



Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

THERAPEUTIC GOODS ACT 1989

Section 10

THERAPEUTIC GOODS ORDER NO. 87

General requirements for the labelling of biologicals

I, Jenny Hefford, delegate of the Minister for Health and Ageing for the purposes of section 10 of the *Therapeutic Goods Act 1989* (the Act) and acting under that section, having consulted with the Therapeutic Goods Committee in accordance with subsection 10(4) of the Act, **HEREBY:**

DETERMINE that the matters specified in this Order shall constitute a standard for biologicals.

Dated this 8 day of July 2011

(signed by)
Jenny Hefford
Delegate of the Minister for Health and Ageing

1. Name of Order

This Order may be cited as Therapeutic Goods Order No. 87 *General requirements for the labelling of biologicals*.

2. Commencement

This Order commences on 31 May 2012.

3. Purpose of this Order

The purpose of this Order is to specify the minimum requirements for the labelling of biological products.

4. Interpretation

(1) In this Order:

Act means the *Therapeutic Goods Act 1989*.

antimicrobial means the ability of a substance to kill or inhibit growth of microorganisms.

autologous use means the use of a biological that is removed from and applied to the same person.

batch number means a number, or a combination of numerals, symbols or letters, which is given by a manufacturer to a batch of goods, to uniquely identify that batch and from which it is possible to trace that batch through all stages of manufacture and distribution.

bioburden has the same meaning as in the Act.

biological has the same meaning as in the Act.

cell(s) means individual cells or a collection of cells when not bound by any form of connective tissue.

collection means removing a biological or a source of a biological from a donor.

container has the same meaning as in the Act.

date of manufacture for a biological means the date (day, month and year) on which the processing of the product, from which the biological is to be packaged, is completed.

donor means any source, whether living or deceased, of blood, blood components, cells or tissues.

expiry date means the date (month and year) after which the biological should not be used.

manufacture has the same meaning as in the Act.

name and address means the name of the sponsor and sufficient information to allow the sponsor to be uniquely identified so as to facilitate public contact and direct communication. The address must include information such as the city or suburb of the sponsor's principal place

of business (not being a post office, cable, telegraphic or code address). The Australian telephone number must also be included.

primary pack has the same meaning as in the Act.

Register has the same meaning as in the Act.

storage means maintaining a substance, material or product under appropriate controlled conditions.

tissue means all constituent parts of the body formed by cells.

5. Application

- (1) Subject to subsection (2), this Order applies to all those therapeutic goods that are biologicals under section 32A of the Act.
- (2) This Order does not set out requirements in relation to transparent covering, where the transparent covering encloses or wraps a container or primary pack containing a biological and where the particulars which are required under this Order to be set out on the label of the container or the primary pack are clearly visible through that transparent covering.

6. General requirements

- (1) Containers of blood, cells and tissues collected from a donor as starting material for a biological must be labelled and traceable to that donor in each step of manufacture of the biological and in relation to the released biological.
- (2) The particulars required by this Order to be included on a label or labels must be clearly visible and must be:
 - (a) in the English language;
 - (b) in durable and legible characters;
 - (c) in letter height of not less than 1.5 millimetres; and
 - (d) in metric units of measurement (if applicable).
- (3) At collection, the following information must be included on the container immediately covering the blood, cells and tissues:
 - (a) unique identification number/alphanumeric linked to donor;
 - (b) type of starting material for the biological;
 - (c) date and time of collection;
 - (d) identification of the collection facility; and
 - (e) identification of the person collecting the starting material for the biological (if applicable).
- (4) At collection of a biological, where the outer surface of the container must remain sterile, and unique identification is not supplied on the sterile packaging, the first externally non-sterile layer of packaging must meet the requirements of subsection (3).

- (5) At collection of a biological, if the container label has insufficient space to incorporate all the requirements of subsection (3), then the requirements in paragraph 3(a) must be set out on the container label and the requirements in paragraphs (3)(b) to (e) must be provided with the product as accompanying documentation.
- (6) At release of a biological, the following information must be included on the container and primary pack in which the biological is packaged:
 - (a) unique identification number/alphanumeric linked to donor;
 - (b) batch number (if applicable);
 - (c) product type and/or product name;
 - (d) sponsor name;
 - (e) sponsor address;
 - (f) description of biological;
 - (g) collection date and/or date of manufacture and/or expiry date;
 - (h) storage conditions;
 - (i) size, volume, weight or concentration (as applicable);
 - (j) international units (if applicable);
 - (k) single patient use (if applicable);
 - (l) sterile (if applicable);
 - (m) additives and/or antimicrobial agents (if applicable);
 - (n) sterilisation/ bioburden reduction method (if applicable);
 - (o) suspending solution (if applicable);
 - (p) 'autologous use only' (if applicable);
 - (q) instructions for thawing (if applicable);
 - (r) instructions for use;
 - (s) contraindications/precautions/adverse effects (if applicable); and
 - (t) instructions for return (if applicable).
- (7) At release of a biological, where the outer surface of the container must remain sterile, and unique identification is not supplied on the sterile packaging, the first externally non-sterile layer of packaging must meet the requirements of subsection (6).
- (8) At release of a biological, if the container and primary pack label have insufficient space to incorporate all the requirements of subsection (6), then the requirements in paragraphs (6)(a) – (d) must be set out on the container label and primary pack label and the requirements in paragraphs(6)(e) to (t) must be provided with the product as accompanying documentation at release.