



Therapeutic Goods (Exempt Monographs) Determination 2021

I, John Skerritt, as delegate of the Minister for Health and Aged Care, make the following determination.

Dated 14 May 2021

Adjunct Professor John Skerritt
Deputy Secretary
Health Products Regulation Group
Department of Health

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1 Name

This instrument is the *Therapeutic Goods (Exempt Monographs) Determination 2021*.

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 <i>Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Order 2021</i> commences. However, this instrument does not commence at all if the <i>Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Order 2021</i> 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Note: This table relates only to the provisions of this instrument as originally made.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 section 3C of the *Therapeutic Goods Act 1989*.

4 Definitions

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) standard;
- (d) therapeutic goods;
- (e) United States Pharmacopoeia-National Formulary.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

nicotine vaping product has the same meaning as in TGO 110.

TGO 110 means the *Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Order 2021*.

Note: TGO 110 is a legislative instrument published on the Federal Register of Legislation at www.legislation.gov.au.

5 Exemption

For subsection 3C(1) of the Act, in relation to each item mentioned in the table in Schedule 1, the 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.

Schedule 1—Exempt monographs

Note: See section 5.

Monographs exempt from the definition of standard

Column 1	Column 2	Column 3	Column 4
Item	Monograph	Pharmacopoeia	Therapeutic goods
1	all monographs applicable to the therapeutic goods	all of the following: (a) British Pharmacopoeia; (b) European Pharmacopoeia; (c) United States Pharmacopoeia-National Formulary	a nicotine vaping product to which TGO 110 applies
