EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Authorised Supply) Amendment (SAS Guidance) Rules 2025

The *Therapeutic Goods Act 1989* (the Act) provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy or performance, 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, Disability and Ageing (the Department).

Subsections 19(7A), 32CM(7A) and 41HC(6) of the Act provide that the Minister may, by legislative instrument, make rules authorising specified classes of health practitioners to supply specified therapeutic goods, biologicals or kinds of medical devices (as relevant) for use in the treatment of specified recipients, provided the goods are supplied in specified circumstances and any specified conditions are satisfied.

These provisions are mainly intended to facilitate access to therapeutic goods with an established history of use in Australia or overseas, in circumstances where those goods are not included in the Australian Register of Therapeutic Goods (the Register), or not otherwise the subject of an exemption, approval or authority under the Act. Legislative instruments made under these provisions support what is known as the 'Special Access Scheme – Category C pathway' (SAS C pathway).

The *Therapeutic Goods (Medicines and OTG—Authorised Supply) Rules 2022* (the Medicines Rules), the *Therapeutic Goods (Biologicals—Authorised Supply) Rules 2022* (the Biologicals Rules) and the *Therapeutic Goods (Medical Devices—Authorised Supply) Rules 2022* (the Devices Rules) are made under subsections 19(7A), 32CM(7A) and 41HC(6) of the Act, respectively. The Medicines Rules, Biologicals Rules and Devices Rules (collectively, the Principal Rules) specify health practitioners, therapeutic goods (medicines, biologicals and medical devices as relevant), circumstances and conditions.

The *Therapeutic Goods (Authorised Supply) Amendment Rules 2025* (the Amendment Rules) amends the Principal Rules to add a number of specified medicines and medical devices, remove a number of specified medicines, biologicals and medical devices, and to make other minor amendments and corrections. The Amendment Rules also makes a minor technical amendment to the Principal Rules to remove references to 'SAS Guidance', which is a guidance document incorporated by reference in the Principal Rules, and instead specify the requirements set out in SAS Guidance relating to the reporting of adverse events and defects in the Principal Rules themselves.

Background

Subsection 19(7A) of the Act provides that the Minister may, by legislative instrument, make rules authorising specified classes of health practitioners to supply specified therapeutic goods (or classes of such goods) for use in the treatment of specified recipients, provided the goods are supplied in the circumstances specified in those rules and the specified conditions (if any) are satisfied.

Subsection 19(7B) of the Act provides that, in making rules under subsection 19(7A), the Minister must comply with such requirements, restrictions or limitations (if any) prescribed in the regulations. Subregulation 12B(5) of the *Therapeutic Goods Regulations 1990* provides that rules made under subsection 19(7A) of the Act must not specify a medicine or a class of medicines if the medicine, or a medicine included in the class, contains a substance of a kind covered by an entry in Schedule 8, 9, or 10 to the Poisons Standard. Health practitioners who supply therapeutic goods pursuant to rules

made under subsection 19(7A) are also required to notify the Secretary in accordance with subsections 19(7C) and 19(7D) of the Act.

In relation to biologicals, subsection 32CM(7A) of the Act provides that the Minister may, by legislative instrument, make rules authorising specified classes of health practitioners to supply a specified biological, for use in the treatment of specified recipients, provided that the biological is supplied in the circumstances specified in those rules and the conditions (if any) are satisfied.

Subsection 32CM(7B) of the Act provides that in making rules under subsection 32CM(7A), the Minister must comply with such requirements, restrictions or limitations (if any) prescribed in the regulations. No regulations have been made for the purposes of subsection 32CM(7B). Health practitioners who supply biologicals pursuant to rules made under subsection 32CM(7A) are also required to notify the Secretary in accordance with subsections 32CM(7C) and 32CM(7D) of the Act.

In relation to medical devices, subsection 41HC(6) of the Act provides that the Minister may, by legislative instrument, make rules authorising specified classes of health practitioners to supply a specified kind of medical device for use in the treatment of specified recipients, provided the kinds of medical devices are supplied in circumstances specified in those rules and the conditions (if any) are satisfied.

Subsection 41HC(6A) of the Act provides that in making rules under subsection 41HC(6), the Minister must comply with such requirements, restrictions or limitations (if any) prescribed in the regulations. No regulations have been made for the purposes of subsection 41HC(6A). Health practitioners who supply kinds of medical devices pursuant to rules made under subsection 41HC(6) of the Act are also required to notify the Secretary in accordance with subsections 41HC(6B) and 41HC(6C) of the Act.

The SAS C pathway is a notification pathway that allows specified health practitioners to supply certain specified unapproved therapeutic goods that are primarily considered by the TGA to have an established history of use. The TGA periodically reviews the unapproved therapeutic goods accessed through the various SAS pathways to determine if any amendments are required to the instruments, including the removal of products due to product inclusion on the Register or safety risks.

Purpose

Main amendments

The Amendment Rules is made under subsections 19(7A), 32CM(7A) and 41HC(6) of the Act. Part 1 of the Amendment Rules amends the Principal Rules to add a number of specified medicines and medical devices, remove a number of specified medicines, biologicals and medical devices, and to make other minor amendments and corrections.

Specifically, the Amendment Rules amend Schedule 1 to the Medicines Rules to:

- specify seven new medicines that are either considered to have an established history of use or that are appropriate for inclusion due to extenuating circumstances where there is a public health need;
- remove entries for six medicines that have now been included in the Register; and
- make minor editorial corrections to the active ingredients in four items.

Similarly, the Amendment Rules amend Schedule 1 to the Devices Rules to:

- specify two new medical devices that are considered to have an established history of use;
- remove entries for ten medical devices that have either been included in the Register, or for which there is an equivalent a medical device included in the Register or are not currently being supplied; and

- update the specified classes of health practitioner that is authorised to supply medical devices for one kind of medical device.

The Amendment Rules also amend Schedule 1 to the Biologicals Rules to remove eight biologicals following the inclusion of equivalent biologicals in the Register.

Other amendments

The Principal Rules specify conditions that must be satisfied, which include conditions relating to notifying the TGA about an adverse event a patient has suffered in relation to a therapeutic good and notifying the TGA of a defect in therapeutic goods. Currently, the conditions specify that these notifications must be made in accordance with the reporting guidelines set out in the SAS Guidance.

The SAS Guidance is published by the TGA to help health practitioners understand their requirements when prescribing 'unapproved' therapeutic goods for an individual patient using the Special Access Scheme. In relation to reporting adverse events and defects relating to the use of unapproved therapeutic goods, the SAS Guidance specifies that health practitioners must report details about any adverse events or defects associated with the use of the goods to the TGA within 15 days of becoming aware of the adverse event or defect.

The SAS Guidance is incorporated by reference in the Principal Rules as in force or existing at a particular time (currently, as at 1 October 2024), meaning any updates to the SAS Guidance would require amendments to the Principal Rules to incorporate the most recent version of the SAS Guidance.

To provide greater transparency in relation to adverse event and defect reporting requirements for health practitioners and remove the need for ongoing amendments to the Principal Rules each time the SAS Guidance is updated, Part 2 of the Amendment Rules amends the Principal Rules to remove the incorporated SAS Guidance document, and to specify the requirement for health practitioners to notify the TGA of adverse events and defects relating to the unapproved goods within 15 days in the Principal Rules themselves.

These amendments do not make any substantive changes to the requirements relating to the notification of adverse events or defects. The effect of these amendments is simply to set out the specific requirements within the conditions themselves, rather than by reference to requirements set out in an incorporated document.

Part 2 of the Amendment Rules also amends the Principal Rules to introduce definitions of 'adverse event' and 'defect', as relevant, consistent with the definitions for those terms in the *Therapeutic Goods (Information Specification—Database of Adverse Event Notifications) Instrument 2023*.

Consultation

Between November 2024 and May 2025, the TGA consulted clinical advisors within the Department in relation to the amendments made by the Amendment Rules to the lists of therapeutic goods in Schedule 1 to each of the Medicines Rules, the Biologicals Rules and the Devices Rules.

The key purpose of this consultation was to confirm that the goods added to the Medicines Rules and the Devices Rules by the Amendment Rules are considered to have an established history of use and are appropriate for supply and use under this pathway. Medicines and kinds of medical devices with indications or intended purposes that meet the established history of use criteria have been included in the revised lists of goods.

A small number of medicines were also included where improved access is required to address a public health need under extenuating circumstances. For example, the entries for isoniazid/rifampicin and isoniazid/rifapentine were included in the Medicines Rules upon recommendation from the

Communicable Diseases Program Section and the National Tuberculosis Advisory Committee. Tuberculosis (TB) remains a public health medicine concern in Australia, and the inclusion of these medicines in the Medicines Rules provides a more efficient mechanism for ensuring access to TB medicines in priority populations experiencing medicine access challenges.

Between November 2024 and January 2025, the TGA also consulted sponsors of therapeutic goods in relation to the proposal to remove relevant goods from the Principal Rules. Therapeutic goods that have sufficient availability and that are included in the Register, or for which an equivalent good is included in the Register, have been removed from the Principal Rules.

The TGA undertook targeted consultation between 25 July 2025 and 1 August 2025 in relation to the amendments to remove the incorporated SAS Guidance document and to specify requirements relating to the notification of adverse events and defects in the Principal Rules themselves.

Stakeholders consulted included State and Territory health departments and peak bodies, including the Australian Health Practitioner Regulation Agency, the Medical Board of Australia, the Dental Board of Australia, the Nursing and Midwifery Board of Australia, the Pharmacy Board of Australia, the Australian Medical Association and the Royal Australian and New Zealand College of Psychiatrists. No concerns were raised in relation to the amendments.

Other details

Details of the Amendment Rules are set out in **Attachment A**.

The Amendment Rules is compatible with 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 Amendment Rules is a disallowable legislative instrument for the purposes of the *Legislation Act 2003*.

The Amendment Rules commence on the day after registration on the Federal Register of Legislation, except Part 2, which commences on the day after the end of the period in which the Amendment Rules could be disallowed in either House of the Parliament.

Details of the *Therapeutic Goods (Authorised Supply) Amendment Rules 2025*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Authorised Supply) Amendment Rules 2025* (the Amendment Rules).

Section 2 – Commencement

This section provides that the Amendment Rules commences on the day after registration on the Federal Register of Legislation, except Part 2 which commences on the day after the end of the period in which the instrument could be disallowed in either House of the Parliament.

The commencement of Part 2 complies with the limitation in item 20 in Part 2 of Schedule 4 to the *Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024*.

Section 3 – Authority

This section provides that the legislative authority for making the Amendment Rules are subsections 19(7A), 32CM(7A) and 41HC(6) of the *Therapeutic Goods Act 1989* (the Act).

Subsection 33(3) of the *Acts Interpretation Act 1901* relevantly provides that, where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character, the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument. The Amendment Rules is made in accordance with that provision.

Section 4 – Schedules

This section provides that each instrument that is specified in a Schedule to the Amendment Rules is amended as set out in the applicable items in the Schedule concerned, and that any other item in a Schedule to the Amendment Rules has effect according to its terms.

The Amendment Rules amends the:

- *Therapeutic Goods (Medicines and OTG—Authorised Supply) Rules 2022* (the Medicines Rules);
- *Therapeutic Goods (Biologicals—Authorised Supply) Rules 2022* (the Biologicals Rules); and
- *Therapeutic Goods (Medical Devices—Authorised Supply) Rules 2022* (the Devices Rules).

Schedule 1—Amendments

Part 1—Main Amendments

Therapeutic Goods (Biologicals—Authorised Supply) Rules 2022

Item 1 – Schedule 1 (table items 1, 2, 4 to 7, 9 and 10)

This item removes the following biologicals from the Biologicals Rules, as access through the 'Special Access Scheme – Category C pathway' (SAS C pathway) is no longer necessary due to the inclusion of equivalent biologicals in the Register:

- AlloDerm GBR RTM (human skin tissue matrix);
- AlloDerm RTM (human skin tissue matrix);
- Grafton DBM Matrix (demineralised human bone tissue);

- MinerOss Cancellous (human bone allograft);
- MinerOss cortical and cancellous (human bone allograft);
- MinerOss Cortical (human bone allograft);
- Puros Cancellous Particulate Allograft (human bone tissue);
- Puros Cortical Particulate Allograft (human bone tissue).

Therapeutic Goods (Medical Devices—Authorised Supply) Rules 2022

Items 2 and 4 – Schedule 1 (table items 2, 3, 5, 6, 12 to 14, 17, 18 and 20)

These items remove the following kinds of medical devices from the Devices Rules, as access through the SAS C pathway is no longer necessary due to either the inclusion of these devices, or equivalent devices, in the Register, or because the device has not recently been supplied through the SAS C pathway:

- Aequalis PerForm Plus Reversed Gleniod – Wright Medical;
- Aequalis PerForm Reversed Glenoid – Wright Medical;
- Biodesign Enterocutaneous Fistula Plug;
- BlastGen (Product No. 1205);
- EmbryoGen (Product No. 1203);
- EmbryoGen & BlastGen (Product No. 1206);
- EmbryoGen V2 (Product No. 1204);
- GM508 CultActive;
- Ilex Skin Protectant;
- Jupiter Sternal Protection Device.

Item 3 – Schedule 1 (cell at table item 15, column 4)

This item amends the specified class of health practitioner that may supply the kind of medical device 'Endotine Forehead' to also include ophthalmologists.

Items 5 and 6 – Schedule 1 (after table item 28 and after table item 35)

These items add the following kinds of medical devices to the Devices Rules:

- Origin Stem, Coxa Vara, Sizes 9 to 18 – Signature Orthopaedics;
- Tauroloack-U25.000 ((cyclo)-taurolidine, citrate (4%) and urokinase (25.000IU)).

Therapeutic Goods (Medicines and OTG—Authorised Supply) Rules 2022

Items 7, 14 and 16 – Schedule 1 (table items 26, 51, 52, 54, 67 and 68)

These items remove the following medicines from the Medicines Rules as access through the SAS C pathway is no longer necessary due to the inclusion of these medicines in the Register:

- disulfiram;
- melatonin (in capsule, immediate release tablet and syrup dosage forms);
- progesterone;
- progesterone in oil.

Items 8, 9, 12, 13 and 15 – Schedule 1 (after table item 27, after table item 33, after table item 42, after table item 45 and after table item 58)

These items add the following medicines to the Medicines Rules:

- escherichia coli/klebsiella, pneumoniae/enterococcus, faecalis/proteus vulgaris;
- gallium-68 DOTA (Tyr3) octreotate;
- imipenem/cilastatin;

- isoniazid/rifampicin;
- isoniazid/rifapentine;
- mycobacterium bovis (bacillus Calmette and guerin (BCG) strain).

These medicines do not contain a substance of a kind covered by an entry in Schedule 8, 9 or 10 to the Poisons Standard.

Items 10, 11, 17 and 18 – Schedule 1 (table item 34, column 2, table item 35, column 2, table item 78, column 2 and table item 87, column 2)

These items make minor corrections to the names of the following medicines in the Medicines Rules:
- gallium-68;
- gallium-68 (Ga-68) – MAA;
- technetium-99m (99m Tc) prostate specific membrane antigen (PSMA)-I&S;
- yttrium-90 (Y-90) citrate.

Part 2—Other amendments

Therapeutic Goods (Biologicals—Authorised Supply) Rules 2022

Item 19 – Section 4 (definition of *adverse event*)

This item introduces a definition for 'adverse event' in section 4 of the Biologicals Rules. This definition is consistent with the definition of adverse event in relation to biologicals in the *Therapeutic Goods (Information Specification—Database of Adverse Event Notifications) Instrument 2023* (the DAEN Instrument).

Item 20 – Section 4 (definition of *SAS Guidance*)

This item repeals the definition of 'SAS Guidance' in section 4 of the Biologicals Rules, consequential to the amendments made below.

Items 21 and 23 – Paragraphs 5(2)(d) and 5(4)(a)

These items amend paragraphs 5(2)(d) and 5(4)(a) of the Biologicals Rules to remove the references to reporting adverse events to the TGA and the sponsor in accordance with the requirements set out in the SAS Guidelines, and replacing them with the requirement for health practitioners to report adverse events to the Therapeutic Goods Administration (TGA) within 15 days of becoming aware of the adverse event.

The effect of these amendments is to set out the specific requirements relating to reporting adverse events within the conditions specified in the Biologicals Rules (without substantive change), rather than by reference to requirements contained in an incorporated document.

Items 22 and 24 – Paragraphs 5(2)(e) and 5(4)(b)

These items amend paragraphs 5(2)(e) and 5(4)(b) of the Biologicals Rules to remove the references to reporting defects to the TGA and the sponsor in accordance with the requirements set out in the SAS Guidelines and replacing them with the requirement for health practitioners to report defects to the TGA within 15 days of becoming aware of the defect.

The effect of these amendments is to set out the specific requirements relating to reporting defects within the conditions specified in the Biologicals Rules (without substantive change), rather than by reference to requirements contained in an incorporated document.

Therapeutic Goods (Medical Devices—Authorised Supply) Rules 2022

Item 25 – Section 4 (definitions of *adverse event* and *defect*)

This item introduces new definitions of 'adverse event' and 'defect' in section 4 of the Devices Rules. These definitions are consistent with the definitions of adverse event and defect in relation to medical devices in the DAEN Instrument.

Item 26 – Section 4 (definition of *SAS Guidance*)

This item repeals the definition of 'SAS Guidance' in section 4 of the Devices Rules, consequential to the amendments made below.

Items 27 and 29 – Paragraphs 5(2)(d) and 5(4)(a)

These items amend paragraphs 5(2)(d) and 5(4)(a) of the Devices Rules to remove the references to reporting adverse events to the TGA and the sponsor in accordance with the requirements set out in the SAS Guidelines, and replacing them with the requirement for health practitioners to report adverse events to the TGA within 15 days of becoming aware of the adverse event.

The effect of these amendments is to set out the specific requirements relating to reporting adverse events within the conditions specified in the Devices Rules (without substantive change), rather than by reference to requirements contained in an incorporated document.

Items 28 and 30 – Paragraphs 5(2)(e) and 5(4)(b)

These items amend paragraphs 5(2)(e) and 5(4)(b) of the Devices Rules to remove the references to reporting defects to the TGA and the sponsor in accordance with the requirements set out in the SAS Guidelines and replacing them with the requirement for health practitioners to report defects to the TGA within 15 days of becoming aware of the defect.

The effect of these amendments is to set out the specific requirements relating to reporting defects within the conditions specified in the Devices Rules (without substantive change), rather than by reference to requirements contained in an incorporated document.

Therapeutic Goods (Medicines and OTG—Authorised Supply) Rules 2022

Item 31 – Section 4 (definition of *adverse event*)

This item introduces a definition for 'adverse event' in section 4 of the Medicines Rules. This definition is consistent with the definition for adverse event in relation to medicines and other therapeutic goods in the DAEN Instrument.

Item 32 – Section 4 (definition of *SAS Guidance*)

This item repeals the definition of 'SAS Guidance' in section 4 of the Medicines Rules, consequential to the amendments made below.

Items 33, 35, 37, 39 and 41 – Paragraphs 5(2)(d), 5(4)(a), 5A(2)(d), 5A(4)(a) and 5A(6)(f)

These items amend paragraphs 5(2)(d), 5(4)(a), 5A(2)(d), 5A(4)(a), and 5A(6)(f) of the Medicines Rules to remove the references to reporting adverse events to the TGA and the sponsor in accordance with the requirements set out in the SAS Guidelines, and replacing them with the requirement for health practitioners to report adverse events to the TGA within 15 days of becoming aware of the adverse event.

The effect of these amendments is to set out the specific requirements relating to reporting adverse events within the conditions specified in the Medicines Rules (without substantive change), rather than by reference to requirements contained in an incorporated document.

Items 34, 36, 38, 40 and 42 – Paragraphs 5(2)(e), 5(4)(b), 5A(2)(e), 5A(4)(b), and 5A(6)(g)

These items amend paragraphs 5(2)(e), 5(4)(b), 5A(2)(e), 5A(4)(b) and 5A(6)(g) of the Medicines Rules to remove the references to reporting defects to the TGA and the sponsor in accordance with the requirements set out in the SAS Guidelines and replacing them with the requirement for health practitioners to report defects to the TGA within 15 days of becoming aware of the defect.

The effect of these amendments is to set out the specific requirements relating to reporting defects within the conditions specified in the Medicines Rules (without substantive change), rather than by reference to requirements contained in an incorporated document.

Attachment B

Statement of Compatibility with Human Rights

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

Therapeutic Goods (Authorised Supply) Amendment Rules 2025

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

Subsections 19(7A), 32CM(7A) and 41HC(6) of the Act provide that the Minister may, by legislative instrument, make rules authorising specified classes of health practitioners to supply specified therapeutic goods, biologicals or kinds of medical devices (as relevant) for use in the treatment of specified recipients, provided the goods are supplied in specified circumstances and any specified conditions are satisfied.

These provisions are mainly intended to facilitate access to therapeutic goods with an established history of use in Australia or overseas, in circumstances where those goods are not included in the Australian Register of Therapeutic Goods (the Register), or not otherwise the subject of an exemption, approval or authority under the Act. Legislative instruments made under these provisions support what is known as the 'Special Access Scheme – Category C pathway' (SAS C pathway).

The *Therapeutic Goods (Medicines and OTG—Authorised Supply) Rules 2022* (the Medicines Rules), the *Therapeutic Goods (Biologicals—Authorised Supply) Rules 2022* (the Biologicals Rules) and the *Therapeutic Goods (Medical Devices—Authorised Supply) Rules 2022* (the Devices Rules) are made under subsections 19(7A), 32CM(7A) and 41HC(6) of the Act, respectively. The Medicines Rules, Biologicals Rules and Devices Rules (collectively, the Principal Rules) specify health practitioners, therapeutic goods (medicines, biologicals and medical devices as relevant), circumstances and conditions.

The *Therapeutic Goods (Authorised Supply) Amendment Rules 2025* (the Amendment Rules) amends the Principal Rules to add a number of specified medicines and medical devices, remove a number of specified medicines, biologicals and medical devices, and to make other minor amendments and corrections. The Amendment Rules also makes a minor technical amendment to the Principal Rules to remove references to 'SAS Guidance', which is a guidance document incorporated by reference in the Principal Rules, and instead specify the requirements set out in SAS Guidance relating to the reporting of adverse events and defects in the Principal Rules themselves.

Background

Subsection 19(7A) of the Act provides that the Minister may, by legislative instrument, make rules authorising specified classes of health practitioners to supply specified therapeutic goods (or classes of such goods) for use in the treatment of specified recipients, provided the goods are supplied in the circumstances specified in those rules and the specified conditions (if any) are satisfied.

Subsection 19(7B) of the Act provides that, in making rules under subsection 19(7A), the Minister must comply with such requirements, restrictions or limitations (if any) prescribed in the regulations. Subregulation 12B(5) of the *Therapeutic Goods Regulations 1990* provides that rules made under subsection 19(7A) of the Act must not specify a medicine or a class of medicines if the medicine, or a medicine included in the class, contains a substance of a kind covered by an entry in Schedule 8, 9, or 10 to the Poisons Standard. Health practitioners who supply therapeutic goods pursuant to rules

made under subsection 19(7A) are also required to notify the Secretary in accordance with subsections 19(7C) and 19(7D) of the Act.

In relation to biologicals, subsection 32CM(7A) of the Act provides that the Minister may, by legislative instrument, make rules authorising specified classes of health practitioners to supply a specified biological, for use in the treatment of specified recipients, provided that the biological is supplied in the circumstances specified in those rules and the conditions (if any) are satisfied.

Subsection 32CM(7B) of the Act provides that in making rules under subsection 32CM(7A), the Minister must comply with such requirements, restrictions or limitations (if any) prescribed in the regulations. No regulations have been made for the purposes of subsection 32CM(7B). Health practitioners who supply biologicals pursuant to rules made under subsection 32CM(7A) are also required to notify the Secretary in accordance with subsections 32CM(7C) and 32CM(7D) of the Act.

In relation to medical devices, subsection 41HC(6) of the Act provides that the Minister may, by legislative instrument, make rules authorising specified classes of health practitioners to supply a specified kind of medical device for use in the treatment of specified recipients, provided the kinds of medical devices are supplied in circumstances specified in those rules and the conditions (if any) are satisfied.

Subsection 41HC(6A) of the Act provides that in making rules under subsection 41HC(6), the Minister must comply with such requirements, restrictions or limitations (if any) prescribed in the regulations. No regulations have been made for the purposes of subsection 41HC(6A). Health practitioners who supply kinds of medical devices pursuant to rules made under subsection 41HC(6) of the Act are also required to notify the Secretary in accordance with subsections 41HC(6B) and 41HC(6C) of the Act.

The SAS C pathway is a notification pathway that allows specified health practitioners to supply certain specified unapproved therapeutic goods that are primarily considered by the TGA to have an established history of use. The TGA periodically reviews the unapproved therapeutic goods accessed through the various SAS pathways to determine if any amendments are required to the instruments, including the removal of products due to product inclusion on the Register or safety risks.

Purpose

Main amendments

The Amendment Rules is made under subsections 19(7A), 32CM(7A) and 41HC(6) of the Act. Part 1 of the Amendment Rules amends the Principal Rules to add a number of specified medicines and medical devices, remove a number of specified medicines, biologicals and medical devices, and to make other minor amendments and corrections.

Specifically, the Amendment Rules amend Schedule 1 to the Medicines Rules to:

- specify seven new medicines that are either considered to have an established history of use or that are appropriate for inclusion due to extenuating circumstances where there is a public health need;
- remove entries for six medicines that have now been included in the Register; and
- make minor editorial corrections to the active ingredients in four items.

Similarly, the Amendment Rules amend Schedule 1 to the Devices Rules to:

- specify two new medical devices that are considered to have an established history of use;
- remove entries for ten medical devices that have either been included in the Register, or for which there is an equivalent a medical device included in the Register or are not currently being supplied; and

- update the specified classes of health practitioner that is authorised to supply medical devices for one kind of medical device.

The Amendment Rules also amend Schedule 1 to the Biologicals Rules to remove eight biologicals following the inclusion of equivalent biologicals in the Register.

Other amendments

The Principal Rules specify conditions that must be satisfied, which include conditions relating to notifying the TGA about an adverse event a patient has suffered in relation to a therapeutic good and notifying the TGA of a defect in therapeutic goods. Currently, the conditions specify that these notifications must be made in accordance with the reporting guidelines set out in the SAS Guidance.

The SAS Guidance is published by the TGA to help health practitioners understand their requirements when prescribing 'unapproved' therapeutic goods for an individual patient using the Special Access Scheme. In relation to reporting adverse events and defects relating to the use of unapproved therapeutic goods, the SAS Guidance specifies that health practitioners must report details about any adverse events or defects associated with the use of the goods to the TGA within 15 days of becoming aware of the adverse event or defect.

The SAS Guidance is incorporated by reference in the Principal Rules as in force or existing at a particular time (currently, as at 1 October 2024), meaning any updates to the SAS Guidance would require amendments to the Principal Rules to incorporate the most recent version of the SAS Guidance.

To provide greater transparency in relation to adverse event and defect reporting requirements for health practitioners and remove the need for ongoing amendments to the Principal Rules each time the SAS Guidance is updated, Part 2 of the Amendment Rules amends the Principal Rules to remove the incorporated SAS Guidance document, and to specify the requirement for health practitioners to notify the TGA of adverse events and defects relating to the unapproved goods within 15 days in the Principal Rules themselves.

These amendments do not make any substantive changes to the requirements relating to the notification of adverse events or defects. The effect of these amendments is simply to set out the specific requirements within the conditions themselves, rather than by reference to requirements set out in an incorporated document.

Part 2 of the Amendment Rules also amends the Principal Rules to introduce definitions of 'adverse event' and 'defect' consistent with the definitions for those terms in the *Therapeutic Goods (Information Specification—Database of Adverse Event Notifications) Instrument 2023*.

Human rights implications

The Amendment Rules 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 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 Amendment Rules takes positive steps to promote the right to health by facilitating the supply of certain therapeutic goods by health practitioners in specified circumstances, and subject to certain

conditions, to patients who may otherwise not be able to access such products in connection with their treatment. As a consequence of the Amendment Rules, relevant kinds of health practitioners are able to supply a number of additional medicines and kinds of medical devices to their patients by way of notification rather than approval, thus reducing relay and enabling the timely availability of such medicines and medical devices to Australian patients in need.

Conclusion

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