change may require a new registration or listing.
-	denotes No approval or Notification is required. Changes may be made without reference to TGA.

What is a Device Product?

A device product is that which results in a single product record in the ARTG. Section 16 of the *Therapeutic Goods Act 1989* refers to separate and distinct goods. For the purposes of implementation of Section 16 for charging of application and evaluation fees, therapeutic devices are taken to be separate and distinct if the goods have a different:

- **name**- where name is interpreted as meaning the 'trade' or proprietary name of the goods which readily identifies the product in the marketplace; or
- **design**- (ECRI classification code level for listable devices only);

or furthermore, if the products have the same

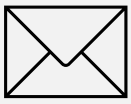
- **characteristics**- (Australian Device Group [ADG] and sterility status); and
- **manufacturer**.

They may be grouped as a therapeutic devices group, unless otherwise specified in *Therapeutic Goods (Single Therapeutic Goods) Order No.1 of 1991.* Please refer to Chapter 1.9 *Reducing Annual Charges.*

At present there are two exceptions where therapeutic devices are listed at the level of manufacturer and not at the individual product level. These are:

- in vitro diagnostics containing material of human origin
- components for artificial limbs

All requests for approvals and notifications of changes must be made on the *Therapeutic Devices Application* form and where relevant, be accompanied by the required additional information or data for evaluation/assessment.



Forward *Therapeutic Devices Application form, Enterprise Details* form (if applicable) and processing fee to:

Business Manager
Business Management Unit
Business and Services Branch, TGA
MDP 122
PO Box 100
WODEN ACT 2606

Where the information is required only by the ARTG, the information should be provided in writing to the

Operations Manager
Australian Register of Therapeutic Goods (ARTG)
Conformity Assessment Branch, TGA
MDP 122
P O Box 100
WODEN ACT 2606

1. Sponsor	**Registered therapeutic devices**	**Listed therapeutic devices (Extra Conditions)**	**Listed therapeutic devices (Standard Conditions)**
Change in sponsor name (same sponsor)	R	R	R
Change in sponsor address	R	R	R
Change in contact person	R	R	R
Change in sponsor	R	R	R

2. Packaging and Labelling - (provided changes consistent with TGO 37 and advertising provisions of Regulations - please refer to Appendices)	**Registered therapeutic devices**	**Listed therapeutic devices (Extra Conditions)**	**Listed therapeutic devices (Standard Conditions)**
Change of container (different specifications) (i) Change of container composition if container contents are biomaterials or container composition is required to conform to a Standard	N	-	-
(ii) Change of container type	A*	-	-
(iii) Change of container closures	-	-	-
Change of supplier of container only (same specifications)	-	-	-
Change of unit pack or pack size	-	-	-
Changes of labelling details **(i)** colour of label	-	-	-
(ii) size of print (having height of 1.00mm or more)	-	-	-
(iii) content - sponsor details, directions, warnings etc.	A	-	-
(iv) claims	A	A (Disinf'ts only)	-
(v) layout	-	-	-

3. Manufacturing Process - includes any change to the final assembled products, the components and accessories (refer Chapter *Good Manufacturing Practice*).	**Registered therapeutic devices**	**Listed therapeutic devices (Extra Conditions)**	**Listed therapeutic devices (Standard Conditions)**
Change of manufacturer's name only	N	N	N
Change of manufacturer site - quality control, release for supply & contract sterilisation[1]	A*	A*	A*
Change of manufacturer site - other steps of manufacture	A	A	-
Change of manufacturing process, evaluated criteria only e.g. assembly, packaging	A	-	-
Change in sterility status	A*	A*	A*
Change in sterilisation technique	A	N	-
Change in species/country of origin of material of animal origin	A	-	-
Change or add a test specification or test method to provide at least equivalent assurances of sterility, reliability or similar safety aspects of the device	N	-	-
Manufacturing quality control procedures e.g. process and packaging material validation specifications, acceptance test specifications	A	-	-

[1] Reference should be made to a current copy of the document *GMP for Subcontracting Manufacturers* available from the TGA Publications Office ph: 1 800 020 653.

4. Finished Product Details - includes components of the assembled device and accessories	**Registered therapeutic devices**	**Listed therapeutic devices (Extra Conditions)**	**Listed therapeutic devices (Standard Conditions)**
Change to intended use/clinical purpose with safety ramifications, including new or extended indications for use	A*	-	-
Change to intended use/clinical purpose with no safety ramifications, including strengthening instructions intended to enhance its safe use	N	-	-
Deletion to contraindications/ warnings	A	-	-
Change to contraindications/ warnings, not concerning a deletion	N	-	-
Change in recommended storage conditions, including new conditions	N	-	-
Extension of recommended shelf life	A	-	-
Reduction of recommended shelf life	-	-	-
Change in product information or clinical manuals which relates to original requirements for registration / listing	A	A	-
Change in service manuals	-	-	-
Change in performance specifications which affect intended use or technological characteristics of the device.	A	-	-
Addition to Pharmaceutical Benefits List	-	-	N
Addition of new product[2] within a grouped registration / listing	A*	A	A
Cessation of a product within a registration/listing	R	R	R
Change of product name	N	N	N
Change of device storage solutions	N	-	-

[2] Definition given at beginning of this document

5. Technological Characteristics - includes components of assembled product and accessories.	**Registered therapeutic devices**	**Listed therapeutic devices (Extra Conditions)**	**Listed therapeutic devices (Standard Conditions)**
Change in structural design / principle of operation	A*	-	-
Change in performance	A*	-	-
Change in software that could affect function of device	A*	-	-
Change in materials **(i)** change in chemistry / chemical composition	A*	-	-
(ii) change in pre & post fabrication treatments	A*	-	-
(iii) change in characteristic properties of finished device	A*	-	-
Change in energy source	A*	-	-
Change in circuit design	A*	-	-
Addition to list of different components of kits/trays/packs	N*	N	N
Deletion to list of different components of kits/trays/packs	-	-	-
Change to mix of different components in any kit/tray/pack	-	-	-
Change in accessories affecting criteria for evaluation (refer Chapter - Registrable Devices)	A*	-	-
Change in physical layout affecting criteria for evaluation (refer Chapter - Registrable Devices)	A*	-	-
Change in quantities of medicated ingredient(s)	A*	N	N
Addition or deletion of ingredient(s)	A*	N*	N*

1. SPONSOR	**Registered Sterilant/ Disinfectant**	**Listed Disinfectant**
a. Change in sponsor name (same sponsor)	R	R
b. Change in sponsor address	R (no fee)	R (no fee)
c. Change in contact person?	R (no fee)	R (no fee)
d. Change in sponsor	R	R

2. FINISHED PRODUCT DETAILS	**Registered Sterilant/ Disinfectant**	**Listed Disinfectant**
a. Change to lower SUSDP poison schedule	R	R
b. Change to higher SUSDP poison schedule	N	N
c. Extension of claims/indications that lead to: (i) changes to the product's classification (ii) no change to product's classification	 A A	 A N
d. Change to product insert information: (i) changes to those sections relating to the product's properties, intended use and directions for use in terms of temperature and time. (ii) amendments incorporating other changes and which are consistent with the approved product details	A N	A N
e. Change in physical or chemical properties	A	A
f. Change in shelf life - increase - decrease	A N	N -
g. Change in directions for use	A	N
h. Change of proprietary name	A*	R
i. Change of recommended storage conditions	A	-

3. FORMULATION	Registered Sterilant/ Disinfectant	Listed Disinfectant
a. Change in amount of active ingredient	A*	R
b. Addition or deletion of active ingredient	A*	A*
c. Change in amount of excipients	A*	R
d. Addition or deletion of excipient	A*	R
e. Change in overages	-	-

4. ACTIVE RAW MATERIALS	Registered Sterilant/ Disinfectant	Listed Disinfectant
a. Change in supplier only	-	-
b. Change in manufacturer	-	-
c. Change in composition of a proprietary ingredient	A	R

5. EXCIPIENTS	Registered Sterilant/ Disinfectant	Listed Disinfectant
a. Change of supplier only	-	-
b. Change of composition of a proprietary ingredient	N	R
c. Change of site synthesis	-	-

6. MANUFACTURING PROCESS	Registered Sterilant/ Disinfectant	Listed Disinfectant
a. Change of principal manufacturer, name only	N	N
b. Change of submanufacturers	N	N
c. Change of site of manufacture:	A*	N*

7. QUALITY CONTROL	**Registered Sterilant/ Disinfectant**	**Listed Disinfectant**
a. Alteration to TGA accepted test methods: (i) Changes which maintain or improve analytical performance (ii) Other changes	 A -	 - -
b. Swap to another test method	A*	-
c. Narrowing the specification range within existing limits	N	-
d. Other amendments to specification ranges	A	-

8. PACKAGING	**Registered Sterilant/ Disinfectant**	**Listed Disinfectant**
a. Change of supplier of container only (same specifications)	-	-
b. Change of container (different material specifications)	A	N (for products covered by SUSDP)
c. Change of container closure	N	-
d. Changes of labelling details (i) Information on the label for product's use/description, claims, indications (ii) Colour of label (iii) Size of print/typeface (iv) Change of manufacturer/sponsor address information etc.	 A* R R R	 N R R R

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