Therapeutic Goods Legislation Amendment (Standards for Labels—International Harmonisation of Ingredient Names) Order 2023

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

Dated 24 April 2023

Nicholas Henderson
Acting First Assistant Secretary
Medicines Regulation Division
Health Products Regulation Group
Department of Health and Aged Care

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1 Name

This instrument is the *Therapeutic Goods Legislation Amendment (Standards for Labels—International Harmonisation of Ingredient Names) Order 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	30 April 2023.	30 April 2023

Note: This table relates only to the provisions of this instrument as originally made.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 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 Subsection 9(10)

Repeal the subsection (not including the note), substitute:

(10) Subsection 9(9) does not apply:

(a) where the medicine is supplied in a small container or a very small container; or

(b) where the medicine is not supplied in a small container or a very small container and is labelled in accordance with subsection 9(11) and Part 1 of Schedule 2—after 30 April 2026; or

(c) where the medicine is not supplied in a small container or a very small container and is labelled in accordance with subsection 9(13) and Part 2 of Schedule 2—after 30 April 2028.

2 At the end of section 9

Add:

(11) An active ingredient specified in Part 1 of Schedule 2, either alone or in combination with any other descriptors, may be included on the main label of a medicine containing that ingredient as specified in that Part for medicine released for supply before 1 May 2026.

(12) To avoid doubt, an active ingredient specified in Part 1 of Schedule 2 must be included on the main label of a medicine containing that ingredient in accordance with the Australian Approved Names List for medicine released for supply on or after 1 May 2026.

(13) An active ingredient specified in Part 2 of Schedule 2, either alone or in combination with any other descriptors, may be included on the main label of a medicine containing that ingredient as specified in that Part for medicine released for supply before 1 May 2028.

(14) To avoid doubt, an active ingredient specified in Part 2 of Schedule 2 must be included on the main label of a medicine containing that ingredient in accordance with the Australian Approved Names List for medicine released for supply on or after 1 May 2028.

3 Schedule 2

Repeal the Schedule, substitute:

Schedule 2

Specified ingredient names

Part 1—Dual labelling name permitted from 1 May 2023 until 30 April 2026

Ingredient name
amobarbital (amylobarbitone)
amphotericin B (amphotericin)
asparaginase (colaspase)
calcitonin salmon (salcatonin)
dactinomycin (actinomycin D)
doxycycline hyclate (hydrochloride)
estropipate (piperazine oestrone)
formoterol (eformoterol)
furosemide (frusemide)
glycopyrronium bromide (glycopyrrolate)
lidocaine (lignocaine)
mecobalamin (co-methylcobalamin)
pentoxifylline (oxpentifylline)
phenobarbital (phenobarbitone)
procaine benzylpenicillin (procaine penicillin)
tetracosactide (tetracosactrin)

Part 2—Dual labelling name permitted from 1 May 2025 until 30 April 2028

Ingredient name
dosulepin (dothiepin)
hydroxycarbamide (hydroxyurea)
tetracaine (amethocaine)
trihexyphenidyl (benzhexol)

Part 3—Dual labelling name

Ingredient name
alimemazine (trimeprazine)
mercaptamine (cysteamine)
Mycobacterium bovis (Bacillus Calmette and Guerin (BCG) strain)

Therapeutic Goods Order No. 92 - Standard for labels of non-prescription medicines

4 Subsection 9(10)

Repeal the subsection (not including the note), substitute:

(10) Subsection 9(9) does not apply:
- (a) where the medicine is supplied in a small container; or
- (b) where the medicine is not supplied in a small container and is labelled in accordance with subsection 9(11) and Part 1 of Schedule 2—after 30 April 2026; or
- (c) where the medicine is not supplied in a small container and is labelled in accordance with subsection 9(13) and Part 2 of Schedule 2—after 30 April 2028.

5 At the end of section 9

Add:

(11) An active ingredient specified in Part 1 of Schedule 2, either alone or in combination with any other descriptors, may be included on the main label of a medicine containing that ingredient as specified in that Part for medicine released for supply before 1 May 2026.

(12) To avoid doubt, an active ingredient specified in Part 1 of Schedule 2 must be included on the main label of a medicine containing that ingredient in accordance with the Australian Approved Names List for medicine released for supply on or after 1 May 2026.

(13) An active ingredient specified in Part 2 of Schedule 2, either alone or in combination with any other descriptors, may be included on the main label of a medicine containing that ingredient as specified in that Part for medicine released for supply before 1 May 2028.

(14) To avoid doubt, an active ingredient specified in Part 2 of Schedule 2 must be included on the main label of a medicine containing that ingredient in accordance with the Australian Approved Names List for medicine released for supply on or after 1 May 2028.

6 Schedule 2

Repeal the Schedule, substitute:

Schedule 2

Specified ingredient names

Part 1—Dual labelling name permitted from 1 May 2023 until 30 April 2026

Ingredient name
amobarbital (amylobarbitone)
amphotericin B (amphotericin)
asparaginase (colaspase)
calcitonin salmon (salcatonin)
dactinomycin (actinomycin D)
doxycycline hyclate (hydrochloride)
estropipate (piperazine oestrone)
formoterol (eformoterol)
furosemide (frusemide)
glycopyrronium bromide (glycopyrrolate)
lidocaine (lignocaine)
mecobalamin (co-methylcobalamin)
pentoxifylline (oxpentifylline)
phenobarbital (phenobarbitone)
procaine benzylpenicillin (procaine penicillin)
tetracosactide (tetracosactrin)

Part 2—Dual labelling name permitted from 1 May 2025 until 30 April 2028

Ingredient name
dosulepin (dothiepin)
hydroxycarbamide (hydroxyurea)
tetracaine (amethocaine)
trihexyphenidyl (benzhexol)

Part 3—Dual labelling name

Ingredient name
alimemazine (trimeprazine)
mercaptamine (cysteamine)
Mycobacterium bovis (Bacillus Calmette and Guerin (BCG) strain)