Therapeutic Goods (Authorised Supply) Amendment Rules 2025

I, Nicholas Henderson, as delegate of the Minister for Health and Ageing, make the following rules.

Dated 18 August 2025

Nicholas Henderson
First Assistant Secretary
Medicines Regulation Division
Health Products Regulation Group
Department of Health, Disability and Ageing

Contents

1 Name

This instrument is the *Therapeutic Goods (Authorised Supply) Amendment Rules 2025*.

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. Sections 1 to 4 and anything in this instrument not elsewhere covered by this table	The day after this instrument is registered.	
2. Schedule 1, Part 1	The day after this instrument is registered.	
3. Schedule 1, Part 2	The day after the end of the period in which this instrument could be disallowed in either House of the Parliament.	

Note 1: This table relates only to the provisions of this instrument as originally made.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.

Note 2: For item 3, this commencement 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*.

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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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

Part 1—Main amendments

Therapeutic Goods (Biologicals—Authorised Supply) Rules 2022

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

Repeal the items.

Therapeutic Goods (Medical Devices—Authorised Supply) Rules 2022

2 Schedule 1 (table items 2, 3, 5, 6 and 12 to 14)

Repeal the items.

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

Repeal the cell, substitute:

ophthalmologist;

plastic surgeon

4 Schedule 1 (table items 17, 18 and 20)

Repeal the items.

5 Schedule 1 (after table item 28)

Insert:

28A	Origin Stem, Coxa Vara, Sizes 9 to 18 – Signature Orthopaedics	hip arthroplasty	orthopaedic surgeon

6 Schedule 1 (after table item 35)

Insert:

35A	Taurolock-U25.000 ((cyclo)-taurolidine, citrate (4%) and urokinase (25.000 IU))	for use as a catheter lock solution, instilled into a port or a silicone or polyurethane catheter-based device at the termination of a treatment, and is withdrawn prior to subsequent treatments	nephrology physician

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

7 Schedule 1 (table item 26)

Repeal the item.

8 Schedule 1 (after table item 27)

Insert:

27A	escherichia coli/klebsiella pneumoniae/enterococcus faecalis/proteus vulgaris	spray	sublingual	management of recurrent urinary tract infections

9 Schedule 1 (after table item 33)

Insert:

33A	gallium-68 DOTA (Tyr3) octreotate	injection	intravenous	PET imaging for localisation of somatostatin receptor positive neuroendocrine tumours (NETs)

10 Schedule 1 (table item 34, column 2)

Repeal the cell, substitute:

gallium-68 (Ga-68)

11 Schedule 1 (table item 35, column 2)

Repeal the cell, substitute:

gallium-68 (Ga-68) - MAA

12 Schedule 1 (after table item 42)

Insert:

42A	imipenem/cilastatin	injection	intravenous	treatment of non-tuberculosis mycobacteria

13 Schedule 1 (after table item 45)

Insert:

45A	isoniazid/rifampicin	dispersible tablets	oral	treatment of latent tuberculosis infection
45B	isoniazid/rifampicin	tablets	oral	treatment of latent tuberculosis infection
45C	isoniazid/rifapentine	tablets	oral	treatment of latent tuberculosis infection

14 Schedule 1 (table items 51, 52 and 54)

Repeal the items.

15 Schedule 1 (after table item 58)

Insert:

58A	mycobacterium bovis (bacillus calmette and guerin (BCG) strain)	injection	intradermal	immunisation against tuberculosis

16 Schedule 1 (table items 67 and 68)

Repeal the items.

17 Schedule 1 (table item 78, column 2)

Omit “Technetium-99m”, substitute “technetium-99m”.

18 Schedule 1 (table item 87, column 2)

Omit “Citrate”, substitute “citrate”.

Part 2—Other amendments

Therapeutic Goods (Biologicals—Authorised Supply) Rules 2022

19 Section 4

Insert:

adverse event means an adverse event that occurs in relation to a person in Australia following the administration of a biological.

Note: An adverse event may not necessarily have a causal relationship with the administration or use of the biological.

20 Section 4 (definition of SAS Guidance)

Repeal the definition.

21 Paragraph 5(2)(d)

Omit "and the sponsor of the biological about the adverse event in accordance with the reporting guidelines set out in the SAS Guidance", substitute "within 15 days of becoming aware of the adverse event".

22 Paragraph 5(2)(e)

Omit "and the sponsor of the biological in accordance with the reporting guidelines set out in the SAS Guidance", substitute "within 15 days of becoming aware of the defect".

23 Paragraph 5(4)(a)

Omit "and the sponsor of the biological about the adverse event in accordance with the reporting guidelines set out in the SAS Guidance", substitute "within 15 days of becoming aware of the adverse event".

24 Paragraph 5(4)(b)

Omit "and the sponsor of the biological in accordance with the reporting guidelines set out in the SAS Guidance", substitute "within 15 days of becoming aware of the defect".

Therapeutic Goods (Medical Devices—Authorised Supply) Rules 2022

25 Section 4

Insert:

adverse event means an adverse event that occurs in relation to a person in Australia following use of a medical device that led, or might have led, to the death of, a serious injury to, or serious deterioration in the health of, that person.

Note: An adverse event may not necessarily have a causal relationship with the administration or use of the medical device.

defect, in relation to a medical device, means any of the following that might lead, or might have led, to the death of, a serious injury to, or serious deterioration in the health of, a person:

(a) any malfunction or deterioration in the characteristics or performance of the medical device;
(b) any inadequacy in the design, production, labelling, instructions for use or advertising materials of the medical device.

26 Section 4 (definition of *SAS guidance*)

Repeal the definition.

27 Paragraph 5(2)(d)

Omit "and the sponsor of the kind of medical device about the adverse event in accordance with the reporting guidelines set out in the SAS Guidance", substitute "within 15 days of becoming aware of the adverse event".

28 Paragraph 5(2)(e)

Omit "and the sponsor of the kind of medical device in accordance with the reporting guidelines set out in the SAS Guidance", substitute "within 15 days of becoming aware of the defect".

29 Paragraph 5(4)(a)

Omit "and the sponsor of the kind of medical device about the adverse event in accordance with the reporting guidelines set out in the SAS Guidance", substitute "within 15 days of becoming aware of the adverse event".

30 Paragraph 5(4)(b)

Omit "and the sponsor of the medical device in accordance with the reporting guidelines set out in the SAS Guidance", substitute "within 15 days of becoming aware of the defect".

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

31 Section 4

Insert:

adverse event means the following:
(a) in relation to a medicine—an adverse event that occurs in relation to a person in Australia following the administration of a medicine;
(b) in relation to a therapeutic good that is not a medicine—an adverse event that occurs in relation to a person in Australia following the use of the therapeutic good that led, or might have led, to the death of, a serious injury to, or serious deterioration in the health of, that person.

Note: An adverse event may not necessarily have a causal relationship with the administration or use of the therapeutic good.

32 Section 4 (definition of *SAS Guidance*)

Repeal the definition.

33 Paragraph 5(2)(d)

Omit "and the sponsor of the medicine about the adverse event in accordance with the reporting guidelines set out in the SAS Guidance", substitute "within 15 days of becoming aware of the adverse event".

34 Paragraph 5(2)(e)

Omit "and the sponsor of the medicine in accordance with the reporting guidelines set out in the SAS Guidance", substitute "within 15 calendar days of becoming aware of the defect".

35 Paragraph 5(4)(a)

Omit "and the sponsor of the medicine about the adverse event in accordance with the reporting guidelines set out in the SAS Guidance", substitute "within 15 days of becoming aware of the adverse event".

36 Paragraph 5(4)(b)

Omit "and the sponsor of the medicine in accordance with the reporting guidelines set out in the SAS Guidance", substitute "within 15 days of becoming aware of the defect".

37 Paragraph 5A(2)(d)

Omit "and the sponsor of the therapeutic good about the adverse event in accordance with the reporting guidelines set out in the SAS Guidance", substitute "within 15 days of becoming aware of the adverse event".

38 Paragraph 5A(2)(e)

Omit "and the sponsor of the therapeutic good in accordance with the reporting guidelines set out in the SAS Guidance", substitute "within 15 days of becoming aware of the defect".

39 Paragraph 5A(4)(a)

Omit "and the sponsor of the therapeutic good about the adverse event in accordance with the reporting guidelines set out in the SAS Guidance", substitute "within 15 days of becoming aware of the adverse event".

40 Paragraph 5A(4)(b)

Omit "and the sponsor of the therapeutic good in accordance with the reporting guidelines set out in the SAS Guidance", substitute "within 15 days of becoming aware of the defect".

41 Paragraph 5A(6)(f)

Omit "and the sponsor of the therapeutic good about the adverse event in accordance with the reporting guidelines set out in the SAS Guidance", substitute "within 15 days of becoming aware of the adverse event".

42 Paragraph 5A(6)(g)

Omit "and the sponsor of the therapeutic good in accordance with the reporting guidelines set out in the SAS Guidance", substitute "within 15 days of becoming aware of the defect".