EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Isosorbide Mononitrate) Amendment Instrument 2022

The *Therapeutic Goods Act 1989* ("the Act") provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy and timely availability of therapeutic goods that are used in, or exported from, Australia. The Act also provides for a scheme allowing pharmacists to substitute certain medicines for other medicines if the Minister has declared there is a serious scarcity of the other medicine. The Act is administered by the Therapeutic Goods Administration ("the TGA") within the Australian Government Department of Health and Aged Care.

Subsection 30EK(1) of the Act provides that the Minister may, by legislative instrument, declare that there is a serious scarcity of a specified medicine ("the scarce medicine") across the whole or a specified part or parts of Australia, and specify the medicine ("the substitutable medicine") that pharmacists are permitted to dispense in substitution for the scarce medicine and the circumstances in which that substitution is permitted.

Subsection 30EK(2) of the Act provides that the Minister may only make an instrument under subsection 30EK(1) if satisfied that the supply of the scarce medicine in Australia is not currently meeting the demand for that medicine for all of the patients in Australia who take that medicine or, alternatively, there is an imminent risk that supply of the scarce medicine in Australia will not, or will not be likely to, meet the demand for that medicine for all of the patients in Australia who take, or who may need to take, that medicine. In either case, there must be a significant risk of adverse health consequences for patients in Australia if they are not able to take the scarce medicine.

Subsection 30EK(3) of the Act provides that both the scarce medicine and the substitutable medicine must contain one or more substances included in Schedule 4 to the current Poisons Standard (i.e. prescription medicines) and must not contain any substances included in Schedule 8 to the current Poisons Standard (i.e. substances for which particular levels of control are required or recommended in order to avoid abuse, misuse or dependence).

The *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Isosorbide Mononitrate) Instrument 2021* ("the Principal Instrument") is a legislative instrument made under subsection 30EK(1) of the Act. It declares registered medicines that contain 120 milligrams of isosorbide mononitrate as the only active ingredient and that are manufactured in the dosage form of a modified release tablet as scarce medicines, and that registered medicines that contain 60 milligrams of isosorbide mononitrate as the only active ingredient and that are manufactured in the dosage form of a modified release tablet are substitutable for the scarce medicine in accordance with the Principal Instrument.

The *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Isosorbide Mononitrate) Amendment Instrument 2022* ("the Amendment Instrument") is made in the context of the ongoing shortage of registered medicines that contain 120 milligrams of the active ingredient isosorbide mononitrate that are manufactured in the dosage form of a modified release tablet. The purpose of the Amendment Instrument is to extend the period of time for which the Principal Instrument remains in force, by changing the date the Principal Instrument remains in force until from 19 December 2022 to 30 June 2023.

Background

Medicine shortages continue to occur for a number of reasons, including manufacturing issues, logistics problems and increases in demand. The TGA receives approximately 105 new medicine shortage notifications every month.

There are currently shortages across Australia of multiple medicines containing 120 milligrams of the active ingredient isosorbide mononitrate, due to manufacturing issues. This includes MONODUR DURULES isosorbide mononitrate 120 milligram tablets (which have been in shortage since 23 August 2021), and IMDUR DURULES isosorbide mononitrate 120 milligram tablets (which have been in shortage since 27 September 2021). These medicines are used for the prophylactic treatment of angina pectoris and their scarcity is having a significant impact on the health and wellbeing of many patients in Australia. As such, there is a significant risk of adverse health consequences for patients in Australia if they are not able to take the scarce medicine.

The Principal Instrument identifies any registered medicine that contains 120 milligrams of isosorbide mononitrate as the only active ingredient and that is manufactured in the dosage form of a modified release tablet as being scarce medicines across the whole of Australia.

The Principal Instrument also has the effect that any registered medicine that contains 60 milligrams of isosorbide mononitrate as the only active ingredient and is manufactured in the dosage form of a modified release tablet, is substitutable by a pharmacist for each scarce medicine, in the circumstances permitted by the Principal Instrument. Two tablets of substitutable medicine are equivalent to one tablet of scarce medicine.

The making of the Principal Instrument (and its extension by the Amendment Instrument) allows pharmacists to substitute the substitutable medicine for the scarce medicine and ensure that patients with the condition outlined above can access suitable treatments without delay. This reduces the risk of interrupted treatment for affected patients, as otherwise patients could not access the substitutable medicine without first having a further appointment with their prescriber.

The Principal Instrument specifies a number of specific and general permitted circumstances that have the effect of confining when a pharmacist may substitute each of the substitutable medicines for the relevant scarce medicine for a patient. The circumstances are designed to ensure that there are carefully determined safety-related parameters in place for patients.

In accordance with subsection 30EK(2) of the Act, the rule-maker is satisfied that there is an imminent risk that supplies of the scarce medicine will not, or will not be likely to, meet the demand for them for all of the patients in Australia who take, or who may need to take, each of them. The rule-maker is also satisfied that there is a significant risk of adverse health consequences for patients in Australia if those patients are unable to take the scarce medicine. There are no other matters prescribed by the regulations for the purposes of paragraph 30EK(2)(c).

In accordance with subsection 30EK(3) of the Act, medicines that contain isosorbide mononitrate are included in Schedule 4 to the current Poisons Standard, and do not contain a substance in Schedule 8 to the current Poisons Standard.

In accordance with subsection 30EK(5) of the Act, the Principal Instrument remains in force until 19 December 2022. However, as shortages of isosorbide mononitrate 120 milligram modified release tablets continue, and supply is not expected to normalise until June 2023, the purpose of the Amendment Instrument is to extend the period of time for which the Principal Instrument remains in force, being until 30 June 2023. If the shortage of the scarce medicines is resolved sooner or if safety concerns are identified, the Principal Instrument may be revoked before its cessation date.

Consultation

The Office of Impact Analysis ("OIA") has advised that the preparation of a policy impact analysis is not required in relation to the creation of the Amendment Instrument as it is unlikely to have more than a minor regulatory impact (OIA ID 44492).

Between 7 and 9 December 2022 the TGA consulted on the proposed extension of the period of the Principal Instrument with the Australian Medical Association, the Cardiac Society of Australia and New Zealand, the Royal Australian College of General Practitioners, state and territory Chief Pharmacists, the Pharmaceutical Society of Australia, the Society of Hospital Pharmacists of Australia, the Pharmacy Guild of Australia, and the Heart Foundation, in order to ensure the substitution protocol and associated permitted circumstances remain appropriate. No concerns were raised in relation to the proposal.

The TGA has also consulted with sponsors of substitutable medicines, to ensure that sufficient supplies are available.

Details of the Amendment Instrument are set out in **Attachment A**.

The Amendment Instrument is compatible with human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in **Attachment B**.

The Amendment Instrument is a disallowable legislative instrument for the purposes of the *Legislation Act 2003* and commences on the day after it is registered on the Federal Register of Legislation.

Attachment A

Details of the *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Isosorbide Mononitrate) Amendment Instrument 2022*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Isosorbide Mononitrate) Amendment Instrument 2022* ("the Amendment Instrument").

Section 2 – Commencement

This section provides that the Amendment Instrument commences on the day after it is registered on the Federal Register of Legislation.

Section 3 – Authority

This section provides that the legislative authority for making the Amendment Instrument is section 30EK of the *Therapeutic Goods Act 1989* ("the Act").

Subsection 33(3) of the *Acts Interpretation Act 1901* relevantly provides that, where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character, the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument. This Amendment Instrument is made in accordance with that provision.

Section 4 – Schedules

This section provides that each instrument that is specified in a Schedule to the Amendment Instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and that any other item in a Schedule to the Amendment Instrument has effect according to its terms.

Schedule 1—Amendments

Schedule 1 amends the *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Isosorbide Mononitrate) Instrument 2021* ("the Principal Instrument").

Item 1 repeals and replaces section 7 of the Principal Instrument to provide that the Principal Instrument remains in force until 30 June 2023.

Attachment B

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*

Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Isosorbide Mononitrate) Amendment Instrument 2022

This disallowable legislative instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of legislative instrument

Subsection 30EK(1) of the Act provides that the Minister may, by legislative instrument, declare that there is a serious scarcity of a specified medicine ("the scarce medicine") across the whole or a specified part or parts of Australia, and specify the medicine ("the substitutable medicine") that pharmacists are permitted to dispense in substitution for the scarce medicine and the circumstances in which that substitution is permitted. The effect of an instrument under subsection 30EK(1) is that, pursuant to section 30EL of the Act, a pharmacist is authorised to dispense the substitutable medicine to a person in substitution for the scarce medicine despite any law of a state or territory that may prohibit such substitution, provided that the substitution is in accordance with the circumstances specified in the instrument under subsection 30EK(1).

Subsection 30EK(2) of the Act provides that the Minister may only make an instrument under subsection 30EK(1) if satisfied that the supply of the scarce medicine in Australia is not currently meeting the demand for that medicine for all of the patients in Australia who take that medicine or, alternatively, there is an imminent risk that supply of the scarce medicine in Australia will not, or will not be likely to, meet the demand for that medicine for all of the patients in Australia who take, or who may need to take, that medicine. In either case, there must be a significant risk of adverse health consequences for patients in Australia if they are not able to take the scarce medicine.

Subsection 30EK(3) of the Act provides that both the scarce medicine and the substitutable medicine must contain one or more substances included in Schedule 4 to the current Poisons Standard (i.e. prescription medicines), and must not contain any substances included in Schedule 8 to the current Poisons Standard (i.e. substances for which particular levels of control are required or recommended in order to avoid abuse, misuse or dependence).

Medicine shortages continue to occur for a number of reasons, including manufacturing issues, logistics problems, and increases in demand. The Therapeutic Goods Administration receives notifications of approximately 105 new medicine shortages every month. The problem of medicines shortages was amplified during the COVID-19 pandemic.

There are currently shortages across Australia of multiple medicines containing 120 milligrams of the active ingredient isosorbide mononitrate, due to manufacturing issues.

These medicines are used for the prophylactic treatment of angina pectoris, and their scarcity is having a significant impact on the health and wellbeing of many patients in Australia. As such, there is a significant risk of adverse health consequences for patients in Australia if they are not able to take the scarce medicine.

The *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Isosorbide Mononitrate) Instrument 2021* ("the Principal Instrument") is a legislative instrument made under subsection 30EK(1) of the Act. It identifies any registered medicine that contains 120 milligrams of isosorbide

mononitrate as the only active ingredient and that is manufactured in the dosage form of a modified release tablet as being scarce medicines across the whole of Australia.

The Principal Instrument also has the effect that any registered medicine that contains 60 milligrams of isosorbide mononitrate as the only active ingredient and that is manufactured in the dosage form of a modified release tablet, as being substitutable by a pharmacist for each scarce medicine, in the circumstances permitted in the Principal Instrument.

The purpose of the *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Isosorbide Mononitrate) Amendment Instrument 2022* ("the Amendment Instrument") is to extend the period of time for which the Principal Instrument remains in force, by changing the date the Principal Instrument remains in force until from 19 December 2022, to 30 June 2023.

Human rights implications

The Amendment Instrument engages the right to health in Article 12 of the International Covenant on Economic, Social and Cultural rights ("the ICESCR"). Article 12 of the ICESCR promotes the right of all individuals to enjoy the highest attainable standards of physical and mental health, and includes an obligation to take reasonable measures within available resources to progressively secure broader enjoyment of the right.

In *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12)* (2000), the United Nations Committee on Economic, Social and Cultural Rights states that health is a 'fundamental human right indispensable for the exercise of other human rights', and that the right to health is not to be understood as the right to be healthy, but includes the right to a system of health protection which provides equal opportunity for people to enjoy the highest attainable level of health.

The Amendment Instrument takes positive steps to promote the right to health by facilitating improved access to the substitutable medicines, and to ameliorate the effects of their uneven availability across the Australian market. By enabling pharmacists to substitute these important products, the Amendment Instrument will support the right to health through helping Australian patients avoid the suffering that may otherwise occur due to an interruption in treatment for their angina pectoris condition.

Conclusion

The Amendment Instrument is compatible with human rights because it promotes the right to health in Article 12 of the ICESCR and otherwise does not raise any other human rights issues.