EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

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

The object of the *Therapeutic Goods Act 1989* (the Act) is to establish and maintain a national system of controls for the quality, safety, efficacy/performance and timely availability of therapeutic goods that are used in Australia or exported from Australia. The Therapeutic Goods Administration (the TGA), which is part of the Department of Health (the Department), is responsible for administering the Act.

Subsection 7AA(2) of the Act provides that the Minister may, by legislative instrument, determine that specified goods (other than goods declared to be therapeutic goods under an order in force under section 7) when used, advertised or presented for supply in a way specified in the determination, are excluded goods for the purposes of this Act. Before making such a determination, the Minister must have regard to the matters listed in subsection 7AA(3), and any other matter the Minister considers relevant (subsection 7AA(4) refers).

Section 4 of the *Therapeutic Goods (Excluded Goods) Order No. 1 of 2011* (the EGO), made under subsection 7(1) of the Act, declares a number of goods for use in humans not to be therapeutic goods for the purposes of the Act. Paragraph 4(q) of the EGO refers to this end to human tissues and cells collected from a patient under the clinical care of a registered medical practitioner, that are manufactured by the practitioner (or a person under their professional supervision) for use in the treatment of the same person from whom they were collected (autologous human cell and tissue (HCT) products). Examples of autologous HCT products include skin grafts for the treatment of burns, bone grafts and bone marrow transplants.

However, there is growing global concern in relation to the risks that such products and related treatments may pose to patient safety, and in relation to the advertising of such products directly to consumers. The *Therapeutic Goods Legislation Amendment (2018 Measures No. 2) Regulations 2018* (the Regulations) amended the *Therapeutic Goods Regulations 1990* to address these concerns by introducing an appropriate level of regulatory oversight for autologous HCT products, commensurate with the safety risks to patients.

Only autologous HCT products that are collected, and manufactured, by a registered medical or dental practitioner in a hospital would continue to be excluded from the regulatory scheme. The principal purpose of the *Therapeutic Goods (Human Cells, Tissues and Organs) Determination 2018* (the Determination) is to reflect this. Amendments to remove paragraph 4(q) from the EGO have also separately been made to ensure consistency with the Regulations.

In addition, the Determination also excludes from the regulatory scheme the products mentioned in paragraphs 4(o), 4(p) and 4(r) of the EGO, which relate to: fresh viable human organs, or parts of human organs, for direct donor-to- host transplantation and used in accordance with applicable laws and standards; fresh viable human haematopoietic progenitor cells for direct donor-to-host transplantation for the purpose of haematopoietic reconstitution; and reproductive tissue for use in assisted reproductive therapy.

It is considered that these goods would be more appropriately covered by a determination under section 7AA(1) because these goods are, in most circumstances, likely to be therapeutic goods.

In relation to these goods, and in relation to the autologous HCT products that are excluded from the regulatory scheme by the Determination (i.e. collected, and manufactured, by a registered medical or dental practitioner in a hospital), the matters mentioned in subsection 7AA(3) of the Act have been carefully considered. In particular, it is noted that:

- as these products, by their nature, are principally likely to be supplied and used in a hospital setting, and as they have been treated under the EGO as not being therapeutic goods for some time, it is not considered likely that they would harm the health of members of the public if they were not regulated under the Act, for the purposes of paragraph 7AA(3)(a) of the Act;
- as the supply and use of these products would principally be controlled by medical practitioners and be the subject of consultation between practitioner and patient, it is not considered appropriate in all the circumstances to apply the national system of controls relating to the quality, safety and efficacy and performance of therapeutic goods established by the Act to regulate them under the Act, for the purposes of paragraph 7AA(3)(b) of the Act;
- as such, the kinds of risks that these products may pose would be best managed by the medical or dental practitioners, including specialists, who would be involved in the transplantation or use of these products in the relevant hospital setting, for the purposes of paragraph 7AA(3)(c) of the Act (in addition, the medical and dental practitioners would be subject to regulation by the Australian Health Practitioner Regulation Agency (APHRA)).

Details of the Determination are set out in the Attachment.

The Act specifies a number of matters that the Minister must have regard to before making a determination under section 7AA (subsections 7AA(3) and (4) refer). These matters have been taken into consideration in the making of this Determination.

The Determination is a legislative instrument for the purposes of the *Legislation Act 2003*.

The Determination commences on 1 July 2018.

Consultation

Public consultations on proposed changes to the regulation of autologous HCT products were undertaken in January 2015 and August 2016. In all, the TGA received 141 submissions from groups or individuals. It was a common view among those making submissions that the current level of regulatory oversight for autologous HCT products was not adequate, and there was almost unanimous support for strengthening the therapeutic goods regulatory framework for HCT products for autologous use. The responses predominantly supported options that would reduce the amount of autologous HCT products that are not covered by regulation under the Act, and support for prohibiting direct to consumer advertising. However, some organisations expressed concern that regulatory change may hinder their business operations. The feedback from these consultations was carefully considered in the design of the proposed amendments.

Authority: Subsection 7AA(2) of the *Therapeutic Goods Act 1989*

ATTACHMENT

Details of the *Therapeutic Goods (Human Cells, Tissues and Organs) Determination 2018*

Section 1 – Name
This section provides for the Determination to be referred to as the *Therapeutic Goods (Human Cells, Tissues and Organs) Determination 2018*.

Section 2 – Commencement
This section provides for the commencement of the Determination on 1 July 2018.

Section 3 – Authority
This section provides that the Determination is made under subsection 7AA(2) of the *Therapeutic Goods Act 1989* (the Act).

Section 4 – Goods that are excluded
This section provides that the listed goods, being goods intended for use in humans, are excluded goods for the purposes of the Act.

Paragraph 4(a) excludes goods that comprise, contain or are derived from human cells and tissues where the collection, manufacture and use occur in the hospital setting, regardless of the level of manipulation and processing of the human cells and tissues, provided it occurs in a hospital. This exclusion only applies in the following circumstances: (1) the patient must be under the clinical care of a medical or dental practitioner; (2) the goods must have been 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; (3) the practitioner must be registered in a State or internal Territory; and (4) the goods must not be advertised directly to consumers.

Paragraph 4(b) excludes fresh viable human organs, or parts of human organs, for direct donor-to- host transplantation and used in accordance with applicable laws and standards.

Paragraph 4(c) excludes fresh viable human haematopoietic progenitor cells for direct donor-to-host transplantation for the purpose of haematopoietic reconstitution.

Paragraph 4(d) excludes reproductive tissue for use in assisted reproductive therapy.

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

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

The *Therapeutic Goods (Human Cells,Tissues and Organs) Determination 2018* (the Determination) is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Legislative Instrument

The object of the *Therapeutic Goods Act 1989* (the Act) is to establish and maintain a national system of controls for the quality, safety, efficacy/performance and timely availability of therapeutic goods that are used in Australia or exported from Australia. Subsection 7AA(2) of the Act provides that the Minister may, by legislative instrument, determine that specified goods (other than goods declared to be therapeutic goods under an order in force under section 7) are excluded goods for the purposes of the Act when used, advertised or presented for supply in a way specified in the determination. The Minister must, however, have regard to the matters listed in subsection 7AA(3) and any other matter the Minister considers relevant.

The *Therapeutic Goods (Excluded Goods) Order No. 1 of 2011* (the EGO), made under subsection 7(1) of the Act, excludes autologous human cells and tissues (HCT) products where the HCT are removed from, and applied to, the same person (with or without processing the cells and tissues). Examples include skin grafts for the treatment of burns and bone marrow transplants. However, due to growing global concern about the risks that such products may pose to patient safety, the *Therapeutic Goods Legislation Amendment (2018 Measures No. 2) Regulations 2018* introduced an appropriate level of regulatory oversight for most of these products.

The purpose of the Determination is to exclude from the regulatory scheme only autologous HCT products that are collected, and manufactured, by a registered medical or dental practitioner in a hospital. Consequential amendments will be made to the EGO. A number of other products are also included in the Determination and will be removed from the EGO. These are: fresh viable human organs, or parts of human organs, for direct donor-to- host transplantation and used in accordance with applicable laws and standards; fresh viable human haematopoietic progenitor cells for direct donor-to-host transplantation for the purpose of haematopoietic reconstitution; and reproductive tissue for use in assisted reproductive therapy.

Human rights implications

As the Determination does not introduce any changes regulations other than to implement the changes outlined above, they do not appear to engage any of the applicable rights or freedoms.

Conclusion

This legislative instrument is compatible with human rights as it does not raise any human rights issues.

Larry Kelly, Delegate of the Minister for Health