Australian Government

Department of Health and Ageing

THERAPEUTIC GOODS ACT 1989
Section 10

THERAPEUTIC GOODS ORDER NO. XX – *General requirements for the labelling of biologicals*

I, Rohan Hammett, delegate of the Minister for Health and Ageing for the purposes 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 that Act, HEREBY:

DETERMINE that the matters specified in this Order shall constitute a standard for biologicals under Part 3-2A of the Act.

Dated this ….. day of ……. 2011

Rohan Hammett
Delegate of the Minister for Health and Ageing

1. Name of Order

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

2. Commencement

This Order commences on the day after the day it is registered on the Federal Register of Legislative Instruments.

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) For the purpose of this Order, the presence of the term "must" in relation to a particular requirement in a provision set out in this Order means that the requirement is to be complied with at all times.

(2) In this Order:

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.

batch number prefix means the prefix which precedes the batch number and clearly indicates that the number is the batch number. Examples of acceptable batch number prefixes include 'Batch Number', 'BATCH NUMBER', 'Batch No.', 'BATCH NO.', 'Batch', 'BATCH', 'B', '(B)', 'B/N', 'Lot Number', 'LOT NUMBER', 'Lot No.', 'LOT NO.', 'Lot' or 'LOT'; or words or symbols to this effect.

bioburden has the same meaning as in "bioburden" in subsection 3(1) of the *Therapeutic Goods Act 1989*, as amended from time to time.

biological has the same meaning as in "biological" in subsection 3(1) of the *Therapeutic Goods Act 1989*, as amended from time to time.

Note that "biological" under the Act means:
(1) Subject to subsection (3), a biological is a thing that:
(a) either:
(i) comprises, contains or is derived from human cells or human tissues; or
(ii) is specified under subsection (2); and
(b) is represented in any way to be, or that is, whether because of the way in which it is presented or for any other reason, likely to be taken to be:

(i) for use in the treatment or prevention of a disease, ailment, defect or injury affecting persons; or
(ii) for use in making a medical diagnosis of the condition of persons; or
(iii) for use in influencing, inhibiting or modifying a physiological process in persons; or
(iv) for use in testing the susceptibility of persons to a disease or ailment; or
(v) for use in the replacement or modification of parts of the anatomy in persons.

(2) The Secretary may, by legislative instrument, specify things for the purposes of subparagraph (1)(a)(ii).
(3) The Secretary may, by legislative instrument, determine that a specified thing is not a biological for the purposes of the Act.

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

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

container has the same meaning as in "container" in subsection 3(1) of the *Therapeutic Goods Act 1989*, as amended from time to time.

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 every 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 "manufacture" in subsection 3(1) of the *Therapeutic Goods Act 1989*, as amended from time to time.

name and address means in respect of a sponsor, means the name of the sponsor and sufficient information to allow the Australian sponsor to be uniquely identified so as to facilitate public contact on matters of complaint, use or general enquiry. The address must include information such as the city or suburb of the sponsor's principal place of business in Australia, (not being a post office, cable, telegraphic or code address). The Australian telephone number may also be included.

primary pack has the same meaning as in "primary pack" in subsection 3(1) of the *Therapeutic Goods Act 1989*, as amended from time to time.

Register has the same meaning as "Register" in subsection 3(1) of the *Therapeutic Goods Act 1989* as amended from time to time**.**

Note "Register" under the Act means the Australian Register of Therapeutic Goods maintained under section 9A.

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

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

the Act means the *Therapeutic Goods Act 1989.*

5. Applications and exemptions

(1) The requirements of this Order apply to those biologicals that come within the operation of Part 3-2A of the Act.

(2) The requirements of this Order do not apply to a biological to which an exemption from compliance with the standard set out in this Order has been granted by the Secretary in accordance with section 14 or 14A of the Act.

(3) The requirements of this Order do not apply to transparent covering, where the transparent covering encloses or wraps a container or primary pack containing a biological and the particulars which are required to be set out on the label of the container or on the primary pack are clearly visible through that transparent covering.

6. General requirements

(1) 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 written:

(a) in the English language; and

(b) in durable and legible characters; and

(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 containing 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;

(e) identification of the person collecting the starting material for the biological (if applicable).

(4) If the container label has insufficient space to incorporate all the requirements of subsection (3), then the requirements in paragraphs (3)(d) and (e) must be provided with the product, as accompanying documentation.

(5) At release, the following information must be included on the container and primary pack label 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 and address;

(e) description of biological;

(f) collection date and/or date of manufacture and/or expiry date;

(g) storage conditions;

(h) size, volume, weight or concentration (as applicable);

(i) international units (if applicable);

(j) single patient use (if applicable);

(k) sterile (if applicable);

(l) additives and/or antimicrobial agents (if applicable);

(m) sterilisation/ bioburden reduction method (if applicable);

(n) suspending solution (if applicable);

(o) 'autologous use only' (if applicable);

(p) instructions for thawing (if applicable) and use;

(q) contraindications/precautions/adverse effects (if applicable);

(r) instructions for return (if applicable).

(6) If the container and primary pack label have insufficient space to incorporate all the requirements of subsection (5), then the requirements in paragraphs (5) (e) to (r) must be provided with the product, as accompanying documentation, at release.