Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Isosorbide Mononitrate) Instrument 2021

made under subsection 30EK(1) of the

Therapeutic Goods Act 1989

Compilation No. 1

Compilation date: 16 December 2022

Includes amendments up to: F2022L01656

Prepared by Department of Health and Aged Care, Canberra

About this compilation

This compilation

This is a compilation of the *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Isosorbide Mononitrate) Instrument 2021* that shows the text of the law as amended and in force on 16 December 2022 (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 Legislation 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 series page on the Legislation 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 series page on the Legislation 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If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.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 (Serious Scarcity and Substitutable Medicine) (Isosorbide Mononitrate) Instrument 2021*.

3 Authority

This instrument is made under section 30EK 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) medicine;

(b) Register;

(c) registered goods.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

pharmacist has the same meaning as in subsection 30EK(6) of the Act.

prescriber means the person who:

(a) is authorised under a law of a state or territory to prescribe medicine, and

(b) prescribed the scarce medicine for the patient.

registered medicine means a medicine that is included in the part of the Register for goods known as registered goods.

scarce medicine has the meaning given by section 5.

substitutable medicine has the meaning given by section 6.

5 Declaration of serious scarcity

For paragraph 30EK(1)(a) of the Act, a serious scarcity of the medicine specified in column 2 of each item in the table in Schedule 1 (the ***scarce medicine***) across the whole of Australia is declared.

6 Substitution of scarce medicine by pharmacists

For paragraph 30EK(1)(b) of the Act, in relation to each item mentioned in the table in Schedule 1, the medicine specified in column 3 (the ***substitutable medicine***) is permitted to be dispensed by a pharmacist in substitution for the scarce medicine specified in column 2, in the circumstances specified in:

(a) column 5 of that item (the ***specific permitted circumstances***); and

(b) the table in Schedule 2 (the ***general permitted circumstances***).

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Note: Substitution is only permitted where both the specific permitted circumstances and the general permitted circumstances exist.

7 Period instrument in force

This instrument remains in force until 30 June 2023.

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Schedule 1—Scarce medicine, substitutable medicine, dose unit equivalence and specific permitted circumstances

Note: See sections 5 and 6.

Scarce medicine, substitutable medicine, dose unit equivalence and specific permitted circumstances

Column 1	Column 2	Column 3	Column 4	Column 5
Item	**Scarce medicine**	**Substitutable medicine**	**Dose unit equivalence**	**Specific permitted circumstances**
1	a registered medicine that: (a) contains 120 milligrams of isosorbide mononitrate as the only active ingredient; and (b) is manufactured in the dosage form of a modified release tablet	a registered medicine that: (a) contains 60 milligrams of isosorbide mononitrate as the only active ingredient; and (b) is manufactured in the dosage form of a modified release tablet	two tablets of substitutable medicine are equivalent to one tablet of scarce medicine	the pharmacist has advised the patient, or the person acting on behalf of the patient, of the number of dose units of substitutable medicine that must be taken by the patient in substitution for the prescribed dose of scarce medicine, based on the dose unit equivalence specified in column 4

Schedule 2—General permitted circumstances

Note: See section 6.

General permitted circumstances	
Column 1	**Column 2**
Item	**Circumstances**
1	the patient, or person acting on behalf of the patient, has evidence of a valid prescription for the scarce medicine, unless otherwise permitted by law
2	the pharmacist does not have access to the scarce medicine
3	the prescriber has not indicated on the prescription for the scarce medicine that substitution is not permitted
4	the pharmacist has exercised professional judgement and determined that the patient is suitable to receive the substitutable medicine
5	the amount of substitutable medicine dispensed would result in the patient receiving sufficient medicine to ensure an equivalent dosage regimen and duration to that prescribed in relation to the scarce medicine
6	the patient, or person acting on behalf of the patient, has consented to receiving the substitutable medicine
7	the pharmacist makes a record of dispensing the substitutable medicine in substitution of the scarce medicine at the time of dispensing
8	the pharmacist has an established procedure to notify the prescriber of the substitution at the time of, or as soon as practical after, dispensing the substitutable medicine

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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.

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Endnote 2—Abbreviation key

ad = added or inserted

am = amended

amdt = amendment

c = clause(s)

C[x] = Compilation No. x

Ch = Chapter(s)

def = definition(s)

Dict = Dictionary

disallowed = disallowed by Parliament

Div = Division(s)

exp = expires/expired or ceases/ceased to have effect

F = Federal Register of Legislation

gaz = gazette

LA = *Legislation Act 2003*

LIA = *Legislative Instruments Act 2003*

(md not incorp) = misdescribed amendment cannot be given effect

mod = modified/modification

No. = Number(s)

o = order(s)

Ord = Ordinance

orig = original

par = paragraph(s)/subparagraph(s) /sub-subparagraph(s)

pres = present

prev = previous

(prev…) = previously

Pt = Part(s)

r = regulation(s)/rule(s)

reloc = relocated

renum = renumbered

rep = repealed

rs = repealed and substituted

s = section(s)/subsection(s)

Sch = Schedule(s)

Sdiv = Subdivision(s)

SLI = Select Legislative Instrument

SR = Statutory Rules

Sub-Ch = Sub-Chapter(s)

SubPt = Subpart(s)

underlining = whole or part not commenced or to be commenced

Endnote 3—Legislation history

Name	Registration	Commencement	Application, saving and transitional provisions
Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Isosorbide Mononitrate) Instrument 2021	17 Sep 2021 (F2021L01286)	18 Sep 2021	—
Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Isosorbide Mononitrate) Amendment Instrument 2022	15 Dec 2022 (F2022L01656)	16 Dec 2022	—

Endnote 4—Amendment history

Provision affected	How affected
s 2…….	rep LA s 48D
s 7…….	rs F2022L01656

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