EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Authorised Supply) Amendment (SAS Guidance) Rules (No. 2) 2024

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 and Aged Care.

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 the specified conditions (if any) 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 are 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'.

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, the Biologicals Rules and the Devices Rules (collectively, "the Principal Rules") specify health practitioners, therapeutic goods (medicines, biologicals or medical devices, as relevant), circumstances and conditions.

The *Therapeutic Goods (Authorised Supply) Amendment (SAS Guidance) Rules (No. 2) 2024* ("the Amendment Rules") amends the Principal Rules to update the definition of 'SAS Guidance' to refer to the updated guidance document titled *Special Access Scheme (SAS): Guidance for health practitioners accessing unapproved therapeutic goods* (Version 3.0, October 2024), as in force or existing on 1 October 2024 ("the SAS Guidance").

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 specified circumstances 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.

The SAS Category C pathway is a notification pathway, allowing specified health practitioners to supply certain specified unapproved therapeutic goods that are considered by the TGA to have an established history of use. The TGA periodically reviews the unapproved therapeutic goods

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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.

Similarly, in relation to biologicals, subsection 32CM(7A) of the Act provides that the Minister may, by legislative instrument, make rules authorising any health practitioner who is included in a specific class of health practitioners to supply a specified biological, for use in the treatment of humans, to the class or classes of recipients specified in the rules, so long as the biological is supplied in the circumstances specified in those rules and the conditions (if any) specified in those rules 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 therapeutic goods 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 specified circumstances and the specified 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.

Purpose

The Medicines Rules, the Biologicals Rules and the Devices Rules are made under subsections 19(7A), 32CM(7A) and 41HC(6) of the Act, respectively. The Principal Rules specify conditions that must be satisfied which include conditions relating to notifying the TGA and the sponsor about an adverse event a patient has suffered in relation to the therapeutic good, and notifying the TGA and the sponsor of a defect in the therapeutic goods. The notification must be in accordance with the reporting guidelines set out in the SAS Guidance.

The SAS Guidance is published by the TGA to assist health practitioners understand their obligations when prescribing ‘unapproved’ therapeutic goods for an individual patient using the Special Access Scheme. As the SAS Guidance published by the TGA was updated in October 2024, the Amendment Rules make amendments necessary to refer to the most recent version of the SAS Guidance.

The updates to the SAS Guidance made in October 2024 provide guidance on the new requirements on pharmacists supplying specified therapeutic vapes for smoking cessation and the management of nicotine dependence to patients 18 years or over without a prescription (subject to conditions and compliance with state and territory laws). The adverse event reporting requirements in the updated SAS Guidance have not changed.

Incorporation by reference

The Amendment Rules incorporate by reference the document titled *Special Access Scheme (SAS): Guidance for health practitioners accessing unapproved therapeutic goods* (Version 3.0, October 2024), which is published by the TGA. This document provides guidance for health practitioners and sponsors involved in providing patients with access to therapeutic goods that are not included in the Register (and are not otherwise the subject of an exemption, approval or

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authority under the Act) through the Special Access Scheme. It outlines the various access pathways and the regulatory obligations when accessing and supplying such therapeutic goods.

The Amendment Rules incorporate the SAS Guidance as in force or existing on 1 October 2024, in accordance with paragraph 14(1)(b) of the *Legislation Act 2003*, which permits a legislative instrument to incorporate a document (that is not an Act or legislative instrument) as it exists at, or before, the time the instrument commences. The SAS Guidance is available for free from the TGA website and may be accessed at www.tga.gov.au.

Consultation

Consultation was not undertaken in relation to the Amendment Rules as the updates made to the SAS guidance do not relate to the adverse event reporting requirements in the Principal Rules. The Amendment Rules, therefore, do not change the effect of the Principal Rules. The amendments simply refer to the latest version of the SAS Guidance.

The Office of Impact Analysis has previously advised that an impact analysis was not required in relation to amendments to the Principal Rules to refer to the updated SAS guidance, as the proposal relates to minor changes to reference an updated guide rather than a substantive policy change (OIA24-07497).

Other details

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

The Amendment Rules are 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 are a disallowable legislative instrument for the purposes of the *Legislation Act 2003*, and commence on the day after registration on the Federal Register of Legislation.

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Attachment A

Details of the *Therapeutic Goods (Authorised Supply) Amendment (SAS Guidance) Rules (No. 2) 2024*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Authorised Supply) Amendment (SAS Guidance) Rules (No. 2) 2024* ("the Amendment Rules").

Section 2 – Commencement

This section provides that the Amendment Rules commence on the day after they are registered on the Federal Register of Legislation.

Section 3 – Authority

This section provides that the legislative authority for making the Amendment Rules is 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 are made in accordance with that provision.

Section 4 – Schedules

This section gives legal effect to the amendments in Schedule 1 to the Amendment Rules.

Schedule 1 – Amendments

This Schedule amends 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").

Item 1 replaces the definition of 'SAS Guidance' in section 4 of the Biologicals Rules to reflect that 'SAS Guidance' means the updated guidance titled *Special Access Scheme (SAS): Guidance for health practitioners accessing unapproved therapeutic goods* (Version 3.0, October 2024), as in force or existing on 1 October 2024.

Item 2 replaces the definition of 'SAS Guidance' in section 4 of the Devices Rules to reflect that 'SAS Guidance' means the updated guidance titled *Special Access Scheme (SAS): Guidance for health practitioners accessing unapproved therapeutic goods* (Version 3.0, October 2024), as in force or existing on 1 October 2024.

Item 3 replaces the definition of 'SAS Guidance' in section 4 of the Medicines Rules to reflect that 'SAS Guidance' means the updated guidance titled *Special Access Scheme (SAS): Guidance for health practitioners accessing unapproved therapeutic goods* (Version 3.0, October 2024), as in force or existing on 1 October 2024.

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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 (SAS Guidance) Rules (No. 2) 2024

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 the specified conditions (if any) are satisfied.

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Background

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The SAS Category C pathway is a notification pathway, allowing specified health practitioners to supply certain specified unapproved therapeutic goods that are 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.

Similarly, in relation to biologicals, subsection 32CM(7A) of the Act provides that the Minister may, by legislative instrument, make rules authorising any health practitioner who is included in a specific class of health practitioners to supply a specified biological, for use in the treatment of humans, to the class or classes of recipients specified in the rules, so long as the biological is supplied in the circumstances specified in those rules and the conditions (if any) specified in those rules 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 therapeutic goods 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 specified circumstances and the specified 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.

Purpose

The Medicines Rules, the Biologicals Rules and the Devices Rules are made under subsections 19(7A), 32CM(7A) and 41HC(6) of the Act, respectively. The Principal Rules specify conditions that must be satisfied which include conditions relating to notifying the TGA and the sponsor about an adverse event a patient has suffered in relation to the therapeutic good, and notifying the TGA and the sponsor of a defect in the therapeutic goods. The notification must be in accordance with the reporting guidelines set out in the SAS Guidance.

The SAS Guidance is published by the TGA to assist health practitioners understand their obligations when prescribing ‘unapproved’ therapeutic goods for an individual patient using the Special Access Scheme. As the SAS Guidance published by the TGA was updated in October 2024, the Amendment Rules make amendments necessary to refer to the most recent version of the SAS Guidance.

The updates to the SAS Guidance made in October 2024 provide guidance on the new requirements on pharmacists supplying specified therapeutic vapes for smoking cessation and the management of nicotine dependence to patients 18 years or over without a prescription (subject to conditions and compliance with state and territory laws). The adverse event reporting requirements in the updated SAS Guidance have not changed.

Human rights implications

The Amendment Rules engage 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

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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 support the right to health by ensuring the Principal Rules include an up-to-date reference to the SAS Guidance, and that any adverse events in relation to therapeutic goods or defects in the therapeutic goods are reported to the TGA (and sponsor of the goods) in accordance with the reporting guidelines set out in the latest version of the SAS Guidance. The requirement in the Principal Rules to notify the TGA of adverse events or defects enables the TGA to investigate safety signals and take necessary action to protect patients from any safety concerns identified and prevent further harm/injury.

Conclusion

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

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