EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Standard for Blood and Blood Components) (TGO 102) Order 2019

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

Subsection 10(1) of the Act relevantly provides that the Minister may, by legislative instrument, make an order determining that matters specified in the order constitute a standard for therapeutic goods or a class of therapeutic goods identified in the order. Offence and civil penalties may apply if therapeutic goods (other than medical devices) that do not comply with an applicable standard are imported, exported or supplied. The Secretary may, however, consent in writing to the import, supply or export of such goods notwithstanding their non-compliance (sections 14 and 14A of the Act refer).

Without limiting the generality of subsection 10(1), subsection 10(2) relevantly provides that an order establishing a standard for therapeutic goods may be specified by reference to a variety of matters including the quality of the goods, the procedures to be undertaken in their manufacture or a monograph in the British or European Pharmacopoeia or in the United States Pharmacopeia-National Formulary. In addition, an order may require matters relating to the standard to be determined in accordance with particular tests.

The *Therapeutic Goods (Standard for Blood and Blood Components) (TGO 102) Order 2019* ("the Order") is made by a delegate of the Minister for Health under section 10 of the Act.

The purpose of the Order is to establish a ministerial standard for therapeutic goods that are blood and blood components. The Order specifies the minimum requirements for the safety and quality of blood and blood components, other than those that are collected or manufactured in a small number of specified circumstances.

The Order repeals and replaces the existing Therapeutic Goods Order No 81 Standard for Blood and Blood Components ("the former Order"), which was made in 2008 and due to sunset on 1 April 2019 under the sunsetting provisions of the *Legislation Act 2003*.

The Order also makes a minor, consequential amendment to the Therapeutic Goods (Manufacturing Principles) Determination 2018 ("the Manufacturing Principles"), under section 36 of the Act, to replace a reference to the former Order in that instrument with a reference to the Order.

The Order commences on 31 March 2019.

Background

The Australian Government is responsible for regulating the quality, safety and efficacy of therapeutic goods. This is principally achieved by specifying ministerial standards for the

manufacture of those products, and otherwise applying default standards specified in international pharmacopoeias.

The Order specifies critical minimum benchmark requirements in relation to safety and quality for therapeutic goods that are blood and blood components. Blood is defined in the Order as whole blood collected from a single human donor that is processed either for transfusion or further manufacturing. Blood components are defined in the Order as specified components of blood (red cells, white cells, platelets or plasma) that can be prepared by centrifugation, filtration or freezing using conventional methodologies in blood establishment. However, the Order makes it clear that the term 'blood components' does not include haematopoietic progenitor cells.

The Order principally requires that blood and blood components to which it applies comply with the requirements specified for such products in the *Guide to the preparation, use and quality assurance of blood components*, 19th edition, 2017, published by the Council of Europe and as in force or existing immediately before the commencement of the Order ("the Guide"), with the proviso, noted in subsection 7(2), that the reference to 'tropical areas' in the Guide that relates to the deferral period for the condition *Tropical infections* in Table 2.2 *Conditions leading to temporary deferral (suspension)* on page 253 of the Guide are to be taken to not include areas within Australia. The Guide can be found (and is freely available) on the internet at https://www.edqm.eu/en/blood-transfusion-guide.

The Guide represents a compendium of requirements that are harmonised across the Council of Europe member states and that are designed to ensure the quality of blood components used in transfusion. It contains standards and recommendations on blood collection, preparation and use of blood and its components, and elements of quality management for blood establishments and hospital blood banks. It represents the basis for the establishment of national regulations for such states, and certain European Directives.

The principal difference between the Order and the former Order is the update from the 14th edition of the Guide to the 19th edition.

The adoption of the 19th edition of the Guide by the Order includes a number of enhancements to the regulation of blood and blood components that have been introduced in Europe to improve the safety and efficacy of blood and blood components since the adoption of the 14th edition of the Guide by the former Order in 2008. These changes include a requirement for donor suitability records and final assessments to be signed by a qualified health professional; reductions in some donor deferral periods to improve supply; and changes to irradiation timeframes for red cells for neonatal and infant small volume transfusions. In so doing, the adoption of the 19th edition of the Guide will help ensure the international consistency and quality of blood and blood components in Australia.

Other than the update of the edition of the Guide as outlined above, only a small number of minor, drafting changes have been made in the Order compared to the former Order.

However, to assist industry to transition, the Order provides a transition period of 12 months (from 31 March 2019 to 30 March 2020) in which the former Order may be conformed with (despite its repeal by section 9 of the Order) as an alternative to the standard for blood and blood components constituted by the Order.

It should also be noted that the Order does not apply to therapeutic goods that are blood or blood components that are:

(a) collected by a medical practitioner, registered under a law of a State or Territory, or a person under the professional supervision of such a practitioner, in the course of medical treatment and for the purposes of diagnosis of, and testing for, a medical condition;

(b) manufactured by a medical practitioner, registered under a law of a State or Territory, or a person under the professional supervision of such a practitioner, for therapeutic application to a patient under the practitioner's care; or

(c) manufactured by a blood donation centre for a medical practitioner, registered under a law of a State or Territory, for therapeutic application to a particular patient under the practitioner's care.

In these instances a treating medical practitioner is taking professional responsibility for the manufacture and use of the product for a patient in their care.

Consequential amendment to the Manufacturing Principles

The Manufacturing Principles are made under section 36 of the Act, and are designed to set out the minimum requirements to be observed in the manufacture of therapeutic goods other than medical devices, to ensure that therapeutic goods are produced to a high quality.

It is a condition of each manufacturing licence that manufacturers of therapeutic goods comply with the manufacturing principles (see subparagraph 40(4)(a)(ii) of the Act). If the holder of a manufacturing licence breaches this (or any other) condition the Secretary can suspend or revoke the licence (see subparagraph 41(1)(a)(viii) of the Act). The Secretary can also refuse to grant a manufacturing licence if satisfied that the applicant for the licence will be unable to comply with the manufacturing principles (see paragraph 38(1)(e) of the Act).

The requirements in relation to blood and blood components are set out in Division 2 of the Manufacturing Principles. These include (relevantly) that:

- a manufacturer of blood and blood components, plasma or haematopoietic progenitor cells must lodge a Technical Master File with an application for a manufacturing licence under Part 3-3 of the Act (section 6 refers); and

- blood, blood components, plasma and haematopoietic progenitor cells must be manufactured in a manner consistent with the relevant Technical Master File lodged for the goods by the manufacturer (section 7 refers).

'Technical Master File' is defined in section 4 of the Manufacturing Principles and this definition includes the following in paragraph b of the definition:

> b. detailed scientific and technical data or information that must satisfy the Secretary that:
>
> > i. the blood or blood components, manufactured using the steps of manufacture mentioned in paragraph (a), will meet Therapeutic Goods Order No.81 – Standards for Blood and Blood Components;

As the Order repeals the former Order, there is therefore a need to update the definition of 'Technical Master File' in section 4 of the Manufacturing Principles to replace the reference to the repealed instrument with an updated reference to the Order.

This change to the Manufacturing Principles is a minor, consequential measure designed to ensure the consistency of the Manufacturing Principles with the Order.

Consultation

The TGA consulted the main industry sponsor of blood and blood components in Australia, the Australian Red Cross Blood Service (the Blood Service), on the proposal to remake the former Order without substantial change other than to update the Guide to the 19th edition. The Blood Service is currently the sole industry organisation involved in the collection and manufacture of blood and blood products for therapeutic use in Australia.

The Blood Service indicated that they were fully supportive of the proposal to prepare the Order, and to update the requirements in the Order to align with the 19th edition of the Guide, particularly as ten years have passed since the former Order adopted the 14th edition of the Guide.

As part of this consultation, the Blood Service undertook a full comparison and gap analysis between the 14th and 19th editions of the Guide to identify all of the differences between the two documents and to assess the impact of moving to the later edition. Following this analysis, which was shared with the TGA, the Blood Service confirmed its position that the impact of the proposed changes would be outweighed by the benefits of adopting the 19th edition. The Blood Service also requested a 12 month transition period for full compliance with the Order to minimise any regulatory impact of the changes. The Order reflects this in the transitional arrangements in section 8 of the Order by providing that despite its repeal by section 9 of the Order, the former Order continues to apply between 31 March 2019 and 30 March 2020 as an alternative to the standard for blood and blood components constituted by the Order.

The Office of Best Practice Regulation (OBPR) has advised that a regulation impact statement is not required in relation to the re-making of the former Order (OBPR reference: 24015).

Incorporation by reference

Paragraph 7(1)(a) of the Order has the effect that the applicable requirements for blood and blood components under the Order include compliance with the *Guide to the preparation, use and quality assurance of blood components* ("the Guide"). The Guide is defined in section 4 of the Order by reference to the 19th edition of that document, published in 2017 by the Council of Europe, as in force or existing immediately before the commencement of this instrument.

The Guide can be found (and is freely available) on the internet at: https://www.edqm.eu/en/blood-transfusion-guide.

Details of the Order are set out in **Attachment A**.

The Order is compatible with the human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in **Attachment B**.

The Order is a disallowable legislative instrument, and commences on 31 March 2019.

Attachment A

Details of the *Therapeutic Goods (Standard for Blood and Blood Components) (TGO 102) Order 2019*

Section 1 Name

This section provides that the name of the Order is the *Therapeutic Goods (Standard for Blood and Blood Components) (TGO 102) Order 2019*. It may also be cited as TGO 102.

Section 2 Commencement

This section provides that the Order commences on 31 March 2019.

Section 3 Authority

This section provides that the legislative authority for making the Order is sections 10 and 36 of the *Therapeutic Goods Act 1989* ("the Act").

Section 4 Definitions

This section sets out definitions for a number of terms used in the Order. In particular these include 'blood', 'blood components' and 'the Guide'. The section also notes that a number of terms have the same meaning as in the Act, including 'manufacture' and 'therapeutic goods'.

Section 5 Standard

This section provides that the Order constitutes a standard for blood and blood components.

Section 6 Application

This section provides that this Order applies to therapeutic goods that are blood and blood components, other than those identified in subsection 6(2) (principally, these are blood and blood components that are collected or manufactured by a registered medical practitioner or someone under their professional supervision, for specified purposes such as for therapeutic application to a patient).

Section 7 Requirements

This section has the effect that the requirements in relation to blood and blood components are principally those set out in the Guide, with the qualification that the reference to 'tropical areas' in the Guide that relates to the deferral period for the condition *Tropical infections* in Table 2.2 *Conditions leading to temporary deferral (suspension)* on page 253 of the Guide are to be taken to not include areas within Australia.

This section also provides that blood and blood components must only be manufactured from blood where samples of that blood test negative for hepatitis B virus (HBV), hepatitis C virus (HCV) and human immunodeficiency virus (HIV-1) using nucleic acid amplification technology, and that blood and blood components must not be manufactured from donors:

(a) who lived in or visited England, Scotland, Wales, Northern Ireland or the Isle of Man for a cumulative period of 6 months or more, at any time on or between 1 January 1980 and 31 December 1996; or

(b) who received a transfusion or injection of blood or blood products while in England, Scotland, Wales, Northern Island or the Isle of Man, at any time on or after 1 January 1980.

Section 8 Transitional arrangements

This section has the effect that, despite its repeal by section 9, the former Order continues to apply as an alternative to the Order as a standard for blood and blood components for the period 31 March 2019 to 30 March 2020. This is designed to allow time for the Blood Service to make any adjustments and preparations necessary for its full compliance with the Order from 31 March 2020.

Section 9 Repeals

This section provides that the instruments specified in Schedule 1 are repealed.

Section 10 Consequential amendments

This section provides that the instruments specified in Schedule 2 are amended as set out in the applicable items in that Schedule.

Schedule 1—Repeals

This Schedule repeals the Therapeutic Goods Order No 81 Standards for Blood and Blood Components.

Schedule 2—Consequential amendments

This Schedule provides for the amendment of the Therapeutic Goods (Manufacturing Principles) Determination 2018 by omitting, in paragraph (b) of the definition of "Technical Master File*"* in section 4, "Therapeutic Goods Order No.81 – Standards for Blood and Blood Components" and substituting "*Therapeutic Goods (Standard for Blood and Blood Components) (TGO 102) Order 2019*".

Attachment B

Statement of Compatibility with Human Rights

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

This disallowable legislative instrument 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 *Therapeutic Goods (Standard for Blood and Blood Components) (TGO 102) Order 2019* ("the instrument") is made by the Minister under section 10 of the *Therapeutic Goods Act 1989* ("the Act").

The matters specified in the instrument constitute a standard for therapeutic goods that are blood and blood components. The purpose of the instrument is to specify important minimum requirements for the safety and quality of blood and blood components, other than those that are collected or manufactured in a small number of specified circumstances (for example, where they are manufactured by a blood donation centre for a medical practitioner for therapeutic application to a particular patient under the practitioner's care).

The instrument also:

- repeals and replaces the existing Therapeutic Goods Order No 81 Standard for Blood and Blood Components ("the former instrument"), which was made in 2018 and is due to sunset on 1 April 2019 under the sunsetting provisions of the *Legislation Act 2003*; and

- makes a minor, consequential amendment to the Therapeutic Goods (Manufacturing Principles) Determination 2018 ("the Manufacturing Principles") to replace a reference to the former instrument with a reference to the instrument to ensure the consistency of the Manufacturing Principles with the new instrument.

The instrument commences on 31 March 2019.

'Blood' is defined in the instrument as whole blood collected from a single human donor that is processed either for transfusion or further manufacturing, and 'blood components' are defined as specified components of blood (red cells, white cells, platelets or plasma) that can be prepared by centrifugation, filtration or freezing using conventional methodologies in blood establishment. However, the instrument makes it clear that the term blood components do not include haematopoietic progenitor cells.

The instrument principally requires that blood and blood components to which it applies comply with the requirements specified for such products in the *Guide to the preparation, use and quality assurance of blood components*, 19th edition, 2017, published by the Council of Europe and as in force or existing immediately before the commencement of the instrument (the Guide), with the proviso, noted in subsection 7(2), that the reference to 'tropical areas' in the Guide that relates to the deferral period for the condition *Tropical infections* in Table 2.2

Conditions leading to temporary deferral (suspension) on page 253 of the Guide are to be taken to not include areas within Australia. The Guide can be found (and is freely available) on the internet at https://www.edqm.eu/en/blood-transfusion-guide.

The Guide represents a compendium of requirements that are harmonised across the Council of Europe member states and that are designed to ensure the quality of blood components used in transfusion. It contains standards and recommendations on blood collection, preparation and use of blood and its components, and elements of quality management for blood establishments and hospital blood banks. It represents the basis for the establishment of national regulations for such states, and certain European Directives.

The principal difference between the instrument and the former order is the update from the 14th edition of the Guide to the 19th edition.

The adoption of the 19th edition of the Guide by the instrument includes a number of enhancements to the regulation of blood and blood components that have been introduced in Europe to improve the safety and efficacy of blood and blood components since the adoption of the 14th edition of the Guide by the former instrument in 2008. These changes include a requirement for donor suitability records and final assessments to be signed by a qualified health professional; reductions in some donor deferral periods to improve supply; and changes to irradiation timeframes for red cells for neonatal and infant small volume transfusions. In so doing, the adoption of the 19th edition of the Guide will help ensure the international consistency and quality of blood and blood components in Australia.

To assist industry to transition to the instrument, it provides a transition period of 12 months (from 31 March 2019 to 30 March 2020) in which the former instrument may still be conformed with (despite its repeal by section 9 of the instrument) as an alternative to the standard for blood and blood components constituted by the instrument.

The instrument also makes a minor, consequential amendment to the Manufacturing Principles to replace a reference to the former instrument in the definition of 'Technical Master File' in section 4 of the Manufacturing Principles with an updated reference to the new instrument.

Human rights implications

The instrument engages the right to health in Article 12 of the *International Covenant on Economic, Social and Cultural Rights* ("the ICESCR").

Article 12 of the ICESCR promotes the right of all individuals to enjoy the highest attainable standard of physical and mental health, and includes an obligation to take reasonable measures within available resources to progressively secure broader enjoyment of the right. In *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12)* (2000), the United Nations Committee on Economic, Social and Cultural Rights states that health is a 'fundamental human right indispensable for the exercise of other human rights', and that the right to health is not to be understood as the right to be healthy, but includes the right to a system of health protection which provides equal opportunity for people to enjoy the highest attainable level of health.

The instrument takes positive steps to promote the right to health by ensuring the quality and safety of blood and blood components by requiring those products to be manufactured in accordance with the Guide. By ensuring that important minimum standards are in place in relation to the safety and quality of blood and blood components in Australia (including in relation to very serious diseases such as human immunodeficiency virus (HIV)), the instrument is designed to ensure that all such products that are supplied in Australia are safe for use, are scientifically and medically appropriate and are of good quality for consumers.

In so doing, the instrument addresses the element of the right to health that relates to the prevention, treatment and control of diseases (Article 12.2(c)) through the establishment of requirements that are designed to avoid the contamination of blood and blood contaminants with serious diseases including HIV, and through supporting the quality of blood and blood components supplied for use in Australia.

The requirements of the instrument are further bolstered in this regard by the criminal, civil and regulatory sanctions that may apply under the Act for persons who import, supply or export therapeutic goods that do not comply with applicable standards.

Conclusion

This instrument is compatible with human rights because it promotes the right to health in Article 12 of the ICESCR as outlined above, and otherwise does not raise any human rights issues.

Jane Cook, delegate of the Minister for Health