

THERAPEUTIC GOODS ORDER

NO. 37

General Requirements for Labels for Therapeutic Devices

Please note that details such as address and phone numbers contained in this Order may have changed since its publication in 1991.

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I, BRIAN HOWE, Minister of State for Community Services and Health, pursuant to subsection 15(1) of the *Therapeutic Goods Act 1966*, DIRECT that, for the purposes of sections 19, 20, 21 and 22 of that Act, a substance or article or a class of substances or articles to which this Order applies shall be labelled in the manner specified in this Order.

PART 1 - PRELIMINARY

Citation

1. This Order may be cited as Therapeutic Goods Order No. 37.

Commencement

2. This Order shall come into operation on the day the Order is notified in the *Commonwealth of Australia Gazette*.

Application

3. This Order applies to therapeutic devices supplied for use except the following devices:
 - (a) a therapeutic device, not being identical with any other therapeutic device, which is manufactured for a specific individual and is supplied for use by that individual;
 - (b) therapeutic devices for dental use (other than devices of human or animal origin and devices that, when used, are implanted directly into bone or soft tissue) that are constructed externally to the mouth and fitted or fixed into the mouth on a temporary or permanent basis to correct an irregularity or deficiency;
 - (c) a therapeutic device for veterinary use;
 - (d) a therapeutic device being diagnostic *goods for in vitro* use;
 - (e) a therapeutic device intended solely for export from Australia; or
 - (f) a therapeutic device intended solely for the purpose of conducting clinical trials.

Interpretation

4. (1) In this Order, unless the contrary intention appears:

"batch", in relation to a therapeutic device, means a quantity of therapeutic devices which are:

- (a) uniform in composition, method of manufacture and probability of chemical or microbial contamination; and
- (b) made in one designated cycle of manufacture and in the case of a product that is sterilized or freeze dried, sterilized or freeze dried in one cycle;

"batch number or serial number", in relation to a therapeutic device means characteristic markings:

- (a) given by a manufacturer to a particular device or to all devices in a batch for the purpose of uniquely identifying that device or batch and which enables that device or batch to be traced through any or all critical stages of its manufacture and supply; and
- (b) which may be immediately preceded by the words "Batch Number", "Batch No.", "Lot", "Lot Number", "Lot No." or "Lot Code", "Serial Number", "Serial No.", or by words having a similar meaning, or by the symbol "B", "(B)" or "ⓑ", "SN", "S/N", or

"FABR".

The date of manufacture may be used as the "batch number or serial number" if clearly identifiable as a date.

"consumer" means a person, authority, or institution to whom or to which a therapeutic device is supplied for use as a therapeutic device but does not include a person to whom a therapeutic device is supplied for the principal purpose of trade in therapeutic devices;

"diagnostic goods for *in vitro* use" means a reagent, instrument or system that is intended to be used in the examination of specimens taken from the body of a person or animal in connection with the diagnosis of a disease, ailment or defect in, or injury to, a person or animal or the monitoring of a condition in a person or animal;

"goods" means goods for therapeutic use;

"implantable", in relation to a therapeutic device, means designed to be implanted into the tissues or body cavities of a person, other than in the teeth, for a period of 30 days or more;

"label" means:

- (a) a display of printed information provided on or attached to:
 - (i) a therapeutic device;
 - (ii) if the therapeutic device is within one or more levels of packaging, that level of packaging or any of those levels of packaging; or
- (b) information that is sealed within a package, but does not include a label which is intended to be returned by the consumer to the supplier or manufacturer as a record of purchase;

"manufacturer", in relation to a therapeutic device, means the person in Australia or overseas who brings the therapeutic device, or on whose behalf the therapeutic device is brought, to its final state as it will be supplied for use;

"model designation", in relation to therapeutic devices, means characteristic markings or distinctive colour characteristics given by a manufacturer to all therapeutic devices that are identical with respect to the design of those therapeutic devices;

"name", in relation to a therapeutic device, means a name that is sufficiently descriptive to indicate the true nature of the therapeutic device to which the name is applied;

"name and address", in relation to a manufacturer or sponsor of a therapeutic device, means:

- (a) (i) where the manufacturer or sponsor has a registered name, that registered name; or
 - (ii) the name of the manufacturer or sponsor of the therapeutic device, including a manufacturer whose place or places of business is or are outside Australia; and
- (b) (i) in the case of a manufacturer or sponsor having a registered name, the

city, town or locality in which the registered office or the registered place of business is situated; or

(ii) in the case of a manufacturer or sponsor not having a registered name, the address of the principal place of business of that manufacturer or sponsor including, where applicable, the street number or numbers, the street name, the town or city, and the State or Territory in Australia or the name of the overseas country, as the case may be, but not including a post office, cable, telegraphic or code address;

"outer package", in relation to a package containing one or more therapeutic devices, means the outermost level of packaging on that number of therapeutic devices which is supplied for use;

"package" means anything in or by which goods are wholly or partly covered, enclosed, restrained, contained or packed that has a closure that must be removed or opened to gain complete access to the goods;

"person" includes a body politic or corporate as well as an individual;

"quantity", in relation to goods, means:

- (a) where the goods consist of discrete units, the number of units in the goods; or
- (b) where the goods are a substance, the nominal weight or volume of the goods;

"registered name";

- (a) in relation to a partnership, firm or business having a name registered in accordance with the appropriate law of any State or Territory; or
- (b) in relation to a company or corporation incorporated in accordance with the appropriate law of any State or Territory, means the registered name of that partnership, firm, business, company or corporation, as the case may be;

"registered trade mark", in relation to a manufacturer or sponsor, means a trade mark registered under the *Trade Marks Act 1955* of which the manufacturer or sponsor is the proprietor or registered user.

"size", in relation to a therapeutic device, means the term that is given by the manufacturer or sponsor of the therapeutic device for the purpose of describing the size or shape of the device and may include:

- (a) the physical measurements of the device; or
- (b) a descriptive expression, including "small" "medium" or large;

"sterile therapeutic device" means a therapeutic device that is, or is represented (by writing or otherwise) to be, sterile;

"substance" means a substance that is a solid, semi-solid, liquid or gaseous element, compound or mixture;

"supplied for use", in relation to a therapeutic device, means supplied in any form in which the therapeutic device would or could normally become available to a consumer;

"sponsor", in relation to a therapeutic device, means a person who:

- (a) exports, or arranges the export of, the goods from Australia; or
- (b) imports, or arranges the importation of, the goods into Australia; or
- (c) in Australia, manufactures the goods, or arranges for another person to manufacture the goods, for supply (whether in Australia or elsewhere);

but does not include a person who:

- (d) exports, imports or manufactures the goods; or
- (e) arranges the exportation, importation or manufacture of the goods; on behalf of another person who, at the time of the exportation, importation, manufacture or arrangement, is a resident of, or is carrying on business in, Australia;

"therapeutic device" means goods, other than goods that are represented to achieve, or are likely to be taken to achieve, any of the principal purposes of their use as a result of chemical action within or upon the body of a person or animal, but does not include therapeutic goods declared by the Secretary by order published in the Gazette, not to be therapeutic devices;

"unit package", in relation to a package containing one or more therapeutic devices, means:

- (a) where the therapeutic device or therapeutic devices, as the case may be, in that package is a sterile therapeutic device or are sterile therapeutic devices and one or more than one level of packaging maintains the sterility of that therapeutic device or all of those therapeutic devices, the outer level of packaging which maintains the sterility of that therapeutic device or of all of those therapeutic devices; and
- (b) in any other case, that level of packaging which is in closest proximity to that therapeutic device or those therapeutic devices and which wholly envelops all of the goods in the package.

(2) For the purposes of this Order, unless the contrary intention appears:

- (a) expressions used in the Order shall have the same meanings as in the *Therapeutic Goods Act 1966*;
- (b) words in the singular number include the plural and words in the plural number include the singular; and
- (c) each number, letter or symbol required or permitted by this Order to be set out on a label shall be set out:
 - (i) in writing in durable printed form (other than hand writing);
 - (ii) in the English language;
 - (iii) in legible characters having a letter height of not less than 1.0 millimetres;
 - (iv) in a metric unit of measurement; and
 - (v) so as to be clearly visible.

PART 2 - GENERAL LABELLING REQUIREMENTS

5. A reference in this Part to a therapeutic device does not include a reference to:
 - (a) a sterile therapeutic device; or
 - (b) a non-sterile implantable therapeutic device.
6. Every therapeutic device to which this Part applies that is supplied for use must have a label or labels in accordance with this Part.
7. One or more than one of the following particulars must be set out on the label or labels such that all of the following particulars are provided with the therapeutic device when it is supplied for use:
 - (a) the name of the therapeutic device;
 - (b) the name and address of the manufacturer or sponsor of the therapeutic device;
 - (c) the batch number or serial number; and
 - (d) where the therapeutic device:
 - (i) is within a package that contains two, or more than two, identical or different therapeutic devices; or
 - (ii) consists in part of a substance;
the name of the goods within that package and the quantity of each of those goods.

PART 3 - STERILE DEVICES AND NON-STERILE IMPLANTABLE THERAPEUTIC DEVICES

8. A reference in this Part to a therapeutic device shall be read as a reference to a sterile therapeutic device or a non-sterile implantable therapeutic device.
9. Every therapeutic device to which this Part applies must have one, or more than one, label on or attached to:
 - (a) the unit package of the therapeutic device; and
 - (b) if the therapeutic device also has an outer package, that outer package.

Unit packages

10. Subject to clauses 11,12,14 and 15, a label on or attached to the unit package of a therapeutic device must set out one or more of the following particulars, or comply with the following requirements, such that all the particulars and requirements are provided on that unit package so as to be visible to a consumer:
 - (a) the name of the therapeutic device;
 - (b) where the therapeutic device:
 - (i) is within a unit package that contains two, or more than two, identical or different therapeutic devices; or
 - (ii) consists in part of a substance,
the name of all the goods within that package and the quantity of each of those goods;
 - (c) where the therapeutic device is manufactured in more than one design or size, the model designation of the therapeutic device or, if there is no model designation, the size of the therapeutic device;
 - (d) where the manufacturer or sponsor intends that the therapeutic device shall be used on one occasion only, the words "Single-use" or "Use only once" or words

having a similar meaning may appear, but the word "disposable" must not be used to indicate this intention;

- (e) the batch number or serial number of the therapeutic device;
- (f) the name of the manufacturer or sponsor of the therapeutic device, or the registered trade mark of the manufacturer or sponsor of the therapeutic device;
- (g) where the therapeutic device is a sterile therapeutic device, the word "Sterile"; and
- (h) where the therapeutic device is a sterile therapeutic device and the sterility of the therapeutic device may be qualified in respect of areas, components or total presentation, an additional statement to this effect may be added.

Small packages

11. Where:

- (a) a therapeutic device is within a unit package and an outer package; and
- (b) by reason of the size of the unit package it is not practicable to set out in a label on or attached to that unit package all the particulars required by Clause 10, it shall be sufficient compliance with this Order if there are set out on the unit package the particulars referred to in paragraphs 10(a), (f) and (g) of this Order.

Individually wrapped goods

12. Where:

- (a) the therapeutic device consists of single use items such as first aid strips, contact lens solutions, swabs or other similar devices;
- (b) each such item is individually wrapped;
- (c) the individual wrapping constitutes the unit package;
- (d) each such item after being so wrapped, is enclosed in an outer package; and
- (e) the outer package is labelled with the particulars referred to in paragraph 10, it shall be sufficient compliance with this Order if there are set out on the unit package the particulars referred to in paragraphs 10(a), (f) and (g) of this Order.

Outer packages

13. Subject to clauses 12 and 15, a label on or attached to the outer package of a therapeutic device must set out all the following particulars:

- (a) the name and address of the manufacturer or sponsor of the therapeutic device;
- (b) where the therapeutic device is a sterile therapeutic device, the particulars referred to in clause 10 other than those referred to in paragraphs 10 (f), (g) and (h);
- (c) where the therapeutic device is a non-sterile implantable therapeutic device, the particulars referred to in clause 10, other than those referred to in paragraphs 10 (f), (g) and (h), and the words "Non-sterile" or "Sterilize before use" or words having a similar meaning.

Transparent packages

14. Where:

- (a) a unit package contains one or more than one identical or different therapeutic devices; and
- (b) by reason of that unit package being made of transparent material, a person could clearly recognise the nature of the therapeutic device or therapeutic devices within that package and count the number of those devices within that package, a label on or attached to the unit package need not include the following particulars:

- (c) the name of the therapeutic device;
- (d) the name of the goods within that unit package; and
- (e) the quantity of each of the goods within that package.

15. Where:

- (a) a therapeutic device is within a unit package, or within a unit package and an outer package;
- (b) the therapeutic device has written on it some or all of the particulars required by clauses 10 and 13 to be set out on a label on or attached to the unit package or the outer package, respectively; and
- (c) by reason of that unit package, or that unit package and that outer package being made of transparent material the particulars written on the therapeutic device are clearly visible without the therapeutic device needing to be manipulated within the package,

those particulars written on the therapeutic device, other than those referred to in paragraphs 10(g) and (h), need not be set out in a label on or attached to the unit package, the outer package or both, as the case may be.

Dated this seventh day of February 1991

BRIAN HOWE

Minister of State for
Community Services and Health

SUPPLEMENTARY NOTES

GENERAL REQUIREMENTS FOR LABELS FOR THERAPEUTIC DEVICES

The following notes are intended to provide advice on matters which cannot readily be included in the requirements of the Order, and in particular to:

- explain the intention of the Order 'General Requirements for Labels for Therapeutic Devices';
- draw to the attention of sponsors those statutory labelling requirements that may be additional to the requirements of this Order; and
- inform device sponsors and users of the facilities available through the Therapeutic Goods Administration for locating the sponsor of a particular device.

The requirements of this Order are considered to be the minimum information which should appear on the label of a therapeutic device, in order to ensure its safe use and to enable it to be traced to the sponsor and to a particular cycle of manufacture.

In developing this Order it was recognised that there would be many other requirements relating to the safe use of particular classes of device which should appear on a label, or be included with the packaging of a device. The diversity of devices is such that it was not considered feasible to address all of these requirements in the Order.


A number of Orders under the Therapeutic Goods Act which relate to specific classes of device and which may include specific labelling requirements are listed in Appendix 1. Sponsors should ensure that their products comply both with this Order and with any other relevant Order under the Act. Where requirements in an Order for a specific class of device are at variance with any requirements of this Order, the requirements of the specific Order apply.

The *Therapeutic Goods Act 1989*, Section 20 (2) (d) when it comes into effect will make it an offence to import, export or supply Registered Therapeutic Devices unless the registration number of the goods is set out on the label of the goods in the prescribed manner. The number may be added to imported goods prior to supply in Australia. **Listed Therapeutic Devices are exempt from this requirement.**

Registered devices are:

- implantable intra-ocular lenses;
- intra-uterine contraceptive devices;
- implantable cardiac pacing systems including pulse generators, defibrillators, cardioverters, antitachycardia devices and their accessories;
- prosthetic heart valves;
- intra-ocular visco-elastic fluids;
- powered drug infusion systems which regulate the flow of infusate;
- therapeutic devices of human or animal origin for use on or in the body of a person.

Sponsors should also ensure that labelling of goods complies with requirements under other Commonwealth legislation, such as the Commerce (Trade Descriptions) Act which requires the name of the country in which the goods were made or produced to be included.

The requirement for identifying batch number permits a wide variety of means of identification. However, the preferred identification is 'Batch number', B, (B) or .

It is possible for specific goods to be granted exemptions by the Secretary from certain specific requirements of the Order, providing such exemptions will not jeopardise the safe use of the device.

Sponsors of therapeutic goods are required to have all of their non exempt products Registered or Listed in the Australian Register of Therapeutic Goods if the information held on the device component of the computerised register is available to enquirers. In particular, if given the label information required by the provisions of this Order, the data held will enable rapid tracing of the Australian sponsor of a device. Persons wishing to obtain information from the register should apply, in writing, to:

Head
Australian Register of Therapeutic Goods
Therapeutic Goods Administration
Commonwealth Department of Community
Services and Health
PO Box 100
WODEN ACT 2606

Telephone 06 286 0222

APPENDIX 1

ORDERS UNDER THE *THERAPEUTIC GOODS ACT 1966* RELEVANT TO THERAPEUTIC DEVICES

Order no. Title

6	Modifications to the monographs of the British Pharmacopoeia for soda lime
8	Standards Adopted from the British Pharmaceutical Codex 1973.
11	Standard for Sterile Therapeutic Goods
15	Standard for Stainless Steel Sutures
16	Standard for Absorbable Sutures
17	Standard for Non-absorbable Sutures
28	Standard for Contraceptive Devices - Diaphragms
31	Contraceptive Devices - Rubber Condoms
32	General Requirements for Labels for Therapeutic Goods
34	Standard for Diagnostic Goods of Human Origin