Therapeutic Goods (Therapeutic Goods Order No. 91 - Standard for labels of prescription and related medicines) Amendment Order 2024

I, Nicholas Henderson, as delegate of the Minister for Health and Aged Care, make the following order.

Dated 2 December 2024

Nicholas Henderson
First Assistant Secretary
Medicines Regulation Division
Health Products Regulation Group

Contents

1 Name

This instrument is the *Therapeutic Goods (Therapeutic Goods Order No. 91 - Standard for labels of prescription and related medicines) Amendment Order 2024.*

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	The day after this instrument is registered.	

Note: This table relates only to the provisions of this instrument as originally made.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 section 10 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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 Order No. 91 – Standard for labels of prescription and related medicines

1 At the end of subsection 10(2)

Add:

; and (g) where the medicine is intended for electrolyte replacement, has a stated volume of 100 millilitres or less, and is manufactured or imported on or after 1 December 2026 – a statement, located immediately below the text mentioned in subsection 9(3), of:

(i) for potassium chloride—the equivalent quantity of potassium chloride in weight (in relation to the stated volume of fill of the injection); and

(ii) for all other active ingredients—the equivalent quantity of each active ingredient in millimoles (in relation to the stated volume of fill of the injection).

2 At the end of subsection 10(3)

Add:

; and (e) where the medicine is intended for electrolyte replacement and is manufactured or imported on or after 1 December 2026 – a statement, located immediately below the text mentioned in subsection 9(3), of:

(i) for potassium chloride—the equivalent quantity of potassium chloride in weight (in relation to the stated volume of fill of the injection); and

(ii) for all other active ingredients—the equivalent quantity of each active ingredient in millimoles (in relation to the stated volume of fill of the injection).

3 At the end of subsection 10(4)

Add:

; and (m) where the medicine is intended for electrolyte replacement and is manufactured or imported on or after 1 December 2026 – a statement, located immediately below the text mentioned in subsection 9(3), of:

(i) for potassium chloride, and unless precluded by the container size—the equivalent quantity of potassium chloride in weight (in relation to the stated volume of fill of the injection); and

(ii) for all other active ingredients—the equivalent quantity of each active ingredient in millimoles (in relation to the stated volume of fill of the injection).

4 Subparagraph 11(2)(f)(i)

After "solution for injection", insert ", and is not intended for electrolyte replacement".

5 Subparagraph 11(2)(f)(v)

After "(whether dilution is required or not)", insert ", and is not intended for electrolyte replacement".

6 At the end of paragraph 11(2)(f)

Add:

; (vi) where the stated volume of the medicine for injection is 100 millilitres or less, and the medicine is intended for electrolyte replacement - the following:

(A) for potassium chloride—as the number of millimoles of potassium chloride in the stated volume of fill of the injection in the container;

(B) for all other active ingredients—as the stated weight of each active ingredient in the stated volume of fill of the injection in the container;

7 After section 11

Insert:

12 Application, savings and transitional provisions

Section 11, as in force immediately before the amendments made by the *Therapeutic Goods (Therapeutic Goods Order No. 91– Standard for labels of prescription and related medicines) Amendment Order 2024*, continues to apply to medicines manufactured or imported before 1 December 2026.