EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Fluoxetine) Amendment Instrument 2024

The *Therapeutic Goods Act 1989* ("the Act") provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy or performance, 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 medicine for other medicine 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 ("the Department").

Subsection 30EK(1) of the Act provides that the Minister may, by legislative instrument, declare that there is a serious scarcity of 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. Alternatively, the Minister must be satisfied that 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) (Fluoxetine) Instrument 2023* ("the Principal Instrument") is a legislative instrument made under subsection 30EK(1) of the Act. It declares that there is a serious scarcity across Australia of specified medicines ("the scarce medicine"), specifies the medicines that pharmacists are permitted to dispense in substitution for the scarce medicine ("the substitutable medicine), and the circumstance in which they may do so.

The Principal Instrument declares one registered medicine to be a scarce medicine, being ZACTIN TABS fluoxetine hydrochloride 20 milligram dispersible tablet blister pack, Australian Register of Therapeutic Goods ("ARTG") registration number 90913 ("ZACTIN TABS"). The Principal Instrument also declares that where a pharmacist is unable to dispense the scarce medicine that has been prescribed to a patient, they may instead dispense a substitutable medicine in accordance with the Principal Instrument. The substitutable medicines that are specified in the Principal Instrument are capsules containing 10 mg fluoxetine hydrochloride or 20 mg fluoxetine hydrochloride.

The *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Fluoxetine) Amendment Instrument 2024* ("the Amendment Instrument") is made in the context of the ongoing shortage of ZACTIN TABS. The purpose of the Amendment Instrument is to extend the period of time that the Principal Instrument remains in force, from 31 May 2024 to 30 September 2024. Consequentially, the

Amendment Instrument also changes the date on which the Principal Instrument is repealed, from 1 June 2024 to the start of 1 October 2024.

Background

Pharmacist Substitution

Medicine shortages continue to occur for a number of reasons, including manufacturing issues (such as shortages of raw materials), logistical issues, or unexpected increases in demand. The TGA receives an average of 120 new medicine shortage notifications every month.

When a medicine is unavailable, community pharmacists have limited scope to substitute another medicine without the prior approval of the prescribing doctor. A pharmacist may substitute a different brand of an equivalent product, which may include an equivalent overseas-registered medicine approved for supply under section 19A of the Act. However, where there is no such equivalent available, the pharmacist cannot substitute a different medicine. If the pharmacist is unable to contact the prescriber to authorise a change to the prescription, the patient may be unable to obtain their medicine. This impedes the timely availability of medicines and risks interruption to treatment, which can impact patient health and cause anxiety and stress for patients.

During 2020, an informal arrangement was implemented between the Commonwealth and the states and territories to allow pharmacist substitution of medicines that are in shortage, with patient consent. However, this informal arrangement was implemented through state and territory legislation, and some state and territory legislation allowed for such provision to be made for pharmacist substitution only during a public health emergency. A need therefore arose for a more consistent and responsive pharmacist substitution scheme to help alleviate the effects of medicine shortages; one allowing substitution arrangements to be in place consistently across all states and territories more quickly (without the need to rely on state and territory legislation), and which reflects the fact that medicine shortages may occur in a range of circumstances, not only where there is a public health emergency.

The *Therapeutic Goods Amendment (2020 Measures No. 2) Act 2021* ("the Amendment Act") amended the Act to introduce a pharmacist substitution scheme in Division 2C of Part 3-2 of the Act. This scheme was developed to help alleviate the effects of medicine shortages, by allowing substitution arrangements to be put in place quickly and consistently across Australia, and without being limited to circumstances where there is a public health emergency.

Under this scheme, section 30EK of the Act provides for the making of a legislative instrument declaring a serious scarcity of specified medicines and specifying the substitutable medicine and permitted circumstances. This operates in tandem with section 30EL of the Act, which provides that, where an instrument is in force under subsection 30EK(1) and a pharmacist is authorised to dispense the scarce medicine under a law of a state or territory, a pharmacist may dispense the substitutable medicine to that person in the circumstances specified in the instrument, despite any law of a state or territory prohibiting substitution.

The Principal Instrument

Across Australia, there is a shortage of ZACTIN TABS. This shortage is due to the manufacturer's voluntary recall of ZACTIN TABS which has resulted in lower levels of available stock for Australian patients. The voluntary recall was due to the identification of unacceptable levels of nitrosamines in batches of ZACTIN TABS which were reported to the TGA. Nitrosamine impurities may increase the risk of developing cancer if exposed to these impurities above acceptable levels, over long periods of time. The voluntary recall only affected the ZACTIN TABS, not other medicines containing fluoxetine.

Medicines that contain the active ingredient fluoxetine are used in the treatment of major depression, obsessive compulsive disorder, and premenstrual dysphoric disorder. As such, the scarcity of this medicine is having, and is anticipated to have, a significant risk of adverse health consequences for patients in Australia if they are unable to take the scarce medicine.

The Principal Instrument supports the management of the shortages of ZACTIN TABS. It declares that there is a serious scarcity of ZACTIN TABS and specifies the substitutable medicines as capsules containing 10 mg fluoxetine hydrochloride or 20 mg fluoxetine hydrochloride.

The Principal Instrument enables pharmacists to substitute a specified substitutable medicine for the scarce medicine, without the patient affected by the unavailability of the scarce medicine needing to return to their prescriber for a new prescription. This means that patients who are prescribed the scarce medicine can access suitable treatment without delay, reducing the risk of interrupted treatment.

The Principal Instrument specifies a number of specific and general permitted circumstances that have the effect of confining the circumstances in which a pharmacist may substitute each of the substitutable medicines for the scarce medicine prescribed to a patient. These 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 the supply of the scarce medicines in Australia is not currently meeting the demand for that medicine for all of the patients in Australia who take that medicine. 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 fluoxetine are included in Schedule 4 to the current Poisons Standard, and the scarce medicine does not contain a substance in Schedule 8 to the current Poisons Standard.

In accordance with subsection 30EK(5) of the Act, the Principal Instrument specified the period of time for which it remains in force, being until 31 May 2024, unless sooner revoked. This reflects the period that the scarce medicine was initially expected to be the subject of a serious scarcity across Australia.

Purpose

The purpose of the Amendment Instrument is to extend the period of time for which the Principal Instrument remains in force, from 31 May 2024 to 30 September 2024. The shortages of ZACTIN TABS and, consequently, the limited availability of fluoxetine in the dosage form of a dispersible tablet, are expected to persist beyond the date the Principal Instrument was intended to remain in force until, with supply and demand expected to stabilise by late September 2024.

The effect of the Amendment Instrument is to enable pharmacists to continue substituting the specified substitutable medicine for the relevant scarce medicines, in the specific and general circumstances that are specified in Principal Instrument, until 30 September 2024. This ensures that patients who are affected by the continued unavailability of the scarce medicines can still access suitable treatment without delay, reducing the risk of interrupted treatment.

The Amendment Instrument also makes a further, consequential amendment to the Principal Instrument — namely, to change the date on which the Principal Instrument is repealed, from 1 June 2024 to 1 October 2024.

Consultation

An impact analysis was not required in relation to the development of the Amendment Instrument, as the making of legislative instruments under section 30EK of the Act is the subject of a standing exemption from the requirement to prepare an impact analysis (OBPR23-04289).

The TGA has been working closely with stakeholders since the relevant provisions in the Amendment Act commenced in February 2021, and have developed the general permitted circumstances in consultation with these groups. Stakeholders include (but are not limited to) the Australian Medical Association, relevant clinical professional colleges and societies, sponsor peak bodies, wholesalers, state and territory Chief Pharmacists, and pharmacy and pharmacist peak bodies.

To develop the Principal Instrument, in late November 2023, the TGA consulted with 17 stakeholders, including the Royal Australian College of General Practitioners, the Royal Australasian College of Physicians, the Royal Australian and New Zealand College of Psychiatrists, the Australian College of Rural and Remote Medicine, the Australian Medical Association, the National Aboriginal Community Controlled Health Organisation, state and territory Chief Pharmacists or health departments, the Pharmaceutical Society of Australia, the Pharmacy Guild of Australia and the Society of Hospital Pharmacists of Australia, to ensure the substitution protocol and associated permitted circumstances are appropriate. The TGA received 8 responses that were all supportive of the proposed Instrument, and feedback was incorporated into the Instrument. The TGA has also consulted with the sponsor of the substitutable medicines to alert them to the potential change in demand.

In developing the Amendment Instrument, the TGA consulted with the same 17 stakeholders and sponsors, to ensure the continued substitution protocol remains appropriate and inform them of its continuation. The TGA received 6 responses, which were all supportive of the proposed amendment.

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*. The Amendment Instrument commences on 31 May 2024, and will be repealed at the start of 1 October 2024, unless it is repealed earlier.

Attachment A

Details of the *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Fluoxetine) Amendment Instrument 2024*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Fluoxetine) Amendment Instrument 2024* ("the Amendment Instrument").

Section 2 – Commencement

This section provides that the Amendment Instrument commences on 31 May 2024.

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 to its terms.

Schedule 1 - Amendments

Schedule 1 amends *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Fluoxetine) Instrument 2023* ("the Principal Instrument").

Item 1 repeals and replaces section 7 of the Principal Instrument to provide that the Amendment Instrument remains in force until 30 September 2024.

Item 2 repeals and replaces section 8 of the Principal Instrument to provide that, unless repealed earlier, the Amendment Instrument is repealed at the start of 1 October 2024.

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) (Fluoxetine) Amendment Instrument 2024

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 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.

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Purpose

The purpose of the Amendment Instrument is to extend the period of time for which the Principal Instrument remains in force, from 31 May 2024 to 30 September 2024. The shortages of ZACTIN TABS and, consequently, the limited availability of fluoxetine in the dosage form of a dispersible tablet, are expected to persist beyond the date the Principal Instrument was intended to remain in force until, with supply and demand expected to stabilise by late September 2024.

The effect of the Amendment Instrument is to enable pharmacists to continue substituting the specified substitutable medicine for the relevant scarce medicines, in the specific and general circumstances that are specified in Principal Instrument, until 30 September 2024. This ensures that patients who are affected by the continued unavailability of the scarce medicines can still access suitable treatment without delay, reducing the risk of interrupted treatment.

Human rights implications

The 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 instrument takes positive steps to promote the right to health by facilitating improved access to the substitutable medicines, and to ameliorate the effects of the limited availability or unavailability of the scarce medicine across the Australian market. By enabling pharmacists to substitute these important medicines, the 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 condition.

Conclusion

This legislative 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.