



Therapeutic Goods (Guidelines for Multi-Site Licences) Instrument 2020

I, Tracey Duffy, as delegate of the Secretary of the Department of Health, make the following instrument.

Dated 31 March 2020

Tracey Duffy
First Assistant Secretary
Medical Devices and Product Quality Division
Health Products Regulation Group
Department of Health

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1 Name

This instrument is the *Therapeutic Goods (Guidelines for Multi-Site Licences) Instrument 2020*.

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	The day after this instrument is registered.	1 April 2020

Note: This table relates only to the provisions of this instrument as originally made.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 38A 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) licence;
- (b) manufacture;
- (c) medicine;
- (d) supply; and
- (e) therapeutic goods.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

blood means whole blood collected from a single human donor and processed either for transfusion or further manufacturing.

blood components means any of the following therapeutic components of blood that can be prepared by centrifugation, filtration or freezing using conventional methodologies in blood establishment:

- (a) red cells;
- (b) white cells;
- (c) platelets;

(d) plasma;
but does not include haematopoietic progenitor cells.

haematopoietic progenitor cells means self-renewing or multi-potent stem cells, or both, capable of maturation into haematopoietic lineages, lineage-restricted pluri-potent progenitor cells, or committed progenitor cells.

in-process material means partly processed starting material that must undergo further manufacturing before it becomes therapeutic goods in final dosage form.

packaging material, in relation to therapeutic goods, means any material used in the packaging of the therapeutic goods, excluding any outer packaging or container required solely to transport the therapeutic goods.

plasma means plasma, separated from human donor blood, intended for a number of purposes including the manufacture of further blood components, the manufacture of which is required to be licensed under Part 3-3 of the Act.

quality system means the organisational structure, responsibilities, procedures, instructions, processes and resources for implementing quality management.

secondary-packaging, in relation to therapeutic goods, means packaging that is not designed to be in direct contact with the goods.

starting material means:

- (a) in relation to therapeutic goods other than blood, blood components, haematopoietic progenitor cells or human tissue—any material used in the manufacture of the therapeutic goods, but excluding packaging material;
- (b) in relation to therapeutic goods that are blood, blood components, haematopoietic progenitor cells or human tissue—any material used in the manufacture of the therapeutic goods that may contact, or be included as an ingredient or component in, the therapeutic goods.

5 Circumstances for multi-site licence—manufacture of therapeutic goods other than blood, blood components, haematopoietic progenitor cells or human tissue

- (1) This section applies to the manufacture of therapeutic goods other than blood, blood components, haematopoietic progenitor cells or human tissue.
- (2) A licence may cover two or more manufacturing sites where all of the following paragraphs apply:
 - (a) steps in the manufacture of the therapeutic goods are to be carried out at one fixed site, and any additional site or sites are to be used for carrying out the following steps:
 - (i) the storage of primary packaging materials, starting materials, in-process materials or finished product; or
 - (ii) the secondary packaging of finished product; or
 - (iii) the release for supply of packaging materials, starting materials, in-process materials, or finished product; and

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- (b) all steps in the manufacture of the therapeutic goods are to be covered by a single quality system; and
 - (c) all sites are capable of being inspected within the relevant period; and
 - (d) all sites are located with sufficient proximity such that the total travel time between the sites under inspection does not exceed 60 minutes.

6 Circumstances for multi-site licence—manufacture of blood, blood components, haematopoietic progenitor cells or human tissue

- (1) This section applies to the manufacture of therapeutic goods that are blood, blood components, haematopoietic progenitor cells or human tissue.
- (2) A licence may cover two or more manufacturing sites where all of the following paragraphs apply:
 - (a) steps in the manufacture of the therapeutic goods are to be carried out at one fixed site, and any additional site or sites are to be used for carrying out the following steps:
 - (i) in relation to a fixed site—the storage of packaging materials, starting materials, in-process materials, or finished product;
 - (ii) in relation to a mobile (non-fixed) site—the collection of blood or blood components; and
 - (b) all steps in the manufacture of the therapeutic goods are to be covered by a single quality system; and
 - (c) all sites are capable of being inspected within the relevant period; and
 - (d) all sites are located with sufficient proximity such that the total travel time between the sites under inspection does not exceed 60 minutes.

7 Repeals

Each instrument that is specified in Schedule 1 is repealed as set out in the applicable items in that Schedule.

Schedule 1—Repeals

Therapeutic Goods (Multi-Site Manufacturing Licences) Guidelines of 2010

1 The whole of the instrument

Repeal the instrument.