

## **EXPLANATORY STATEMENT**

### *Therapeutic Goods Act 1989*

#### *Therapeutic Goods (Standard for Human Albumin) (TGO 111) Order 2022*

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 Act is administered by the Therapeutic Goods Administration (“the TGA”) within the Australian Government Department of Health.

Subsection 10(1) of the Act 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. Subsection 10(2) provides that an order establishing a standard for therapeutic goods may be specified by reference to (among others) a monograph in the British Pharmacopoeia or the European Pharmacopoeia. Under subsection 10(3A) of the Act, the Minister may vary or revoke an order made under subsection 10(1) by legislative instrument.

Importantly, a person who imports, exports or supplies therapeutic goods that do not conform to an applicable standard may be subject to offence and civil penalty provisions in sections 14 and 14A of the Act. The Secretary may, however, give consent in writing in relation to the importation, exportation or supply of therapeutic goods that do not conform to an applicable standard, in accordance with those sections.

The *Therapeutic Goods (Standard for Human Albumin) (TGO 111) Order 2022* (“the Order”) is made under section 10 of the Act for the purpose of establishing a ministerial standard for human albumin used as a therapeutic good, by reference to the monograph for human albumin in the British Pharmacopoeia and the European Pharmacopoeia. The Order repeals and replaces the Therapeutic Goods Order No. 90 Standard for human albumin (“the Former Order”), which would otherwise sunset on 1 April 2022.

### **Background**

The Australian Government is responsible for regulating the quality, safety and efficacy of therapeutic goods. This is achieved in part by specifying ministerial standards under section 10 of the Act by reference to a range of matters, including the manufacture of therapeutic goods, and by otherwise applying default standards that are constituted by statements in international pharmacopoeias defined in subsection 3(1) of the Act, being the British Pharmacopoeia, European Pharmacopoeia and United States Pharmacopoeia-National Formulary.

The Former Order is a standard that specifies that albumin from humans must comply with the monograph for human albumin in the British Pharmacopoeia or the European Pharmacopoeia, with the effect of principally excluding the monograph for human albumin in the United States Pharmacopoeia-National Formulary. The United States Pharmacopoeia-National Formulary was excluded by the Former Order due to:

- concerns regarding the potential clinical implications or regulatory impacts arising from significant inconsistencies in the requirements set out in the United States Pharmacopoeia-National formulary in comparison to the British Pharmacopoeia and the European Pharmacopoeia, including the lack of Nucleic Acid Amplification Technology testing of starting plasma, and concerns that this could present an increased risk of infectious disease and inadequate product characterisation; and
- the monograph not being self-contained. That is, the monograph refers to, or relies on, United States of America (US) legislation or decisions of the US Food and Drug Administration.

These concerns remain current in relation to the approach taken in the United States Pharmacopoeia-National Formulary, and accordingly the Order has the effect of repealing and replacing the Former Order without modification.

### **Incorporation by reference**

The Order specifies requirements for human albumin by reference to the British Pharmacopoeia and the European Pharmacopoeia. The note in section 4 of the Order makes it clear that each pharmacopoeia is as defined in subsection 3(1) of the Act. Subsection 10(4) of the Act expressly allows for dynamic incorporation of documents in an order made under subsection 10(1) of the Act, despite subsection 14(2) of the *Legislation Act 2003* (“the Legislation Act”). These pharmacopoeias are incorporated in the Order as in force or existing from time to time, in accordance with these provisions and may be accessed from [www.pharmacopoeia.com/](http://www.pharmacopoeia.com/) and <https://pheur.edqm.eu/home>.

While unfortunately these pharmacopoeias are not available for free, it is anticipated that the persons most affected by their adoption in this Order (sponsors of human albumin for therapeutic use), would be in possession of these documents in order to manufacture the medicine or ingredients. As important international benchmarks for the safety and quality of human albumin products, it would be infeasible from a regulatory perspective to not adopt such benchmarks on the basis that the publications are not available for free.

However, by prior written arrangement with the TGA, members of the public may request to view the pharmacopoeias without charge at the TGA office in Symonston, ACT.

It should also be noted that the National Library’s Trove online system ([www.trove.nla.gov.au](http://www.trove.nla.gov.au)) allows users to identify libraries in Australia that are open to the public where editions (in most cases, earlier editions) of the pharmacopoeias may be viewed (for example, the University of Tasmania or the University of Western Australia in relation to the British Pharmacopoeia). Members of the public may also approach any library that participates in inter-library loans with those university libraries to request an inter-library loan, or to obtain a photocopy of a particular part of a monograph for personal study or research (but not for commercial purposes). Fees apply in relation to the making of such a request. Enquiries should be made with local libraries, state libraries or the National Library.

### **Consultation**

A Regulation Impact Statement is not required in relation to the making of the Order on the basis that the Order remakes the Former Order without substantive changes (OPBR21-01205).

Between 22 October and 19 November 2021, the TGA undertook targeted consultation with peak industry stakeholders and selected medicine sponsors that would be directly impacted by the Order. The TGA only received 2 responses (one from a peak body, the other from an industry sponsor), both of which stated their support for the making of the Order in the same terms as the Former Order.

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 for the purposes of the Legislation Act and commences on 31 March 2022.

## **Details of the *Therapeutic Goods (Standard for Human Albumin) (TGO 111) Order 2022***

### **Section 1 – Name**

This section provides that the name of the instrument is the *Therapeutic Goods (Standard for Human Albumin) (TGO 111) Order 2022* (“the Order”), and that the Order may also be cited as TGO 111.

### **Section 2 – Commencement**

This section provides that the Order commences on 31 March 2022.

### **Section 3 – Authority**

This section provides that the legislative authority for making the Order is section 10 of the *Therapeutic Goods Act 1989* (“the Act”).

Subsection 10(1) of the Act 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. Under subsection 10(3A) of the Act, the Minister may vary or revoke an order made under subsection 10(1) by legislative instrument.

### **Section 4 – Definitions**

This section provides the definitions of key terms used in the Order, being ‘Act’ and ‘human albumin’. This section also notes that some expressions used in the Order, including ‘British Pharmacopoeia’, ‘European Pharmacopoeia’, ‘export only medicine’ and ‘standard’, have the same meaning as in the Act.

### **Section 5 – Standard**

This section provides that matters specified in the Order constitute a standard for human albumin.

### **Section 6 – Application**

This section provides that the Order applies to human albumin, other than human albumin that is an export only medicine, or an ingredient or component in the manufacture of an export only medicine.

### **Section 7 – Requirements**

This section provides that the requirements for human albumin are the requirements that are stated in an individual or general monograph applicable to human albumin in the British Pharmacopoeia or the European Pharmacopoeia, as interpreted in accordance with the General Notices section of the British Pharmacopoeia or the European Pharmacopoeia.

### **Section 8 – Repeals**

This section provides that each instrument in Schedule 1 to the Order is repealed as set out in the applicable items in that Schedule.

### **Schedule 1 – Repeals**

This Schedule provides that the Therapeutic Goods Order No. 90 Standard for human albumin is repealed.

## Statement of Compatibility with Human Rights

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

### *Therapeutic Goods (Standard for Human Albumin) (TGO 111) Order 2022*

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 legislative instrument

The *Therapeutic Goods (Standard for Human Albumin) (TGO 111) Order 2022* (“the instrument”) is made under section 10 of the *Therapeutic Goods Act 1989* (“the Act”) for the purpose of establishing a ministerial standard for human albumin used as a therapeutic good, by reference to a monograph that is applicable to human albumin in the British Pharmacopoeia and the European Pharmacopoeia. The instrument repeals and replaces the Therapeutic Goods Order No. 90 Standard for human albumin (“the former instrument”), which would otherwise sunset on 1 April 2022.

The Australian Government is responsible for regulating the quality, safety and efficacy of therapeutic goods. This is achieved in part by specifying ministerial standards under section 10 of the Act by reference to a range of matters, including the manufacture of therapeutic goods, and by otherwise applying default standards that are constituted by statements in international pharmacopoeias defined in subsection 3(1) of the Act, being the British Pharmacopoeia, European Pharmacopoeia and United States Pharmacopoeia-National Formulary.

The former instrument is a standard that specifies that albumin from humans must comply with the monograph for human albumin in the British Pharmacopoeia or the European Pharmacopoeia, principally with the effect of excluding the monograph for human albumin in the United States Pharmacopoeia-National Formulary.

The United States Pharmacopoeia-National Formulary was excluded by the former instrument due to:

- concerns regarding the potential clinical implications or regulatory impacts arising from significant inconsistencies in the requirements set out in the United States Pharmacopoeia-National formulary in comparison to the British Pharmacopoeia and the European Pharmacopoeia, including the lack of Nucleic Acid Amplification Technology testing of starting plasma, which could present an increased risk of infectious disease and inadequate product characterisation; and
- the monograph not being self-contained. That is, the monograph refers to, or relies on, United States of America (US) legislation or decisions of the US Food and Drug Administration.

These concerns remain current in relation to the approach in the USP, and accordingly the instrument has the effect of repealing and replacing the former instrument without modification.

#### 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 standards of physical and mental health.

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 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 safety, quality and efficacy of human albumin for therapeutic use by continuing to exclude the United States Pharmacopeia-National Formulary as an accepted standard for human albumin, to safeguard against the risks that may be associated with reliance on the United States Pharmacopeia-National Formulary in this regard, including in particular the potential risk of infectious disease transmission, as well as the potential regulatory impacts resulting from inconsistent requirements in comparison to the British Pharmacopoeia and the European Pharmacopoeia.

### **Conclusion**

The order is compatible with human rights because it maintains and supports the right to health in Article 12 of the ICESCR and otherwise does not raise any other human rights issues.