Therapeutic Goods (Exempt Monographs) Amendment Determination 2025

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

Dated 27 June 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 (Exempt Monographs) Amendment Determination 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. 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Note: This table relates only to the provisions of this instrument as originally made.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 3C 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 (Exempt Monographs) Determination 2021

1 Section 4 (note)

Repeal the note, substitute:

Note: A number of expressions used in this instrument are defined in subsection 3(1) of the Act, including the following:

(a) British Pharmacopoeia;
(b) European Pharmacopoeia;
(c) export only medicine;
(d) listed goods;
(e) medicine;
(f) Register;
(g) standard;
(h) therapeutic goods;
(i) United States Pharmacopeia-National Formulary.

2 Section 5 (at the end of the heading)

Add "**of entire monographs**".

3 After section 5

Insert:

6 Exemption of parts of monographs

For subsection 3C(2) of the Act, in relation to each item mentioned in the table in Schedule 2, the statements in monographs specified in column 2, in the pharmacopoeia specified in column 3, are exempt for the purposes of paragraph (b), (c) or (d) of the definition of ***standard*** in subsection 3(1) of the Act, in relation to the therapeutic goods specified in column 4.

4 After Schedule 1

Insert:

Schedule 2—Exempt parts of monographs

Note: See section 6.

Parts of monographs exempt from the definition of standard			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Statements in monographs**	**Pharmacopoeia**	**Therapeutic goods**
1	the statement in monograph 3053 that the label states the name of any stabilisers and other excipients	each of the following: (a) British Pharmacopoeia; (b) European Pharmacopoeia	medicines that: (a) are listed goods or eligible for listing, other than export only medicines; and (b) contain a whole live microorganism,

Parts of monographs exempt from the definition of standard			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Statements in monographs**	**Pharmacopoeia**	**Therapeutic goods**
			other than *arthrospira maxima* or *arthrospira platensis*, as an active ingredient