Therapeutic Goods Amendment (Excluded Goods) Determination 2019

I, Jane Cook, as delegate of the Minister for Health, make the following determination.

Dated 20 June 2019

Jane Cook
First Assistant Secretary
Medicines Regulation Division
Health Products Regulation Group
Department of Health

Contents

1 Name

This instrument is the *Therapeutic Goods Amendment (Excluded Goods) Determination 2019*.

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.	

Note: This table relates only to the provisions of this instrument as originally made.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 7AA of the *Therapeutic Goods Act 1989*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

Therapeutic Goods (Excluded Goods) Determination 2018

1 Section 3

Omit "Act", substitute "*Therapeutic Goods Act 1989*".

2 Section 4

Insert:

haematopoietic progenitor cells has the meaning given by clause 1 of Part 1 of Schedule 9 to the Regulations.

Regulations means the *Therapeutic Goods Regulations 1990*.

3 Schedule 2 (after table item 4)

Insert:

4A	goods in relation to which the following paragraphs apply: (a) the goods comprise, contain or are derived from, human cells or human tissues collected from a patient (the ***relevant patient***) who is under the clinical care of a medical or dental practitioner (the ***relevant practitioner***); (b) the relevant practitioner is registered in a State or internal Territory; (c) subject to paragraph (d), all steps in the manufacture of the goods are carried out by, or under the professional supervision of, the relevant practitioner in a hospital in a State or internal Territory (the ***relevant hospital***); (d) if a step in the manufacture of the goods relating to the storage or testing of the goods is not carried out in the relevant hospital, it is carried out by a person under contract with the relevant hospital	when the goods are: (a) used for the relevant patient, who is a patient of the relevant hospital; and (b) not advertised directly to consumers
4B	goods that are fresh viable human haematopoietic progenitor cells	when used for direct donor-to-host transplantation for the purpose of

		haematopoietic reconstitution
4C	goods that are fresh viable human organs or parts of human organs	when used for direct donor-to-host transplantation
4D	goods that are human reproductive tissue	when used in assisted reproductive therapy

4 Schedule 2 (note at the end)

Repeal the note.

Schedule 2—Repeals

Therapeutic Goods (Human Cells, Tissues and Organs) Determination 2018

1 The whole of the instrument

Repeal the instrument.