

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Cefalexin) 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 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.

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 or, alternatively, 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) (Cefalexin) Instrument 2022* (“the 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 medicine (“the scarce medicine”), specifies the medicine that pharmacists are permitted to dispense in substitution for the scarce medicine (“the substitutable medicine”), and the circumstances in which they may do so.

The Instrument declares registered medicines that contain cefalexin in various strengths of the capsule and powder for oral liquid or suspension dosage forms, to be scarce medicines. The Instrument also declares that where a pharmacist is unable to dispense a scarce medicine prescribed to the patient, they may instead dispense a substitutable medicine (with various substitutable medicines specified for each scarce medicine), in accordance with the Instrument.

Background

Medicine shortages continue to occur for a number of reasons, including manufacturing issues, such as shortages of raw materials, as well as logistics problems and increases in demand. The TGA receives approximately 105 new medicine shortage notifications every month. The problem of medicine shortages was amplified during the COVID-19 pandemic.

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. That instrument 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.

Purpose

Across Australia, shortages of registered medicines containing cefalexin have occurred in relation to multiple strengths and products. These include medicines containing cefalexin of various strengths that are manufactured in capsule and powder for oral liquid or suspension dosage forms. The shortages of the different strengths and dosage forms are either due to manufacturing issues or an unexpected increase in demand. Medicines containing cefalexin are used to treat a variety of bacterial infections, including some forms of pneumonia and chest infections, ear infections, skin infections, tonsillitis, bacterial sinusitis, and urinary tract infections. The scarcity of these medicines is having, and is anticipated to have, 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 unable to take the scarce medicine.

The making of the Instrument enables pharmacists to substitute the specified substitutable medicine for a 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 a scarce medicine can access suitable treatment without delay, reducing the risk of interrupted treatment.

The 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.

The *specific* permitted circumstances that apply in each case depend, in part, on the dosage form of the substitutable medicine. For example, for substitutable medicines that are manufactured in the dosage form of a powder for oral liquid or suspension, the pharmacist must ensure that the correct dose of substitutable medicine is written in millilitres on the dispensing label. The pharmacist must also ensure that, where multiple bottles of substitutable medicine are dispensed, the patient's treatment course will be completed prior to the expiry of each of the substitutable medicine bottles. Conversely, where the scarce medicine is in the dosage form of a powder for oral liquid or suspension, and the substitutable medicine is in the dosage form of a capsule, the pharmacist must only dispense the substitutable medicine for the scarce medicine where the prescribed dose of scarce medicine is divisible by 250 mg and, further, where they have ensured that the patient can take the substitutable medicine in a capsule dosage form. The pharmacist must also ensure that the correct quantity of capsules that must be taken by the patient in substitution for the prescribed dose of scarce medicine is written on the dispensing label, regardless of whether the scarce medicine is in the dosage form of a capsule or powder for oral liquid or suspension.

However, some *specific* permitted circumstances apply regardless of the dosage form in which the substitutable medicine is manufactured. For example, in all cases, the pharmacist must advise the patient, or 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 of the prescribed dose of scarce medicine. The pharmacist must also always ensure that the patient, or person acting on behalf of the patient, has access to information to support them in safely administering the substitutable medicine.

The same *general* permitted circumstances are also specified for each substitutable medicine including, for example, that 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, and that the prescriber has not indicated on the prescription for the scarce medicine that substitution is not permitted.

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 cefalexin are included in Schedule 4 to the current Poisons Standard, and the scarce medicines do not contain a substance in Schedule 8 to the current Poisons Standard.

In accordance with subsection 30EK(5) of the Act, the Instrument specifies the period of time for which it remains in force, being until 31 July 2023, unless sooner revoked. This reflects the period that each of the scarce medicines are expected to be the subject of a serious scarcity across Australia. If the shortage of the scarce medicines is resolved sooner or if safety concerns are identified, the Instrument may be revoked before its cessation date.

Unless repealed earlier, this Instrument will be automatically repealed at the start of 1 August 2023.

Consultation

The Office of Impact Analysis ("OIA") has advised that the preparation of an impact analysis is not required in relation to the creation of the Instrument as it is unlikely to have more than a minor regulatory impact (OBPR22-03800).

The TGA has been working closely with stakeholders since the relevant provisions in the Amendment Act commenced in February 2021, and has 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.

In developing this Instrument, in December 2022, the TGA consulted with 17 stakeholders, including the Royal Australian College of General Practitioners, Royal Australasian College of Physicians, Australian Paediatric Society, Australasian Society of Infectious Diseases, Royal Australasian College of Surgeons, Australian Medical Association, state and territory Chief Pharmacists, the Pharmaceutical Society of Australia, the Pharmacy Guild of Australia, and the Society of Hospital Pharmacists of Australia, to ensure that the substitution protocol and associated permitted circumstances are appropriate. The TGA received 9 responses, which were all supportive of the proposed Instrument, and feedback provided as part of these responses was incorporated into the Instrument. The TGA has also consulted with sponsors of substitutable medicines to alert them to the potential change in demand.

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

The 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 Instrument is a disallowable legislative instrument for the purposes of the *Legislation Act 2003* and commences on 21 December 2022. The Instrument will be repealed at the start of 1 August 2023, unless it is repealed earlier.

Details of the *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Cefalexin) Instrument 2022*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Cefalexin) Instrument 2022* (“the Instrument”).

Section 2 – Commencement

This section provides that the Instrument commences on 21 December 2022.

Section 3 – Authority

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

Section 4 – Definitions

This section provides the definition of terms used in the Instrument. This section also notes that some expressions used in the Instrument, namely, ‘medicine’, ‘Register’ and ‘registered goods’, have the same meaning as in the Act.

Section 5 – Declaration of serious scarcity of medicine

This section provides a declaration that a serious scarcity of the medicine specified in column 2 of each item in the tables in Part 1 and Part 2 of Schedule 1 exists across the whole of Australia.

Section 6 – Substitution of scarce medicine by pharmacists

This section provides that, for each item in the tables in Schedule 1, a medicine specified in column 3 is a substitutable medicine that may be dispensed by a pharmacist in substitution for the scarce medicine specified in column 2, in the circumstances specified in column 5 of that item (the specific permitted circumstances) and in the table in Schedule 2 (the general permitted circumstances).

Section 7 – Period instrument in force

This section provides that the Instrument remains in force until 31 July 2023.

Section 8 – Repeals

This section provides that, unless repealed earlier, the Instrument is repealed at the start of 1 August 2023.

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

This Schedule specifies the scarce medicines, substitutable medicines and specific permitted circumstances for the purpose of sections 5 and 6. The specified scarce medicines and specified substitutable medicines are medicines that contain cefalexin. The scarce medicines are all registered medicines. However, the specified substitutable medicines are not limited to medicines registered on the Australian Register of Therapeutic Goods, and may be medicines that are approved for supply under section 19A of the Act.

Part 1 of Schedule 1 relates to scarce medicines that are in liquid or suspension preparations.

Columns 2 and 3 of the table in Part 1 of Schedule 1 specify:

- In item 1—the scarce medicine as a registered medicine that contains cefalexin 125 mg/5 mL in a 100 mL oral liquid or suspension and is manufactured in the dosage form of a powder for oral liquid or suspension, as relevant, and the substitutable medicine as being a medicine that contains cefalexin 250 mg/5 mL in a 100 mL oral liquid or suspension and is manufactured in the dosage form of a powder for oral liquid or suspension, as relevant.
- In item 2—the scarce medicine as a registered medicine that contains cefalexin 125 mg/5 mL in a 100 mL oral liquid or suspension and is manufactured in the dosage form of a powder for oral liquid or suspension, as relevant, and the substitutable medicine as being a medicine that contains 250 mg cefalexin and is manufactured in the dosage form of a capsule.
- In item 3—the scarce medicine as a registered medicine that contains cefalexin 250 mg/5 mL in a 100 mL oral liquid or suspension and is manufactured in the dosage form of a powder for oral liquid or suspension, as relevant, and the substitutable medicine as being a medicine that contains cefalexin 125 mg/5 mL in a 100 mL oral liquid or suspension and is manufactured in the dosage form of a powder for oral liquid or suspension, as relevant.
- In item 4—the scarce medicine as a registered medicine that contains cefalexin 250 mg/5 mL in a 100 mL oral liquid or suspension and is manufactured in the dosage form of a powder for oral liquid or suspension, as relevant, and the substitutable medicine as being a medicine that contains 250 mg cefalexin and is manufactured in the dosage form of a capsule.

Part 2 of Schedule 1 relates to scarce medicines that are in capsule form. Columns 2 and 3 of the table in Part 2 of Schedule 1 specify:

- In item 1—the scarce medicine as a registered medicine that contains 500 mg cefalexin and is manufactured in the dosage form of a capsule, and the substitutable medicines as being a medicine that contains 250 mg cefalexin and is manufactured in the dosage form of a capsule.

Column 4 of the tables in Schedule 1 specifies the equivalent dose of each scarce medicine and substitutable medicine for the purposes of the permitted circumstances in column 5. For example, in relation to Item 1 of the table in Part 1 of Schedule 1, 250 mg of cefalexin is equivalent to 5 mL of a medicine that contains cefalexin 250 mg/5 mL in a 100 mL oral liquid or suspension.

Column 5 of the tables in Part 1 and Part 2 of Schedule 1 sets out several specific permitted circumstances that apply in relation to each item.

In relation to items 1 and 3 in Part 1 of Schedule 1, where the scarce medicine and substitutable medicine are in liquid form, the specific permitted circumstances set out in Column 5 are that the pharmacist has:

- (1) advised the patient, or person acting on behalf of the patient, of the number of dose units in millilitres 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. This ensures that the patient, or person acting on behalf of the patient, understands the amount of substitutable medicine that must be administered to the patient for the patient to

obtain a therapeutic benefit equivalent to that provided by the prescribed dose of scarce medicine; and

- (2) ensured that the correct dose of substitutable medicine is written in millilitres on the dispensing label attached to the substitutable medicine. This is to ensure that the patient has a clear statement to refer to of the correct dose of substitutable medicine that they must take, reducing the risk that the patient will administer an unsafe or insufficient amount of substitutable medicine; and
- (3) ensured that, where multiple bottles of substitutable medicine are dispensed, the patient's treatment course will be completed prior to the expiry of each bottle of the substitutable medicine. This is to ensure that patients are provided with enough substitutable medicine to complete their treatment course within the expiry of the substitutable medicine; and
- (4) ensured that the patient, or person acting on behalf of the patient, has access to information to support them in administering the substitutable medicine. This requires pharmacists to advise the patient, or person acting on behalf of the patient, where they may obtain further information relating to the substitutable medicine that is being dispensed, and how it can be safely administered. This additional information may include the Consumer Medicines Information leaflet in relation to the substitutable medicine.

In relation to items 2 and 4 in Part 1 of Schedule 1, where the scarce medicine is in liquid form and the substitutable medicine is in the dosage form of a capsule, the specific permitted circumstances that apply to each item are that the pharmacist has:

- (1) ensured that the patient can take the substitutable medicine in a capsule dosage form. This requires the pharmacist to determine whether the patient is capable of taking medication in a capsule dosage form, and therefore whether it is appropriate to substitute the substitutable medicine for the scarce medicine; and
- (2) only substituted the substitutable medicine for the scarce medicine where the prescribed dose of scarce medicine is divisible by 250 mg (i.e. 250 mg, 500 mg, 750 mg, or 1 gram). This prevents the pharmacist from dispensing a dose of substitutable medicine that exceeds the dose of scarce medicine prescribed to the patient; and
- (3) advised the patient, or 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. This ensures that the patient, or person acting on behalf of the patient, understands the amount of substitutable medicine that must be administered to the patient for the patient to obtain a therapeutic benefit equivalent to that provided by the prescribed dose of scarce medicine; and
- (4) ensured that the correct quantity of capsules for each dose of substitutable medicine is written on the dispensing label. This is to ensure that the patient has a clear statement to refer to of the correct dose of substitutable medicine that they must take, reducing the risk that the patient will administer an unsafe or insufficient amount of substitutable medicine; and
- (5) ensured that the patient, or person acting on behalf of the patient, has access to information to support them in administering the substitutable medicine. This requires pharmacists to advise the patient, or person acting on behalf of the patient, where they may obtain further information relating to the substitutable medicine that is being dispensed, and how it can be safely administered. This additional information may include, but is not limited to, the Consumer Medicines Information leaflet in relation to the substitutable medicine.

In relation to item 1 in Part 2 of Schedule 1, where both the scarce and substitutable medicine are in the dosage form of a capsule, the specific permitted circumstances that apply to each item are that the pharmacist has:

- (1) advised the patient, or 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. This ensures that the patient, or person acting on behalf of the patient, understands the amount of substitutable medicine that must be administered to the patient for the patient to obtain a therapeutic benefit equivalent to that provided by the prescribed dose of scarce medicine; and

- (2) ensured that the correct quantity of capsules for each dose of substitutable medicine is written on the dispensing label. This is to ensure that the patient has a clear statement to refer to of the correct dose of substitutable medicine that they must take, reducing the risk that the patient will administer an unsafe or insufficient amount of substitutable medicine; and
- (3) ensured that the patient, or person acting on behalf of the patient, has access to information to support them in administering the substitutable medicine. This requires pharmacists to advise the patient, or person acting on behalf of the patient, where they may obtain further information relating to the substitutable medicine that is being dispensed, and how it can be safely administered. This additional information may include, but is not limited to, the Consumer Medicines Information leaflet in relation to the substitutable medicine.

Schedule 2—General permitted circumstances

This Schedule specifies the general permitted circumstances in which a substitution of medicine may occur. For the purpose of section 6, substitution may only occur where these circumstances exist.

The general permitted circumstances prescribed are as follows:

- (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, i.e. there must be evidence of a prescription for the scarce medicine, which authorises the pharmacist to dispense the scarce medicine (if it were available) to the patient;
- (2) the pharmacist does not have access to the scarce medicine, i.e. the pharmacist must only substitute a medicine if the scarce medicine is not available to the pharmacist;
- (3) the prescriber has not indicated on the prescription for the scarce medicine that substitution is not permitted, i.e. if the prescriber has indicated on the prescription that substitution is not permitted, the pharmacist must not dispense the substitutable medicine as this may pose a significant safety risk to the patient. If a prescriber has indicated that substitution, even with a generic product, is not suitable then the substitutable medicine must not be dispensed;
- (4) the pharmacist has exercised professional judgement and determined that the patient is suitable to receive the substitutable medicine. This requires the pharmacist to exercise professional judgement in relation to the particular patient and their circumstances to assess whether substitution is appropriate for the particular patient. For example, if the pharmacist is of the view that the patient may be sensitive to an excipient ingredient in the substitutable medicine, then the pharmacist must not dispense the substitutable medicine to the patient;
- (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. This is to ensure the pharmacist dispenses enough of the substitutable medicine to provide the patient with an equivalent treatment regimen (dosage and duration) as the scarce medicine;
- (6) the patient, or person acting on behalf of the patient, has consented to receiving the substitutable medicine. If a person does not wish to receive the substitutable medicine, then the pharmacist must not dispense 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. This is to ensure that there is a record of the medicine that was actually dispensed to a patient, in case any safety concerns arise;
- (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. There are strong safety reasons for ensuring that the prescriber is aware of the particular medicine that has been dispensed to their patient. The prescriber would otherwise assume that the patient was dispensed the prescribed medicine and would not know about the substitution without notice of this from the dispensing pharmacist.

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) (Cefalexin) 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

The *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Cefalexin) Instrument 2022* (“the instrument”) is a legislative instrument made under subsection 30EK(1) of the Act. It declares that there is a serious scarcity across Australia of a specified medicine, specifies the medicine that pharmacists are permitted to dispense in substitution for the scarce medicine, and the circumstances in which they may do so.

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. 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).

Medicine shortages continue to occur for a number of reasons, including manufacturing issues such as shortages of raw materials, as well as logistics problems and increases in demand. The TGA receives approximately 105 new medicine shortage notifications every month. The problem of medicine shortages was amplified during the COVID-19 pandemic.

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 timely availability of medicines and risks interruption to treatment, which can impact patient health and also cause anxiety and stress for patients.

The *Therapeutic Goods Amendment (2020 Measures No. 2) Act 2021* amended the Act to introduce such a scheme in Division 2C of Part 3-2 of the Act. Section 30EK of the Act provides for the making of an instrument declaring a serious scarcity and specifying the scarce medicine, substitutable medicine and permitted circumstances.

The instrument declares registered medicines that contain cefalexin in various strengths of the capsule and powder for oral liquid or suspension dosage forms to be scarce medicines. The instrument also declares that where a pharmacist is unable to dispense a medicine containing cefalexin in the strength and/or dosage form prescribed by the patient’s prescriber, they may instead dispense a substitutable medicine in accordance with the instrument. The specified substitutable medicines are not limited to medicines registered on the Australian Register of Therapeutic Goods, and may be imported and

supplied under an approval granted by the Secretary of the Department of Health and Aged Care under section 19A of the Act.

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

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

The *specific* permitted circumstances that apply in each case depend, in part, on the dosage form of the substitutable medicine. For example, for substitutable medicines that are manufactured in the dosage form of a powder for oral liquid or suspension, the pharmacist must ensure that the correct dose of substitutable medicine is written in millilitres on the dispensing label. The pharmacist must also ensure that where multiple bottles of substitutable medicine are dispensed, the patient's treatment course will be completed prior to the expiry of each of the substitutable medicine bottles. Conversely, where the scarce medicine is manufactured in the dosage form of a powder for oral liquid or suspension, and the substitutable medicine is in the dosage form of a capsule, the pharmacist must only dispense the substitutable medicine for the scarce medicine where the prescribed dose of scarce medicine is divisible by 250 mg and, further, where they have ensured that the patient can take the substitutable medicine in a capsule dosage form. The pharmacist must also ensure that the correct quantity of capsules that must be taken by the patient in substitution for the prescribed dose of scarce medicine is written on the dispensing label, regardless of whether the scarce medicine is in the dosage form of a capsule or powder for oral liquid or suspension.

However, some *specific* permitted circumstances apply regardless of the dosage form in which the substitutable medicine is manufactured. For example, in all cases, the pharmacist must advise the patient, or 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 of the prescribed dose of scarce medicine. The pharmacist must also always ensure that the patient, or person acting on behalf of the patient, has access to information to support them in safely administering the substitutable medicine

The same *general* permitted circumstances are also specified for each substitutable medicine including, for example, that 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, and that the prescriber has not indicated on the prescription for the scarce medicine that substitution is not permitted.

The instrument specifies the period of time for which it remains in force, being until 31 July 2023, unless sooner revoked. This reflects the period that each of the scarce medicines are expected to be the subject of a serious scarcity across Australia. If the shortage of the scarce medicines is resolved sooner or if safety concerns are identified, the instrument may be revoked before its cessation date. Unless repealed earlier, the instrument will be automatically repealed at the start of 1 August 2023.

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 medicines 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.