EXPLANATORY STATEMENT

*Therapeutic Goods Act 1989*

*Therapeutic Goods Legislation Amendment (2018 Measures No. 2) Regulations 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 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 63(1) of the Act provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing matters required or permitted to be prescribed by the Act or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

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 which are intended for use in humans not to be therapeutic goods for the purposes of the Act. Paragraph 4q of the EGO lists 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.

Autologous HCT products have historically sat outside the TGA’s regulatory oversight as they have been considered an extension of medical practice. However, there is growing global concern in relation to the risks that such products and related treatments may pose to patient safety (including the possibility of very serious illnesses), and in relation to the advertising of such products directly to consumers.

The purpose of the *Therapeutic Goods Legislation Amendment (2018 Measures No. 2) Regulations 2018* (the Regulations) is to amend the *Therapeutic Goods Regulations 1990* to address these concerns by introducing regulatory oversight for autologous HCT products, commensurate with the safety risks to patients.

The Regulations prohibit the advertising of such products to consumers, regulate most autologous HCT products as therapeutic goods and require any autologous HCT products that undergo a certain level of processing to be included in the Australian Register of Therapeutic Goods (the Register). Only autologous HCT products that are collected, and manufactured, by a registered medical or dental practitioner in a hospital will continue to be excluded from the regulatory scheme. A determination under section 7AA of the Act will be made for this purpose.

These measures bring Australia into closer alignment with international regulation in this area. Amendments to remove paragraph 4q from the EGO will also be made to ensure consistency with the Regulations.

The Regulations also make a number of unrelated amendments to the *Therapeutic Goods Regulations 1990* (the TG Regulations) and the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) to, for example:

* exempt tampons and menstrual cups from the requirement to be included in the Register or covered by a manufacturing licence, and to similarly exempt packs containing tampons or menstrual cups (and certain other kinds of therapeutic goods) put together by charities for homeless or disadvantaged women;
* correct the spelling of ‘homeopathic’ to ‘homoeopathic’, to ensure consistent spelling of this term throughout the TG Regulations; and
* clarify one of the criteria for the current evaluation timeframe of 120 working days for completing an evaluation of an application for marketing approval for prescription medicines.

Details of the Regulations are set out in the Attachment.

The Act specifies no conditions that need to be satisfied before the power to make the Regulations may be exercised.

The Regulations are a legislative instrument for the purposes of the *Legislation* *Act 2003*.

The Regulations commence 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. The TGA received 141 submissions from groups or individuals. It was a common element of 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.. The responses predominantly supported options that would reduce the amount of autologous HCT products that are not covered by regulation under the Act, and also supported 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 63(1) of the *Therapeutic Goods Act 1989*

**ATTACHMENT**

**Details of the *Therapeutic Goods Legislation Amendment (2018 Measures No. 2) Regulations 2018***

Section 1 – Name

This section provides for the Regulations to be referred to as the *Therapeutic Goods Legislation Amendment (2018 Measures No. 2) Regulations 2018.*

Section 2 – Commencement

This section provides for the commencement of the Regulations on 1 July 2018.

Section 3 – Authority

This section provides that the Regulations are made under the *Therapeutic Goods Act 1989* (the Act).

# Section 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 the Regulations has effect according to its terms.

Schedule 1 – Amendments

**Part 1 – Medical Devices**

***Therapeutic Goods (Medical Devices) Regulations 2002***

**Item 1– After Division 4.1B**

This item introduces a new Division 4.1C and regulation 4.3G to the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) , with the effect of adding (for the purposes of subsection 41EJ(5A) of the Act) a new automatic condition that applies to conformity assessment certificates issued by the Secretary under section 41EC of the Act. The condition in regulation 4.3G only applies in relation to medical devices that contain a substance of a kind covered by an entry in a Schedule to the current Poisons Standard. These are currently injectable tissue reconstructive, augmentation and restoration materials, including collagen; medical devices which include anticoagulants; artificial tears; urinary catheters; or intra-articular fluids.

The condition requires that manufacturers of such products to whom a conformity assessment certificate is issued do not supply these medical devices if the supply would contravene Part 2 of the current Poisons Standard. That is, the requirements in Part 2 of the current Poisons Standard needs to be complied with. These include, for example, requirements relating to labelling, storage and disposal.

**Item 2 – At the end of Division 5.2**

This item adds a new regulation 5.13 to Division 5.2 of the MD Regulations which imposes an equivalent automatic condition on the inclusion of a kind of medical device in the Register as the above item, in relation to medical devices that contain a substance of a kind covered by an entry in a Schedule to the current Poisons Standard (injectable tissue reconstructive, augmentation and restoration materials, including collagen; medical devices which include anticoagulants; artificial tears; urinary catheters; or intra-articular fluids).

**Item 3 – In the appropriate position in Part 11**

This item adds new Division 11.8 to the MD Regulations and new regulations 11.35 and 11.36 which provide for transitional arrangements in relation to the new conditions that are introduced by items 1 and 2 above, with the effect that:

* new regulation 4.3G applies to a conformity assessment certificate issued before, on or after 1 July 2018; and
* new regulation 5.13 applies to a kind of medical device included in the Register before, on or after 1 July 2018.

**Part 2 – Variation of entries in Register**

***Therapeutic Goods Regulations 1990***

**Item 4 – Regulation 2 (definition of TGA notifications process guidance document)**

This item repeals the definition of *TGA notifications process guidance document* in regulation 2 of the *Therapeutic Goods Regulations 1990* (the TG Regulations), and substitutes a definition which refers to the most recent version (version 3.0) of the document entitled ‘*Notifications process–requests to vary biologicals and registered medicines where quality, safety and efficacy are not affected*’.

**Item 5 – Subregulation 10AAB(2) (table item 6)**

This item repeals table item 6 in subregulation 10AAB(2) to remove an unintended duplication of a ‘particular ‘code’, “AAMC”, in this subregulation. The correct item for code AMMC is item 54, and as such item 6 is not needed.

**Part 3 – Evaluation of prescription and other medicines**

***Therapeutic Goods Regulations 1990***

**Item 6 – subregulation 16DA(1)**

This item omits references to paragraphs 16C(3)(b) and 16D(3)(b) in subregulation 16DA(1) of the TG Regulations and substitutes references to paragraphs 16C(3)(a) and (b) and 16D(3)(a) and (b).

Paragraphs 16C(3)(a) and 16D(3)(a) require that the conditions in subregulation 16DA(1) be satisfied for the 120 working day evaluation period to apply. Therefore, this addition clarifies that the conditions in subregulation 16DA(1) relate to paragraphs 16C(3)(a) and 16D(3)(a) as well (not just paragraphs 16C(3)(b) and 16D(3)(b)) and have to be satisfied for the 120 working day evaluation period to apply.

**Item 7 – paragraph 16DA(1)(b)**

This item repeals paragraph 16DA(1)(b) in the TG Regulations because the condition in this paragraph, that the medicine was approved overseas within 12 months before the application was made in Australia, is only intended to be a condition for the 120 working day evaluation period in paragraphs 16C(3)(a) and 16D(3)(a) (i.e. it was not intended to be a condition for the 175 working day evaluation period).

Previously, this condition needed to be satisfied for the 175 day evaluation timeframe in paragraphs 16C(3)(b) and 16D(3)(b). However, this item clarifies that this condition does not need to be satisfied for the 175 day evaluation period to apply.

**Item 8 – Before paragraph 16DA(2)(a)**

This item includes a condition that the medicine was approved overseas within 12 months before the application was made in Australia in subregulation 16DA(2), with the effect that this condition, therefore, needs to be satisfied for the 120 working day evaluation period in subregulations 16C(3)(a) and 16D(3)(a) to apply. Following the amendment made by the above item, it does not need to be satisfied for the 175 day evaluation period to apply.

**Part 4 – Homoeopathic preparations**

***Therapeutic Goods Regulations 1990***

**Item 9 – Schedule 4 (items 4A and 5)**

This item changes the spelling of ‘homeopathic’ to ‘homoeopathic’ to ensure consistent spelling of this term throughout the TG Regulations.

**Item 10 – Schedule 14 (item 6)**

This item changes the spelling of ‘homeopathic’ to ‘homoeopathic’ to ensure consistent spelling of this term throughout the regulations.

**Part 5 – Biologicals**

***Therapeutic Goods Regulations 1990***

**Items 11 to 13 – Regulation 2 (definitions of *Class 2, Class 3 and Class 4 biological*)**

These items amends the definitions of ***Class 2 biological***, ***Class 3 biological*** and ***Class 4 biological*** in the TG Regulations, principally to clarify the boundaries between the different classes of biologicals. No amendments are required to the definition of a ‘Class 1 biological’ as it is clearly defined in regulation 2 of the TG Regulations as ‘a biological that is mentioned in Schedule 16 as a Class 1 biological’ (at present there are no Class 1 biologicals).

In particular, a revised definition of ***Class 2 biological*** has been introduced that reflects the amendments made to the definition of ***minimal manipulation*** (see items 15 and 17 below). A Class 2 biological is a biological that, principally, has been subjected to only minimal manipulation by way of processing after collection, is only for homologous use and is not prescribed in Schedule 16 to the TG Regulations as being a Class 1, Class 3 or Class 4 biological. A biological that is prescribed in Schedule 16 as being a Class 2 biological also meets this definition.

**Item 14 – Regulation 2 (definition of *homologous use*)**

This item substitutes the definition of ***homologous use*** to provide that it has the meaning given by new regulation 3B (see item 17 below).

**Item 15 – Regulation 2 (definition of *minimal manipulation*)**

This item substitutes the definition of ***minimal manipulation*** to provide that it has the meaning given by new regulation 3B (see item 17 below).

**Item 16 – Regulation 2**

This item amends regulation 2 to introduce a definition of ***original cells or tissues,*** which has the meaning given by new regulation 3B (see item 17 below).

**Item 17 – At the end of Part 1**

This item introduces new section 3B to the TG Regulations, which sets out several critical definitions that relate to goods comprising, containing or that are derived from human cells or tissues:

* ***original cells or tissues*** is defined as those human cells or tissues that the goods comprise, contain or are derived from (subregulations 3B(1) and (2));
* a new definition of ***minimal manipulation*** links the level of manipulation with the intended use of the product. Such a link is necessary to understand the risk of changes to the function of the cells or tissues that result from the manufacturing process applied and enables an appropriate classification to be given to the resulting biological. The amended definition provides more certainty and also better aligns with definitions used in overseas regulatory schemes, such as in Europe and the United States. The previous definition of ***minimal manipulation*** set out a list of actions, but did not link the level of manipulation to the intended use of the product (subregulation 3B(3));
* ***homologous use*** is defined as meaning, principally, the use of the goods to repair, reconstruct, replace or supplement the cells or tissues of the recipient, provided that the goods will perform the same basic function in the recipient as the original cells or tissues performed in the person from whom they were collected. This definition is designed to provide further clarity and harmonisation with the definitions used in overseas regulatory schemes.

**Item 18 – Regulation 16AB**

Regulation 16AB of the TG Regulations specifies timeframes, for the purposes of section 32DQ of the TG Act, within which a person in relation to whom a biological is included in the Register, and who is aware of specified information relating to the adverse effects of biologicals, must provide that information to the Secretary. The specified periods are as follows:

1. within 48 hours after the person first becomes aware of the event or occurrence if the information relates to an event or occurrence that represents a serious threat to public health;
2. within 10 days after the person first becomes aware of the event or occurrence if the information relates to an event or occurrence that led to the death, or serious deterioration in the state of health of a patient, a user of the biological or another person;
3. within 30 days after the person first becomes aware of the event or occurrence if the information relates to an event or occurrence that, if it occurred again, might lead to the death, or serious deterioration in the state of health, of a patient, a user of the biological or another person.

Item 18 amends regulation 16AB to provide that these periods also apply in relation to the reporting of information that is required under the condition specified in item 14 of the table in Schedule 5A to the TG Regulations.

**Items 19 – Paragraphs 16AB(b) and (c)**

This item makes consequential amendments to paragraphs 16AB(b) and (c) of the TG Regulations to reflect that the provisions apply in relation to goods included in item 14 of the table in Schedule 5A, as well as to biologicals.

**Item 20 – In the appropriate position in Part 9**

This item introduces a new Division 9 into Part 9 of the TG Regulations to provide transitional arrangements for products that met the exemption specified in paragraph 4(q) of the *Therapeutic Goods (Excluded Goods) Order No 1 of 2011* on or before 30 June 2018, but which would no longer be exempt from regulation under the TG Act under the currently arrangements that commence on 1 July 2018.

This item also introduces new regulations 64 - 66, which are outlined below.

*Regulation 64*:

* ***Amendment Regulations*** is defined as these Regulations, i.e., the *Therapeutic Goods Legislation Amendment (2018 Measures No. 2) Regulations 2018*;
* ***finally determined*** has the same meaning as in Division 11.1 of the MD Regulations. Principally, this would be the first time that both of the following conditions are met – when a decision has been made not to grant the application, and there is no longer any possibility of a change in the outcome of the decision (the concept of an application being ‘finally determined’ is not relevant if at any time the application is successful);
* ***transitional goods*** is defined as goods that were goods to which paragraph 4(q) of the *Therapeutic Goods (Excluded Goods) Order No.1 of 2011* applied on 30 June 2018, were of a kind supplied in Australia on or before that date and column 2 of item 14 of Schedule 5A to the TG Regulations does not apply to the goods (see below).

Paragraph 4(q) of the *Therapeutic Goods (Excluded Goods) Order No 1 of 2011* (EGO) excludes the following human tissue and cell products from being ‘therapeutic goods’ for the purposes of the TG Act:

human tissue and cells that are:

1. collected from a patient who is under the clinical care and treatment of a medical practitioner registered under a law of a State or an internal Territory; and
2. manufactured by that medical practitioner, or by a person or persons under the professional supervision of that medical practitioner, for therapeutic application in the treatment of a single indication and in a single course of treatment of that patient by the same medical practitioner, or by a person or persons under the professional supervision of the same medical practitioner.

The EGO is made under section 7 of the TG Act and is not a legislative instrument. The EGO is available on the TGA website at the following link:

<https://www.tga.gov.au/therapeutic-goods-excluded-goods-order-no-1-2011>. While the definition of ‘transitional goods’ refers to the operation of the EGO, it does not incorporate that instrument into the TG Regulations.

*Regulation 65*:

Therapeutic goods that are ‘biologicals’ are required by Division 4 of Part 3-2A to be included in the Register, subject to any applicable exemption, approval or authorisation. Part 3-2 makes similar provision in relation to the registration and listing of medicines. This item inserts new regulation 65, which provides an exemption for transitional goods from the requirement to be included in the Register under these Parts.

Under new subregulations 65(1) and (3), transitional goods are exempt from the requirements of Part 3-2 (except sections 30EA, 31A and 31C to 31F) and Division 4 of Part 3-2A for a period of up to 12 months (i.e. up to 30 June 2019). New subregulation 65(4) provides that these exemptions are subject to the condition that the sponsor must report to the Secretary information that indicates that use of the goods may have an unintended harmful effect. Such information is to be reported within the timeframes specified by regulation 16AB.

These exemptions extend beyond 30 June 2019 in certain circumstances.

Under new subregulation 65(4), if:

* a sponsor applied for registration, listing or inclusion of transitional goods in the Register on or before 30 June 2019; and
* the application passes preliminary assessment on or before 30 June 2019;

then the exemption cease to have effect when the application is finally determined, lapses or is withdrawn, if that occurs on or after 1 July 2019.

New subregulation 65(5) further provides that if a sponsor applies for an approval of the transitional goods under section 32CK of the Act (which relates to approvals for special and experimental uses), the exemption will cease to have effect when the application is finally determined or withdrawn, if that occurs on or after 1 July 2019.

New subregulation 65(6) ensures that transitional goods which are exempt under new subregulation 65(1) are prescribed for the purposes of subsections 42DL(12) and 42DLB(9) of the TG Act, which relate to general advertising offences and civil penalties. This has the effect that the advertising of transitional goods is prohibited.

*Regulation 66:*

New regulation 66 provides an exemption for transitional goods from the operation of

Part 3-3 of the TG Act. This Part imposes certain regulatory requirements concerning the manufacturing of therapeutic goods. In particular, a person must not manufacture therapeutic goods in Australia without a licence granted under Part 3-3. Transitional goods will be exempt from the operation of Part 3-3 up until 30 June 2019 (new subregulation 66(2)).

New subregulation 66(3) provides for an extension of the exemption in certain circumstances. If, on or before 30 June 2019, each person who carries out a manufacturing step in relation to the transitional goods applies for a manufacturing licence under section 37 of the TG Act, then the exemption is extended until the last of those applications is finally determined or withdrawn, where that occurs on or after 1 July 2019.

**Item 21 – Schedule 5A (at the end of the table)**

Schedule 5A to the TG Regulations lists certain therapeutic goods (principally medicines or biologicals) that are exempt from the requirement to be registered, listed or included in the Register, subject to specified conditions. This item introduces new item 13 at the end of the table in this Schedule, which has the effect of exempting from the requirement to be included in the Register therapeutic goods that meet the following criteria:

* the goods comprise, contain or are derived from human cells or tissues which are collected from a patient who is under the clinical care of a medical or dental practitioner registered under a law of a State or an internal Territory; and
* the goods were manufactured by that practitioner, or by a person under the professional supervision of that practitioner,
* the single indication of the goods is homologous use on that patient, and in a single clinical procedure, and by that same practitioner, or by a person under the professional supervision of that practitioner; and
* the goods have only been subjected to minimal manipulation.

(See item 17 above in relation to the definitions of ***homologous use*** and ***minimal manipulation***.)

These goods are exempt from the requirement to be included in the Register, provided that the condition in column 3 of item 14 is complied with. This condition requires a sponsor to report to the Secretary information that indicates that the use of the goods may have an unintended harmful effect within the periods specified by regulation 16AB.

**Item 22 –Schedule 7 (at the end of the table)**

Item 22 introduces new item 21 at the end of the table in Schedule 7 to the TG Regulations to include therapeutic goods that meet the same criteria as that specified in item 14 of the table in Schedule 5A. This amendment has the effect that these goods will also be exempt from the operation of Part 3-3 of the Act, and so a licence under that Part will not be required in relation to the manufacture of these goods.

**Item 23 – Schedule 16**

Schedule 16 to the TG Regulations sets out the classes of biologicals for the purposes of the definitions of Class 1, Class 2, Class 3 or Class 4 biologicals in regulation 2. There are currently no biologicals mentioned in Schedule 16, but this Schedule is reserved for future use.

Item 23 repeals the Schedule and substitutes a new Schedule which specifies the following groups of products for the purposes of the definition of ***Class 4 biological*** in regulation 2:

* biologicals that comprise or contain live animal cells, tissues or organs;
* biologicals that comprise, contain or are derived from human cells or tissues that have been modified to artificially introduce one or more functions of the cells or tissues, and these functions were not intrinsic to the cells or tissues when they were collected from the donor;
* pluripotent stem cells;
* biologicals derived from pluripotent stem cells.

**Part 6 – Menstrual cups and tampons**

***Therapeutic Goods Regulations 1990***

**Item 24 – Schedule 5 (at the end of the table)**

This item introduces a new item 14 in Schedule 5 to the TG Regulations which covers tampons and menstrual cups. The purpose of this item is to exempt tampons and menstrual cups from the operation of Parts 3-2 and 3-2A of the Act, the requirements for inclusion in the Register. The menstrual cups and tampons still need to comply with the relevant standard for such products, the *Therapeutic Goods Order No. 82 – Standard for Tampons – Menstrual*.

**Item 25 – Schedule 5A (at the end of the table)**

Schedule 5A to the TG Regulations lists certain therapeutic goods (principally medicines or biologicals) that are exempt from the requirement to be registered, listed or included in the Register, subject to specified conditions. This item introduces new item 14 at the end of the table in this Schedule, which has the effect of exempting from the requirement to be included in the Register certain packs containing tampons and menstrual cups. The purpose of this item is to enable charities to supply packs which contain menstrual cups or tampons and other low-risk therapeutic goods that are included in the Register to disadvantaged women for free, without requiring these charities to include the packs in the Register.

This item exempts packs that contain tampons and menstrual cups, but do not contain biologicals, medicines mentioned in Part 1 of Schedule 10, medical devices classified as Class IIa or higher or IVD medical device that are Class 2 or higher, from the operation of Parts 3-2 and 3-2A of the Act if a number of conditions are met. Principally, these are that the packs are not supplied by persons other than charities or for a charge or to persons other than homeless of disadvantaged women. In addition, the other therapeutic goods in the packs (other than the tampons and menstrual cups) need to be included in the Register and the individual packaging of any individually packaged medical devices or medicines in the pack must not be broken or removed.

For example, if Band-Aids were included in the packs, the individual packaging of each Band-Aid must not be removed or broken. This would not, however, prevent a box of 100 Band-Aids being opened and a few Band-Aids being included in each pack (if the individual wrapping for each Band-Aid is not removed or broken).

**Item 26 – Schedule 8 (at the end of the table)**

This item introduces a new item 7 in Schedule 8 to the TG Regulations to exempt charities from the operation of Part 3-3 of the Act if the charities manufacture packs that contain tampons or menstrual cups and other low-risk therapeutic goods that are included in the Register, provided the same conditions outlined above are met.

**Part 7 – Variation fees for OTC medicines**

***Therapeutic Goods Regulations 1990***

**Item 27 – Clause 3 of Schedule 9 (table item 2CB)**

This item repeals the current item and substitute a new item 2CB which is the same as the current item but includes a nil fee where, in the case of a single entry in the Register, the request is made together with a request of a kind mentioned in new item 5 of Part 3 in relation to the same entry. The effect of this is that where a request of the kind to which item 2CB applies is made in addition to an application of the kind to which new item 5 of Part 3 applies, no fee is payable in respect of the request to which item 2CB would otherwise apply. For example, if a sponsor makes a C1(section 9D) application in relation to an entry in the Register and makes a request under section 9D(2C) of the Act to make one or more variations to the same entry in the Register, the sponsor will only need to pay the fee in new item 5 of Part 3, not the fee in item 2CB of Part 1.

**Item 28 – Clause 3 of Schedule 9 (table item 2CD)**

This item repeals the current item and substitutes a new item 2CD which is the same as the current item but includes a nil fee, for each group of up to 20 entries, where the request is made together with a request of a kind mentioned in new item 5 of Part 3 in relation to the same group of entries. The effect of this is that where a request of the kind to which item 2CD applies is made to up to 20 entries in addition to an application of the kind to which new item 5 of Part 3 applies, no fee is payable in respect of the request to which item 2CD would apply. For example, if a sponsor makes a C1(section 9D) application in relation to up to 20 entries in the Register and makes a request under section 9D(2C) of the Act to make one or more variations to the same entries in the Register, the sponsor will only need to pay the fee in new item 5 of Part 3, not the fee in item 2CD of Part 1.

**Item 29 – Clause 4 of Schedule 9 (table items 5 and 6)**

This item repeals the current items 5 and 6 in Clause 4 of Schedule 9 (as amended by the *Therapeutic Goods Legislation Amendment (Fees and Other Amendments) Regulations 2018*) and substitutes a new item 5. The new item 5 provides that where an application listed in this item is made in relation to up to 20 entries in the register, only one fee would need to be paid. For example, if a sponsor made a C3 (section 9D) application in relation to 18 entries in the Register, the sponsor would only need to pay $8,330.

**Statement of Compatibility with Human Rights**

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

**Therapeutic Goods Legislation Amendment (2018 Measures No.2) Regulations 2018**

The *Therapeutic Goods Legislation Amendment (2018 Measures No.2) Regulations 2018* (the Regulations) 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 Regulations are made under subsection 63(1) of the *Therapeutic Goods Act 1989* (the Act), and amend the *Therapeutic Goods Regulations 1990* (the TG Regulations) and *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) - principally, to introduce an appropriate level of regulatory oversight for human cells and tissues that are collected from a patient for use in the treatment of the same person from whom they were collected (autologous human cell and tissue (HCT) products) – e.g. skin grafts for the treatment of burns, bone grafts and bone marrow transplants.

Autologous HCT products have historically sat outside the TGA’s regulatory oversight, as they have been considered an extension of medical practice (reflected in section 4 of the *Therapeutic Goods (Excluded Goods) Order No.1 of 2011* (the EGO), which refers to this end to these products as collected from a patient under the clinical care of a registered medical practitioner and manufactured by the practitioner or a person under their supervision for use in the same patient). 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.

 In particular, the Regulations have the effect of: prohibiting the advertising of such products to consumers; regulating most autologous HCT products as therapeutic goods; and requiring any autologous HCT products that undergo a certain level of processing (after collection from the patient’s body) that, principally, involves changing the biological characteristics, physiological function or structural properties of the original cells or tissues, to be included in the Australian Register of Therapeutic Goods (the Register) in order to be lawfully supplied.

Only autologous HCT products collected and manufactured by a registered medical or dental practitioner in a hospital will continue to be excluded from the regulatory scheme (a determination under section 7AA of the Act will separately be made for this purpose, and paragraph 4q will also be removed from the EGO).

The Regulations also make a number of minor, unrelated amendments, to:

* exempt tampons and menstrual cups from the requirement to be included in the Register or to be covered by a manufacturing licence, and to similarly exempt packs containing tampons or menstrual cups (and certain other kinds of therapeutic goods) composed by charities for homeless or disadvantaged women;
* correct the spelling of ‘homeopathic’ to ‘homoeopathic’; and
* clarify one criteria for the evaluation timeframe of 120 working days for completing an evaluation of an application for marketing approval for prescription medicines.

**Human rights implications**

As the Regulations do not introduce any changes to the TG Regulations or MD Regulations other than to implement the measures outlined above, it does not 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.

**Greg Hunt, Minister for Health**