

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

*Therapeutic Goods Act 1989*

I, LARRY KELLY, a delegate of the Minister for Health for the purposes of section 7AA of the *Therapeutic Goods Act 1989* (the Act) and acting under subsection 7AA(2) of the Act, make the following determination specifying goods that are excluded goods for the purposes of the Act.

Dated 15 June 2018

(*signed by*)

**LARRY KELLY**

Delegate of the Minister for Health

1 Name of Determination

This Determination is the *Therapeutic Goods (Human Cells, Tissues and Organs) Determination 2018*.

2 Commencement

This Determination commences on 1 July 2018.

3 Authority

This Determination is made under subsection 7AA(2) of the *Therapeutic Goods Act 1989*.

4 Goods that are excluded goods

The following specified goods, being goods intended for use in humans, are excluded goods for the purposes of the *Therapeutic Goods Act 1989*:

1. Therapeutic goods in relation to which the following apply:
2. the goods comprise, contain or are derived from human cells or human tissues collected from a patient who is under the clinical care of a medical or dental practitioner;
3. the goods were manufactured by, or under the professional supervision of, the practitioner in a hospital in a State or internal Territory for that patient who must be a patient of that hospital;
4. the practitioner is registered in a State or internal Territory;
5. the goods are not advertised directly to consumers;
6. fresh viable human organs, or parts of human organs, for direct donor-to- host transplantation and used in accordance with applicable laws and standards;
7. fresh viable human haematopoietic progenitor cells for direct donor-to-host transplantation for the purpose of haematopoietic reconstitution;
8. reproductive tissue for use in assisted reproductive therapy.