Therapeutic Goods (Standard for Biologicals—Labelling Requirements) (TGO 107) Order 2021

I, John Skerritt, as delegate of the Minister for Health and Aged Care, make the following order.

Dated 24 September 2021

Adjunct Professor John Skerritt
Deputy Secretary
Health Products Regulation Group
Department of Health

Contents

Part 1—Preliminary

1 Name

(1) This instrument is the *Therapeutic Goods (Standard for Biologicals—Labelling Requirements) (TGO 107) Order 2021*.

(2) This instrument may also be cited as TGO 107.

2 Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	**Column 2**	**Column 3**
Provisions	**Commencement**	**Date/Details**
1. The whole of this instrument	30 September 2021.	30 September 2021

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under section 10 of the *Therapeutic Goods Act 1989*.

4 Definitions

Note: A number of expressions used in this instrument are defined in subsection 3(1) of the Act, including the following:

(a) batch;
(b) bioburden;
(c) biological;
(d) container;
(e) label;
(f) manufacture;
(g) primary pack;
(h) Register;
(i) standard.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

allogeneic use, in relation to a biological that comprises, contains or is derived from HCT materials, means administration to, or application in the treatment of, a person other than the person from whom the HCT materials used in the manufacture of the biological were collected.

autologous use, in relation to a biological that comprises, contains or is derived from HCT materials, means administration to, or application in the treatment of, the person from whom the HCT materials used in the manufacture of the biological were collected.

Class 1 biological has the same meaning as in the Regulations.

Class 2 biological has the same meaning as in the Regulations.

Class 3 biological has the same meaning as in the Regulations.

Class 4 biological has the same meaning as in the Regulations.

directed allogeneic use, in relation to a biological that comprises, contains or is derived from HCT materials, means allogeneic use for which all of the following paragraphs apply:

(a) the HCT materials used in the manufacture of the biological are collected by, or under the professional supervision or direction of, a medical or dental practitioner; and

(b) the biological is manufactured for administration to, or application in the treatment of, a designated patient who has a pre-existing condition by, or under the professional supervision or direction of, a medical or dental practitioner; and

(c) the medical or dental practitioners mentioned in paragraphs (a) and (b) are registered in a State or internal Territory.

expiry date has the same meaning as in the Regulations.

HCT materials means one or more of the following materials:

(a) human cells;

(b) human tissues;

(c) human stool;

that are collected for use in the manufacture of a biological and are:

(d) materials intended to comprise, or be contained in, the biological; or

(e) materials from which the biological is intended to be derived.

Regulations means the *Therapeutic Goods Regulations 1990*.

5 Standard

The matters specified in this instrument constitute a standard for biologicals in relation to labelling.

6 Application

(1) This instrument applies in relation to biologicals supplied in Australia, other than biologicals that are mentioned in item 13 of Schedule 5A to the Regulations, subject to compliance with the condition specified in that item.

(2) This instrument does not apply in relation to biologicals exported from Australia, other than the requirements specified in subsections 9(3) and 10(2).

7 Transitional arrangements

(1) In this section:

former instrument means the Therapeutic Goods Order No. 87 *General requirements for the labelling of biologicals*, as in force immediately before the commencement of the repeal instrument.

repeal instrument means the *Therapeutic Goods (Standards for Biologicals) Repeal Instrument 2021*.

transition period means the period beginning on 30 September 2021 and ending on 30 September 2022.

(2) Despite the repeal of the former instrument by the repeal instrument, the former instrument continues to apply for the duration of the transition period, such that the standard for biologicals in relation to labelling constituted by the former instrument may be conformed with as an alternative to the standard for biologicals in relation to labelling constituted by this instrument.

Part 2—Labelling requirements

8 General requirements

(1) The information that is displayed on a label of a biological or HCT materials must be:
  (a) in English; and
  (b) clearly visible and not obscured; and
  (c) in legible and durable characters, with a letter height of not less than 1.5 millimetres; and
  (d) in metric units of measurement.

(2) The label of a biological or HCT materials must:
  (a) be securely attached to the container and primary pack in which the biological or HCT materials are supplied; and
  (b) maintain integrity and remain attached to the container and primary pack at the relevant storage conditions for the biological and HCT materials.

(3) The container of a biological or HCT materials must be labelled to ensure traceability to the donor of the HCT materials at each step of manufacture.

(4) To avoid doubt, the requirements set out in this instrument do not apply in relation to transparent coverings, where those coverings enclose or wrap:

(a) a container containing HCT materials; or

(b) a container or primary pack containing a biological; and

the information required to be on or attached to the container or primary pack is clearly visible and not obscured by the covering.

9 Labels of HCT materials

(1) Subject to subsections (2) and (3), HCT materials must be labelled in accordance with the following:

(a) all information specified in the table in Schedule 1:

(i) must be on or attached to the container of the HCT materials; or

(ii) where the HCT materials are packaged in a sterile container—may instead be on or attached to the first external non-sterile layer of packaging of the HCT materials.

(2) If there is not sufficient space on the container of the HCT materials to include all information specified in the table in Schedule 1, then:

(a) the information specified in item 1 of the table in Schedule 1 must be on or attached to the container; and

(b) the information specified in items 2 to 5 of the table in Schedule 1 must be supplied with the container.

(3) HCT materials exported from Australia must be labelled with information specified in item 1 of Schedule 1, that is on or attached:

(a) to the container of the HCT materials; or

(b) where the HCT materials are packaged in a sterile container—to the first external non-sterile layer of packaging of the HCT materials.

10 Labels of biologicals

(1) Subject to subsection (2), a biological must be labelled in accordance with the following:

(a) all Part 1 information:

(i) must be on or attached to the container and the primary pack of the biological; or

(ii) where the biological is packaged in a sterile container— may instead be on or attached to the first external non-sterile layer of packaging and the primary pack of the biological; and

(b) all Part 2 information must be:

(i) on or attached to the container or the primary pack of the biological; or

(ii) supplied with the container or the primary pack of the biological, including where the information is contained in an electronic reference document, with a link or QR code to the document on or attached to the container or the primary pack of the biological.

(2) A biological exported from Australia must be labelled with information specified in item 1 of Part 1 of Schedule 2, that is on or attached:

(a) to the container or the primary pack of the biological; or

(b) where the biological is packaged in a sterile container—to the first external non-sterile layer of packaging and the primary pack of the biological.

(3) In this section:

Part 1 information, in relation to a biological, means the information specified in an item of the table in Part 1 of Schedule 2 if:

(a) the expression "in all cases" is mentioned in column 3 of that item; or

(b) the circumstances mentioned in column 3 of that item exist in relation to the biological.

Part 2 information, in relation to a biological, means the information specified in an item of the table in Part 2 of Schedule 2 if:

(a) the expression "in all cases" is mentioned in column 3 of that item; or

(b) the circumstances mentioned in column 3 of that item exist in relation to the biological.

Schedule 1—Labels in relation to HCT materials

Note: See section 9.

Information that must be on or attached to the container of HCT materials	
Column 1	**Column 2**
Item	**Information**
1	either of the following in relation to the donor: (a) unique identification number or alphanumeric; or (b) machine-readable code
2	the type of HCT materials
3	the date and time of the collection of the HCT materials
4	the name and address of the collection facility
5	the name of the designated person (if any) collecting the HCT materials

Schedule 2—Labels in relation to biologicals

Note: See section 10.

Part 1—Information on or attached to containers and primary packs

Information that must be on or attached to the container and primary pack of biologicals		
Column 1	**Column 2**	**Column 3**
Item	**Information**	**Circumstances**
1	either of the following in relation to the donor: (a) unique identification number or alphanumeric; or (b) machine-readable code	in all cases
2	the batch number	there is a batch number in relation to the biological
3	the product type or name	in all cases
4	both of the following: (a) the words "autologous use only"; and (b) the name or identifier of the intended recipient	the biological is for autologous use
5	the name or identifier of the designated patient	the biological is for directed allogeneic use
6	the name of the sponsor of the biological	in all cases

Part 2—Information on, attached to, or supplied with containers or primary packs

Information that must be on, attached to, or supplied with primary packs of biologicals		
Column 1	**Column 2**	**Column 3**
Item	**Information**	**Circumstances**
1	both of the following: (a) the words "autologous use only"; (b) the name or identifier of the intended recipient	the biological is for autologous use
2	the name or identifier of the designated patient	the biological is for directed allogeneic use
3	the name of the sponsor of the biological	in all cases
4	all of the following in relation to the sponsor's principal place of business in Australia: (a) the address; (b) the phone number; (c) the email address	in all cases
5	a description of the biological	in all cases
6	the approved indications of the biological	the biological is included in the Register as a Class 3 biological or Class 4 biological
7	the approved intended clinical use of the biological	the biological is included in the Register as a Class 1 biological or Class 2 biological
8	a description of the therapeutic uses of the biological	the biological is not included in the Register
9	the expiry date of the biological	in all cases
10	the storage conditions applicable to the biological	in all cases
11	the size, volume, weight or concentration of the biological, as applicable	there is a size, volume, weight or concentration associated with the biological
12	the words "single patient use"	the biological is for single patient use
13	the word "sterile" or words to that effect	the biological is sterile
14	the name of the additives or antimicrobial agents, as applicable	the biological has been treated with additives or antimicrobial agents
15	the name of the sterilisation or bioburden reduction process, as applicable	the biological has been subject to a sterilisation or bioburden reduction process
16	the name of the suspending solution	the biological is stored in a suspending solution

Information that must be on, attached to, or supplied with primary packs of biologicals		
Column 1	**Column 2**	**Column 3**
Item	**Information**	**Circumstances**
17	the instructions for preparation	the biological requires specific instructions for preparation
18	the instructions for use	in all cases
19	the precautions for use and special warnings	in all cases
20	the contraindications	in all cases
21	a description of the kinds of interactions	the biological may have interactions with other biologicals, medicines, or a physiological process of the intended recipient
22	a description of the incompatibilities	the biological may have incompatibilities
23	a warning of the potential impact on fertility, pregnancy, or breastfeeding, as applicable	the biological may have an impact on fertility, pregnancy, or breastfeeding
24	a warning of the potential impact on allergies	the biological may have an impact on allergies
25	a warning of the effect on personal behaviours and a description of those effects	the biological may affect the personal behaviours of the intended recipient
26	a warning of the adverse or undesirable effects	the biological may have adverse or undesirable effects
27	the instructions for reporting adverse events	in all cases
28	the instructions for return of the biological	the biological may be returned to the sponsor
29	the information on biochemical, biodynamic or biokinetic properties, as applicable	the biological is a Class 3 or Class 4 biological and there is information in relation to the biochemical, biodynamic or biokinetic properties of the biological
30	the information and outcomes of the clinical trials	the biological is a Class 3 or Class 4 biological in relation to which clinical trials have been undertaken
31	the information and outcomes from the preclinical safety studies about the risks relating to: (a) effects on fertility; (b) use in pregnancy; (c) genotoxicity; and (d) carcinogenicity	the biological is a Class 3 or Class 4 biological in relation to which preclinical safety studies have been undertaken