EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Abatacept) 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 medicines for other medicines if the Minister has declared there is a serious scarcity of the other medicine. The Act is administered by the Therapeutic Goods Administration ("the TGA") within the Australian Government Department of Health and Aged Care.

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

Subsection 30EK(2) of the Act provides that the Minister may only make an instrument under subsection 30EK(1) if satisfied that the supply of the scarce medicine in Australia is not currently meeting the demand for that medicine for all of the patients in Australia who take that medicine or, alternatively, 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, the Minister must also be satisfied there is 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) (Abatacept) Instrument 2024* ("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 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 Instrument declares two registered medicines to be scarce medicines, being ORENCIA abatacept (rch) 125 mg single dose syringe subcutaneous injection ultrasafe passive needle guard and flange extender, and ORENCIA abatacept (rch) 125 mg single dose ClickJect prefilled autoinjector. 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 a substitutable medicine in accordance with the Instrument. The substitutable medicines that are specified in the Instrument are medicines containing 125 mg abatacept as the only active ingredient, in the dosage form of either a prefilled autoinjector (as substitute for the single dose syringe) or single dose syringe (as substitute for the prefilled autoinjector). The Instrument has the effect that one single unit dose of the scarce medicine is substitutable for a single unit dose of the substitutable medicine, in the relevant permitted circumstances.

Background

Medicine shortages continue to occur for a number of reasons, ranging from shortages of raw materials to natural 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 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.

Purpose

There are shortages across Australia of two medicines containing 125 milligrams of the active ingredient abatacept. The shortage of the prefilled autoinjector is due to manufacturing issues. The shortage of the single dose syringe is due to the unexpected increase in demand caused by shortfall in supply of the prefilled autoinjector.

Abatacept is principally used to treat rheumatoid arthritis, psoriatic arthritis and polyarticular juvenile idiopathic arthritis, and the scarcity of such medicines will 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 affected patients in Australia if they are not able to access the scarce medicines.

The Instrument identifies two medicines as being scarce medicines across the whole of Australia:

- ORENCIA abatacept (rch) 125 mg single dose syringe subcutaneous injection ultrasafe passive needle guard and flange extender (registration number 206764); and

- ORENCIA abatacept (rch) 125 mg single dose ClickJect prefilled autoinjector (registration number 236039).

The Instruments identifies that each of these medicines may be substituted by a medicine in the presentation of the other medicine. That is, the single dose syringe may be substituted by a medicine in the form of an autoinjector, and vice versa. Both the scare medicines and the substitutable medicines contain the active ingredient *abatacept* in the same quantity, and the specified substitutable medicines include medicines that are not included in the Register (i.e. the substitutable medicines may be the subject of some other exemption, approval or authority). The substitutable medicines are considered to be safe and effective treatments for the relevant conditions when substituted for each respective scarce medicine in the circumstances permitted under the Instrument. The scarce medicines and substitutable medicines are the same except for the presentation of the medicines (in a single dose syringe or prefilled autoinjector) and method of administration.

The making of the Instrument enables pharmacists to substitute a 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 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 a substitutable medicines for the relevant scarce medicine prescribed to a patient. The 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. These include that the pharmacist must ensure that the patient is at least 18 years of age and must have advised the patient (or person acting on behalf of the patient) of instructions for administration of the substitutable medicine or to obtain such instructions from a suitable qualified health practitioner. The pharmacist must also always 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 for the prescribed dose of scarce 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 th scarce medicines in Australia is not currently meeting the demand for them for all of the patients in Australia who take, or who may need to take, each of them, and 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 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 abatacept are included in Schedule 4 to the current Poisons Standard, and do not contain a substance in Schedule 8 to the current Poisons Standard.

In accordance with subsection 30EK(5) of the Act, the Instrument specifies the period for which it remains in force, being until 31 October 2024. This reflects the period that the scarce medicine is expected to be the subject of 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.

Unless repealed earlier, this Instrument will be automatically repealed at the start of 1 November 2024.

Consultation

An impact analysis was not required in relation to the development of the 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.

In developing the Instrument, during the period 19 April 2024 to 15 May 2024, the TGA consulted with the Australian Rheumatology Association, the Australian Medical Association, the Royal Australian College of General Practitioners, the Australian College of Rural and Remote Medicine, the Australasian Society of Clinical Immunology and Allergy, state and territory Chief Pharmacists, the Pharmaceutical Society of Australia, the Society of Hospital Pharmacists of Australia, the Pharmacy Guild of Australia and Arthritis Australia, to ensure that the substitution protocol and associated permitted circumstances are appropriate. The TGA received 7 responses that were all supportive of the proposed Instrument, and feedback was incorporated into the Instrument.

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 15 May 2024. The Instrument will be repealed at the start of 1 November 2024, unless repealed earlier.

Attachment A

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

Section 1 – Name

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

Section 2 – Commencement

This section provides that the Instrument commences on 15 May 2024.

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 expression used in the Instrument, including 'health practitioner' and 'medicine', 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 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 October 2024.

Section 8 – Repeals

This section provides that, unless repealed earlier, the Instrument is repealed at the start of 1 November 2024.

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.

Column 2 of the tables in Part 1 and Part 2 of Schedule 1 specifies the following scarce medicines:

- ORENCIA abatacept (rch) 125 mg single dose syringe subcutaneous injection ultrasafe passive needle guard and flange extender (registration number 206764); and
- ORENCIA abatacept (rch) 125 mg single dose ClickJect prefilled autoinjector (registration number 236039).

Column 3 of the tables in Part 1 and Part 2 in Schedule 1 specifies that medicines containing 125 mg abatacept as the only active ingredient, and manufactured in the dosage form of a prefilled autoinjector (as substitute for the single dose syringe) or single dose syringe (as substitute for the prefilled autoinjector), are substitutable medicines.

Column 4 of the tables in Part 1 and Part 2 in Schedule 1 specifies that one single dose unit of scarce medicine is substitutable for one single dose unit of substitutable medicine.

Column 5 of the table in Schedule 1 sets out the specific permitted circumstances. In all cases, the patient must be at least 18 years of age and that the pharmacist must advise the patient (or person acting on behalf of the patient) of:

- suitable instructions in relation to the administration process of the substitutable medicine; or to obtain instructions from their prescriber, or a suitably qualified health practitioner (which is defined as a health practitioner who is a general practitioner, nurse, pharmacist, rheumatologist or immunologist) in relation to the administration process of the substitutable medicine; and
- 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 the Instrument (i.e. that one prefilled autoinjector or single dose syringe of the substitutable medicine containing abatacept (rch) 125mg is equivalent to one single dose syringe or prefilled autoinjector, respectively, of the scarce medicine containing abatacept (rch) 125mg).

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) (Abatacept) 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 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(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, 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, the Minister must also be satisfied there is 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) (Abatacept) Instrument 2024* ("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 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 Instrument declares two registered medicines to be scarce medicines, being ORENCIA abatacept (rch) 125 mg single dose syringe subcutaneous injection ultrasafe passive needle guard and flange extender, and ORENCIA abatacept (rch) 125 mg single dose ClickJect prefilled autoinjector. 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 a substitutable medicine in accordance with the Instrument. The substitutable medicines that are specified in the Instrument are medicines containing 125 mg abatacept as the only active ingredient, in the dosage form of either a prefilled autoinjector (as substitute for the single dose syringe) or single dose syringe (as substitute for the

prefilled autoinjector). The Instrument has the effect that one single unit dose of the scarce medicine is substitutable for a single unit dose of the substitutable medicine, in the relevant permitted circumstances.

Background

Medicine shortages continue to occur for a number of reasons, ranging from shortages of raw materials to natural 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 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.

Purpose

There are shortages across Australia of two medicines containing 125 milligrams of the active ingredient abatacept. The shortage of the prefilled autoinjector is due to manufacturing issues. The shortage of the single dose syringe is due to the unexpected increase in demand caused by shortfall in supply of the prefilled autoinjector.

Abatacept is principally used to treat rheumatoid arthritis, psoriatic arthritis and polyarticular juvenile idiopathic arthritis, and the scarcity of such medicines will 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 affected patients in Australia if they are not able to access the scarce medicines.

The Instrument identifies two medicines as being scarce medicines across the whole of Australia:

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- ORENCIA abatacept (rch) 125 mg single dose ClickJect prefilled autoinjector (registration number 236039).

The Instruments identifies that each of these medicines may be substituted by a medicine in the presentation of the other medicine. That is, the single dose syringe may be substituted by a medicine in the form of an autoinjector, and vice versa. Both the scare medicines and the substitutable medicines contain the active ingredient *abatacept* in the same quantity, and the specified substitutable medicines include medicines that are not included in the Register (i.e. the substitutable medicines may be the subject of some other exemption, approval or authority). The substitutable medicines are considered to be safe and effective treatments for the relevant conditions when substituted for each respective scarce medicine in the circumstances permitted under the Instrument. The scarce medicines and substitutable medicines are the same except for the presentation of the medicines (in a single dose syringe or prefilled autoinjector) and method of administration.

The making of the Instrument enables pharmacists to substitute a 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 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 a substitutable medicines for the relevant scarce medicine prescribed to a patient. The 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. These include that the pharmacist must ensure that the patient is at least 18 years of age and must have advised the patient (or person acting on behalf of the patient) of instructions for administration of the substitutable medicine or to obtain such instructions from a suitable qualified health practitioner. The pharmacist must also always 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 for the prescribed dose of scarce 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 th scarce medicines in Australia is not currently meeting the demand for them for all of the patients in Australia who take, or who may need to take, each of them, and 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 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 abatacept are included in Schedule 4 to the current Poisons Standard, and do not contain a substance in Schedule 8 to the current Poisons Standard.

In accordance with subsection 30EK(5) of the Act, the Instrument specifies the period for which it remains in force, being until 31 October 2024. This reflects the period that the scarce medicine is expected to be the subject of serious scarcity across Australia.

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 products, 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

The 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.