



Therapeutic Goods (Exempt Monographs) Determination 2021

made under section 3C of the
Therapeutic Goods Act 1989

Compilation No. 2

Compilation date: 1 January 2024

Includes amendments up to: F2023L01680

Prepared by Department of Health and Aged Care, Canberra

About this compilation

This compilation

This is a compilation of the *Therapeutic Goods (Exempt Monographs) Determination 2021* that shows the text of the law as amended and in force on 1 January 2024 (the **compilation date**).

The notes at the end of this compilation (the **endnotes**) include information about amending laws and the amendment history of provisions of the compiled law.

Uncommenced amendments

The effect of uncommenced amendments is not shown in the text of the compiled law. Any uncommenced amendments affecting the law are accessible on the Register (www.legislation.gov.au). The details of amendments made up to, but not commenced at, the compilation date are underlined in the endnotes. For more information on any uncommenced amendments, see the Register for the compiled law.

Application, saving and transitional provisions for provisions and amendments

If the operation of a provision or amendment of the compiled law is affected by an application, saving or transitional provision that is not included in this compilation, details are included in the endnotes.

Modifications

If the compiled law is modified by another law, the compiled law operates as modified but the modification does not amend the text of the law. Accordingly, this compilation does not show the text of the compiled law as modified. For more information on any modifications, see the Register for the compiled law.

Self-repealing provisions

If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

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1 Name

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

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*.

regulations means the *Therapeutic Goods Regulations 1990*.

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

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

therapeutic vaping substance has the same meaning as in Regulations.

therapeutic vaping substance accessory has the same meaning as in Regulations.

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 therapeutic vaping substance or therapeutic vaping substance accessory to which TGO 110 applies |
| 2 | antithrombin III human | United States Pharmacopoeia-National Formulary | therapeutic goods |
| 3 | factor IX complex | United States Pharmacopoeia-National Formulary | therapeutic goods |
| 4 | pancreatin | United States Pharmacopoeia-National Formulary | therapeutic goods |
| 5 | pancrelipase | United States Pharmacopoeia-National Formulary | therapeutic goods |
| 6 | plasma protein fraction | United States Pharmacopoeia-National Formulary | therapeutic goods |

Endnotes

Endnote 1—About the endnotes

The endnotes provide information about this compilation and the compiled law.

The following endnotes are included in every compilation:

Endnote 1—About the endnotes

Endnote 2—Abbreviation key

Endnote 3—Legislation history

Endnote 4—Amendment history

Abbreviation key—Endnote 2

The abbreviation key sets out abbreviations that may be used in the endnotes.

Legislation history and amendment history—Endnotes 3 and 4

Amending laws are annotated in the legislation history and amendment history.

The legislation history in endnote 3 provides information about each law that has amended (or will amend) the compiled law. The information includes commencement details for amending laws and details of any application, saving or transitional provisions that are not included in this compilation.

The amendment history in endnote 4 provides information about amendments at the provision (generally section or equivalent) level. It also includes information about any provision of the compiled law that has been repealed in accordance with a provision of the law.

Misdescribed amendments

A misdescribed amendment is an amendment that does not accurately describe how an amendment is to be made. If, despite the misdescription, the amendment can be given effect as intended, then the misdescribed amendment can be incorporated through an editorial change made under section 15V of the *Legislation Act 2003*.

If a misdescribed amendment cannot be given effect as intended, the amendment is not incorporated and “(md not incorp)” is added to the amendment history.

Endnotes

Endnote 2—Abbreviation key

Endnote 2—Abbreviation key

| | |
|--|--|
| ad = added or inserted | orig = original |
| am = amended | par = paragraph(s)/subparagraph(s) /sub-subparagraph(s) |
| amdt = amendment | pres = present |
| c = clause(s) | prev = previous |
| C[x] = Compilation No. x | (prev...) = previously |
| Ch = Chapter(s) | Pt = Part(s) |
| def = definition(s) | r = regulation(s)/rule(s) |
| Dict = Dictionary | reloc = relocated |
| disallowed = disallowed by Parliament | renum = renumbered |
| Div = Division(s) | rep = repealed |
| exp = expires/expired or ceases/ceased to have effect | rs = repealed and substituted |
| F = Federal Register of Legislation | s = section(s)/subsection(s) |
| gaz = gazette | Sch = Schedule(s) |
| LA = <i>Legislation Act 2003</i> | Sdiv = Subdivision(s) |
| LIA = <i>Legislative Instruments Act 2003</i> | SLI = Select Legislative Instrument |
| (md not incorp) = misdescribed amendment cannot be given effect | SR = Statutory Rules |
| mod = modified/modification | Sub-Ch = Sub-Chapter(s) |
| No. = Number(s) | SubPt = Subpart(s) |
| o = order(s) | <u>underlining</u> = whole or part not commenced or to be commenced |
| Ord = Ordinance | |

Endnote 3—Legislation history

Endnote 3—Legislation history

| Name | Registration | Commencement | Application, saving and transitional provisions |
|--|------------------------------|---------------------|--|
| <i>Therapeutic Goods (Exempt Monographs) Determination 2021</i> | 19 May 2021 (F2021L00594) | 01 Oct 2021 | — |
| <i>Therapeutic Goods (Exempt Monographs) Amendment Determination 2022</i> | 28 Mar 2022 (F2022L00401) | 31 Mar 2022 | — |
| <i>Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Amendment (Vaping) Order 2023</i> | 15 Dec 2023 (F2023L01680) | 01 Jan 2024 | — |

Endnotes

Endnote 4—Amendment history

Endnote 4—Amendment history

| Provision affected | How affected |
|---------------------------|-----------------------------|
| s 2..... | rep LA s 48D |
| s 4..... | am F2023L01680 |
| Schedule 1..... | am F2022L00401; F2023L01680 |