EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Metformin) Instrument 2025

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 relevantly 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, Disability and Ageing.

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) (Metformin) Instrument 2025* ("the Instrument") is a legislative instrument made under subsection 30EK(1) of the Act in relation to certain medicines containing 1000 mg metformin in immediate-release tablets. It declares that there is a serious scarcity across Australia of specified scarce medicine, specifies the substitutable medicine that pharmacists are permitted to dispense in substitution for the scarce medicine, and the circumstances in which they may do so.

The Instrument declares six registered medicines to be scarce medicines, being:

- FORMET 1000 metformin hydrochloride 1000 mg tablet bottle, Australian Register of Therapeutic Goods ("ARTG") registration number 91112;
- FORMET 1000 metformin hydrochloride 1000 mg tablet blister pack, ARTG registration number 91113;
- DIAFORMIN VIATRIS metformin hydrochloride 1000 mg film-coated tablet blister pack, ARTG registration number 206735;
- METFORMIN GH metformin hydrochloride 1000 mg tablet blister pack, ARTG number 284975;
- METFORMIN SANDOZ metformin hydrochloride 1000 mg tablet blister pack, ARTG number 292865; and
- DIAFORMIN 1000 metformin hydrochloride 1000 mg tablet blister pack, ARTG number 82207.

The 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 the substitutable medicine in accordance with the Instrument. To this end, the substitutable medicines that are specified in the Instrument are medicines that are registered on the ARTG or subject to an approval under section 19A of the Act, that are manufactured in the dosage form of a tablet and contain either 1000 mg or 500 mg of metformin as the only active ingredient.

Background

Medicine shortages continue to occur for a number of reasons, ranging from shortages of raw materials to national disasters, logistical difficulties, 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 dosage form and strength 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.

In 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 allows 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 that allows substitution arrangements to be in place consistently across all States and Territories more quickly (but does not 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. Such an 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

There are current shortages of several medicines containing 1000 mg metformin in immediate-release tablets in Australia. These medicines are not expected to be in shortage beyond 30 June 2025, however fluctuations in stock levels in the supply chain may impact patients and health professionals beyond this date. The Instrument therefore remains in force until 31 August 2025, unless repealed earlier, to mitigate disruptions to patients accessing the scarce medicine.

The scarce medicines each contain 1000 mg metformin, which is approved in Australia for the treatment of type 2 diabetes mellitus. The current shortages of the scarce medicines are having, and

are expected 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 specified substitutable medicines are medicines that are registered on the ARTG or subject to an approval under section 19A of the Act, that are manufactured in the dosage form of a tablet and contain either 500 mg or 1000 mg of metformin as the only active ingredient. Subject to the specific permitted circumstances in column 5 of the table in Schedule 1 to the Instrument, pharmacists may dispense the substitutable medicines in either an immediate-release or modified-release formulation.

The making of the Instrument enables pharmacists to substitute the specified substitutable medicines for the scarce medicines, 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 Instrument specifies a number of specific and general permitted circumstances that have the effect of confining the circumstances in which a pharmacist may substitute the substitutable medicine 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.

Certain *specific* permitted circumstances are specified for the substitutable medicine. Some of these are designed to limit the circumstances in which pharmacists may substitute with a substitutable medicine that is of a different strength or formulation to the scarce medicine. Other specific permitted circumstances require pharmacists to advise the patient, or person acting on behalf of the patient, of matters that include (among other things):

- the differences between the scarce medicine and the substitutable medicine; and
- suitable instructions for safely and effectively administering the substitutable medicine.

The *general* permitted circumstances specified for the substitutable medicine include, 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 medicine in Australia is not currently meeting, or that there is an imminent risk that supply of the scarce medicine in Australia will not likely meet, 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, metformin is 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 Instrument specifies the period that the Instrument remains in force, being until 31 August 2025, unless sooner revoked. This reflects the period that the scarce medicines are expected to be the subject of a serious scarcity across Australia. If the shortage of the scarce medicine is resolved sooner or if safety concerns are identified, the Instrument may be revoked before its cessation date.

The Instrument will be automatically repealed at the start of 1 September 2025, unless repealed earlier.

Consultation

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 May 2025, the TGA consulted with the Royal Australian and New Zealand College of Obstetricians and Gynaecologists, Australian Diabetes Educators Association, Royal Australasian College of Physicians, Royal Australian College of General Practitioners, Australian Diabetes Society, Australia and New Zealand Society for Paediatric Endocrinology and Diabetes, the Australian College of Rural and Remote GPs, Endocrine Society of Australia, Australasian Diabetes in Pregnancy Society, Australian Medical Association, Pharmacy Guild of Australia, Pharmaceutical Society of Australia, Advanced Pharmacy Australia, Diabetes Australia, National Aboriginal Community Controlled Health Organisation, and State and Territory health departments.

The TGA received 14 responses, including three responses from State and Territory health departments. Most stakeholders were supportive of the proposed Instrument. However, several stakeholders expressed concern regarding the substitution of immediate-release metformin tablets with extended-release metformin tablets, particularly in cases where patients are prescribed more than 2 g of metformin a day. This feedback was considered and changes were made to address those concerns by limiting substitution only to circumstances where the patient is prescribed 2 g or less of metformin a day and limiting substitution with modified-release formulations only where immediate-release formulations are not available, which is reflected in the specific permitted circumstances in Schedule 1.

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 28 May 2025. The Instrument will be repealed at the start of 1 September 2025, unless it is repealed earlier.

Details of the *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Metformin) Instrument 2025*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Metformin) Instrument 2025* ("the Instrument").

Section 2 – Commencement

This section provides that the Instrument commences on 28 May 2025.

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, including 'medicine', 'pharmacist', 'Register', 'registered goods' and 'registration number', 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 table in 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 table 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 August 2025.

Section 8 – Repeals

This section provides that, unless repealed earlier, the Instrument is repealed at the start of 1 September 2025.

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

This Schedule specifies the scarce medicine, substitutable medicine and specific permitted circumstances for the purpose of sections 5 and 6.

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

- the scarce medicines as being:
  - FORMET 1000 metformin hydrochloride 1000 mg tablet bottle, Australian Register of Therapeutic Goods ("ARTG") registration number 91112;
  - FORMET 1000 metformin hydrochloride 1000 mg tablet blister pack, ARTG registration number 91113;
  - DIAFORMIN VIATRIS metformin hydrochloride 1000 mg film-coated tablet blister pack, ARTG registration number 206735;
  - METFORMIN GH metformin hydrochloride 1000 mg tablet blister pack, ARTG number 284975;
  - METFORMIN SANDOZ metformin hydrochloride 1000 mg tablet blister pack, ARTG number 292865;
  - DIAFORMIN 1000 metformin hydrochloride 1000 mg tablet blister pack, ARTG number 82207; and
- the substitutable medicine as being a registered medicine, or a medicine subject to an approval under section 19A of the Act, that is manufactured in the dosage form of a tablet, and contains either:
  - 500 mg of metformin as the only active ingredient; or
  - 1000 mg of metformin as the only active ingredient.

Column 4 of table item 1 in Schedule 1 specifies the equivalent dose of the scarce medicine and the substitutable medicine for the purposes of the permitted circumstances in column 5. It specifies that one 1000 mg tablet of the scarce medicine is equivalent to:

- one 1000 mg tablet of substitutable medicine; or
- two 500 mg tablets of substitutable medicine

Subject to the specific permitted circumstances (particularly in paragraphs (b) and (c)) in column 5 of the table (outlined below), the substitutable medicine may contain metformin in either an immediate-release or modified-release formulation.

Column 5 of table item 1 in Schedule 1 sets out the specific permitted circumstances that apply in relation to the item.

The specific permitted circumstances are that:

- the prescribed dose of the scarce medicine must not be more than 2 g of metformin a day;
- when substituting with 500 mg immediate-release tablets of the substitutable medicine—the pharmacist does not have access to 1000 mg immediate-release tablets of the substitutable medicine. This ensures that, if available, 1000 mg immediate-release tablets must be dispensed in the first instance and only where 1000 mg immediate-release tablets are unavailable, then 500 mg immediate-release tablets can be dispensed;
- when substituting with modified-release tablets of substitutable medicine—the pharmacist does not have access to immediate-release tablets of substitutable medicine This ensures that, where available, immediate-release tablets are dispensed instead of modified-release tablets. That is, modified-release tablets are only dispensed if there are no immediate-release tablets available;
- the pharmacist has advised the patient, or person acting on behalf of the patient:
  - of the number of dose units of substitutable medicine that must be administered to 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
    - of the differences between the scarce medicine and substitutable medicine. 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;
    - of suitable instructions for administering the substitutable medicine. This requires the pharmacist to explain to the patient, or person acting on behalf of the patient, the steps for administering the substitutable medicine to the patient; and
- where the substitutable medicine is a modified-release tablet—the pharmacist has advised the patient, or person acting on behalf of the patient:
    - that dosing is limited to once daily. This ensures that use of the substitutable medicine is safe and effective and is in line with the recommended dosing instructions.

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.

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) (Metformin) Instrument 2025

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 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 relevantly 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, Disability and Ageing.

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, 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) (Metformin) Instrument 2025* ("the Instrument") is a legislative instrument made under subsection 30EK(1) of the Act in relation to certain medicines containing 1000 mg metformin in immediate-release tablets. It declares that there is a serious scarcity across Australia of specified scarce medicine, specifies the substitutable medicine that pharmacists are permitted to dispense in substitution for the scarce medicine, and the circumstances in which they may do so.

The Instrument declares six registered medicines to be scarce medicines, being:

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- METFORMIN SANDOZ metformin hydrochloride 1000 mg tablet blister pack, ARTG number 292865; and
- DIAFORMIN 1000 metformin hydrochloride 1000 mg tablet blister pack, ARTG number 82207.

The 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 the substitutable medicine in accordance with the Instrument. To this end, the substitutable medicines that are specified in the Instrument are medicines that are registered on the ARTG or subject to an approval under section 19A of the Act, that are manufactured in the dosage form of a tablet and contain either 1000 mg or 500 mg of metformin as the only active ingredient.

Background

Medicine shortages continue to occur for a number of reasons, ranging from shortages of raw materials to national disasters, logistical difficulties, 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 dosage form and strength 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.

In 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 allows 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 that allows substitution arrangements to be in place consistently across all States and Territories more quickly (but does not 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. Such an 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

There are current shortages of several medicines containing 1000 mg metformin in immediate-release tablets in Australia. These medicines are not expected to be in shortage beyond 30 June 2025. The Instrument therefore remains in force until 31 August 2025, unless repealed earlier, to mitigate disruptions to patients accessing the scarce medicine.

The scarce medicines each contain 1000 mg metformin, which is approved in Australia for the treatment of type 2 diabetes mellitus. The current shortages of the scarce medicines are having, and are expected 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 specified substitutable medicines are medicines that are registered on the ARTG or subject to an approval under section 19A of the Act, that are manufactured in the dosage form of a tablet and contain either 500 mg or 1000 mg of metformin as the only active ingredient. Subject to the specific permitted circumstances in column 5 of the table in Schedule 1 to the Instrument, pharmacists may dispense the substitutable medicines in either an immediate-release or modified-release formulation.

The making of the Instrument enables pharmacists to substitute the specified substitutable medicines for the scarce medicines, 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 Instrument specifies a number of specific and general permitted circumstances that have the effect of confining the circumstances in which a pharmacist may substitute the substitutable medicine 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.

Certain *specific* permitted circumstances are specified for the substitutable medicine. Some of these are designed to limit the circumstances in which pharmacists may substitute with a substitutable medicine that is of a different strength or formulation to the scarce medicine. Other specific permitted circumstances require pharmacists to advise the patient, or person acting on behalf of the patient, of matters that include (among other things):

- the differences between the scarce medicine and the substitutable medicine; and
- suitable instructions for safely and effectively administering the substitutable medicine.

The *general* permitted circumstances specified for the substitutable medicine include, 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 medicine in Australia is not currently meeting, or that there is an imminent risk that supply of the scarce medicine in Australia will not likely meet, 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, metformin is 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 Instrument specifies the period that the Instrument remains in force, being until 31 August 2025, unless sooner revoked. This reflects the period that the scarce medicines are expected to be the subject of a serious scarcity across Australia. If the shortage of the scarce medicine is resolved sooner or if safety concerns are identified, the Instrument may be revoked before its cessation date.

The Instrument will be automatically repealed at the start of 1 September 2025, unless repealed earlier.

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 medicine, 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.