Therapeutic Goods (Medicines—Authorised Supply) Amendment (Vaping) Rules 2023

I, Anthony Lawler, as delegate of the Minister for Health and Aged Care, make the following rules.

Dated 15 December 2023

Professor Anthony Lawler
Deputy Secretary
Health Products Regulation Group
Department of Health and Aged Care

Contents

1 Name

This instrument is the *Therapeutic Goods (Medicines—Authorised Supply) Amendment (Vaping) Rules 2023*.

2 Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information

Column 1	Column 2	Column 3
Provisions	**Commencement**	**Date/Details**
1. The whole of this instrument	At the same time as the commencement of the *Therapeutic Goods Legislation Amendment (Vaping) Regulations 2023*. However, this instrument does not commence at all if the *Therapeutic Goods Legislation Amendment (Vaping) Regulations 2023* does not commence.	

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under subsections 19(7A), 32CM(7A) and 41HC(6) of the *Therapeutic Goods Act 1989*.

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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

Therapeutic Goods (Medicines—Authorised Supply) Rules 2022

1 Section 1

After "*Medicines*", insert "*and OTG*".

2 Section 4 (at the end of the note)

Add:

; (h) therapeutic goods.

3 Section 4

Insert:

active ingredient has the same meaning as in the Regulations.

nurse practitioner means a person who is:

(a) registered under a law of a state or internal territory as a registered nurse; and

(b) endorsed as a nurse practitioner by the Nursing and Midwifery Board of Australia.

Note: The Nursing and Midwifery Board of Australia works in partnership with the Australian Health Practitioner Regulation Agency.

Regulations means the *Therapeutic Goods Regulations 1990*.

4 Section 4 (definition of *SAS guidance*)

Repeal the definition, substitute:

SAS Guidance means the document titled *Special Access Scheme (SAS): Guidance for health practitioners accessing unapproved therapeutic goods* (Version 1.0, January 2023) published by the Therapeutic Goods Administration, as in force or existing at 1 January 2024.

Note: The SAS Guidance is published at www.tga.gov.au.

5 Section 4

Insert:

therapeutic vaping kit has the same meaning as in the Regulations.

therapeutic vaping pack has the same meaning as in Regulations.

therapeutic vaping substance has the same meaning as in the Regulations.

6 After section 5

Insert:

5A Authorisation—therapeutic vaping goods

Supply by a medical practitioner or nurse practitioner

(1) A health practitioner who is a medical practitioner or a nurse practitioner is authorised to supply a therapeutic good to a patient of that practitioner where:

(a) the therapeutic good is within the class of therapeutic goods specified in column 2 of an item in the table in Schedule 1A; and

(b) the therapeutic good is in the dosage form specified in column 3 of that item; and

(c) the therapeutic good is to be administered by the route specified in column 4 of that item; and

(d) the supply is for the indication specified in column 5 of that item; and

(e) the supply is to a patient who is 16 years of age or over; and

(f) the conditions specified in subsection (2) are satisfied.

(2) The medical practitioner or nurse practitioner must:

(a) inform the patient, or a parent or a guardian of the patient, that the therapeutic good is not a listed good or registered good; and

(b) obtain informed consent from the patient, or a parent or a guardian of the patient, in relation to, and before, the supply of the therapeutic good; and

(c) supply the therapeutic good in accordance with good medical practice; and

(d) if the medical practitioner becomes aware that the patient has suffered an adverse event in relation to the therapeutic good—notify the Therapeutic Goods Administration and the sponsor of the therapeutic good about the adverse event in accordance with the reporting guidelines set out in the SAS Guidance; and

(e) if the medical practitioner becomes aware of a defect in the therapeutic good—notify the Therapeutic Goods Administration and the sponsor of the therapeutic good in accordance with the reporting guidelines set out in the SAS Guidance.

Supply to a patient of a medical practitioner or nurse practitioner

(3) A health practitioner is authorised to supply a therapeutic good to a patient of a medical practitioner or a nurse practitioner (the ***treating practitioner***) where:

(a) the therapeutic good is within the class of therapeutic goods specified in column 2 of an item in the table in Schedule 1A; and

(b) the supply is requested by the treating practitioner; and

(c) the therapeutic good is in the dosage form specified in column 3 of that item; and

(d) the therapeutic good is to be administered by the route specified in column 4 of that item; and

(e) the supply is for the indication specified in column 5 of that item; and

(f) the supply is to a patient who is 16 years of age or over; and

(g) the conditions specified in subsection (4) are satisfied.

(4) The health practitioner supplying the therapeutic good must:

(a) if the health practitioner becomes aware that the patient has suffered an adverse event in relation to the therapeutic good—notify the Therapeutic Goods Administration and the sponsor of the therapeutic good about the adverse event in accordance with the reporting guidelines set out in the SAS Guidance; and

(b) if the health practitioner becomes aware of a defect in the therapeutic good—notify the Therapeutic Goods Administration and the sponsor of the therapeutic good in accordance with the reporting guidelines set out in the SAS Guidance.

7 After Schedule 1

Insert:

Schedule 1A—Therapeutic vaping goods

Note: See section 5A.

Specified therapeutic goods

Column 1	Column 2	Column 3	Column 4	Column 5
Item	**Class of therapeutic goods**	**Dosage form**	**Route of administration**	**Indication**
1	therapeutic vaping substances or therapeutic vaping substance accessories that: (a) contain nicotine as the only active ingredient; (b) are the subject of a notification under item 15 in Schedule 5A to the Regulations; and (c) are not the subject of a determination by the Secretary under item 15 in Schedule 5A to the Regulations	liquid or solid	inhalation	any one or more of the following: (a) use for smoking cessation; (b) management of nicotine dependence
2	therapeutic vaping substances or therapeutic vaping substance accessories that: (a) do not contain any active ingredients; (b) are the subject of a notification under item 15 in Schedule 5A to the	liquid or solid	inhalation	any one or more of the following: (a) use for smoking cessation; (b) management of nicotine dependence

Specified therapeutic goods				
Column 1	**Column 2**	**Column 3**	**Column 4**	**Column 5**
Item	**Class of therapeutic goods**	**Dosage form**	**Route of administration**	**Indication**
	Regulations; and (c) are not the subject of a determination by the Secretary under item 15 in Schedule 5A to the Regulations			
3	therapeutic vaping kits that: (a) contain one or more therapeutic vaping substances or therapeutic vaping substance accessories; and (b) are the subject of a notification under item 15 in Schedule 5A to the Regulations; and (d) are not the subject of a determination by the Secretary under item 15 in Schedule 5A to the Regulations	liquid or solid	inhalation	any one or more of the following: (a) use for smoking cessation; (b) management of nicotine dependence
4	goods in a therapeutic vaping pack that: (a) are or contain one or more therapeutic vaping substances or therapeutic vaping substance accessories; and (b) are the subject of a notification under item 15 in Schedule 5A to the Regulations; and (c) are not the subject of a determination by the Secretary under item 15 in Schedule 5A to the Regulations	liquid or solid	inhalation	any one or more of the following: (a) use for smoking cessation; (b) management of nicotine dependence

Therapeutic Goods (Biologicals—Authorised Supply) Rules 2022

8 Section 4 (definition of *SAS guidance*)

Repeal the definition, substitute:

SAS Guidance means the document titled *Special Access Scheme (SAS): Guidance for health practitioners accessing unapproved therapeutic goods* (Version 1.0, January 2023) published by the Therapeutic Goods Administration, as in force or existing at 1 January 2024.

Note: The SAS Guidance is published at www.tga.gov.au.

Therapeutic Goods (Medical Devices—Authorised Supply) Rules 2022

9 Section 4 (definition of *SAS guidance*)

Repeal the definition, substitute:

SAS Guidance means the document titled *Special Access Scheme (SAS): Guidance for health practitioners accessing unapproved therapeutic goods* (Version 1.0, January 2023) published by the Therapeutic Goods Administration, as in force or existing at 1 January 2024.

Note: The SAS Guidance is published at www.tga.gov.au.