EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

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

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) (Abatacept) 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 two medicines as scarce medicines, 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, and has the effect that each are specified as being substitutable for the other in the relevant permitted circumstances.

Background

Medicine shortages have become an increasing problem in recent years, for a number of reasons, including a decrease in local manufacturing, logistics problems and increases in demand. The TGA receives approximately 105 new medicine shortage notifications every month. The problem of medicine shortages has been amplified as a result of 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.

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 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, that does not rely on state and territory legislation and that both allows substitution arrangements to be in place consistently across all states and territories more quickly, and reflects 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, with the new provisions commencing on 20 February 2021. Under the scheme, section 30EK of the Act provides for the making of a legislative instrument declaring a serious scarcity and specifying the scarce medicine, 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, then 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.

There are currently shortages, or anticipated to be shortages, across Australia of multiple presentations of medicines containing 125 milligrams of the active ingredient abatacept, due to manufacturing issues. Abatacept is principally used to treat rheumatoid arthritis, psoriatic arthritis and polyarticular juvenile idiopathic arthritis and the scarcity of such medicines is having or 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 medicine.

The Instrument identifies two medicines as being scarce medicines across the whole of Australia, and has the effect that each is specified as being substitutable for the other in the circumstances permitted in the Instrument:

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

Both medicines contain the active ingredient abatacept and are considered to be safe and effective treatments for the relevant conditions when substituted for each other in the circumstances permitted under the Instrument for each such substitution. These medicines are the same except for the presentation of the medicines (in a single dose syringe or pre-filled autoinjector) and method of administration.

The making of the Instrument reflects that, while both of these medicines are the subject of a serious scarcity, small but variable quantities of each are likely to be intermittently available in the market. Allowing pharmacists to substitute one for the other is designed to alleviate the effects of this variability and ensure that patients with the conditions outlined above are able to access suitable treatments without delay. This reduces the risk of interrupted treatment for affected patients, as otherwise they could not access the substitutable medicine before having a further appointment with their specialist prescriber.

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

In accordance with subsection 30EK(2) of the Act, the rule-maker is satisfied that there is an imminent risk that supplies of each of these medicines will not, or will not be likely to, meet the demand for them for all of the patients in Australia who take, or who may need to take, each of them, 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 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 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 remains in force until 30 April 2022, 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.

Consultation

The Office of Best Practice Regulation ("OBPR") has advised that the preparation of a regulation impact statement is not required in relation to the creation of the Instrument as it is unlikely to have more than a minor regulatory impact (OBPR22-01634).

In developing the Instrument, during the period 20 January to 7 February 2022 the TGA consulted with the Australian Rheumatology Association, the Australasian College of Dermatologists, the Australian Medical Association, the Royal Australian College of General Practitioners, state and territory Chief Pharmacists, the Pharmaceutical Society of Australia, the Society of Hospital Pharmacists of Australia, the Pharmacy Guild of Australia and Arthritis Australia to ensure the substitution protocol and associated permitted circumstances are appropriate. There was general support from stakeholders regarding the Instrument, with only minor amendments requested for clarity to some of the words used in the Instrument.

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

The Instrument is compatible with the 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 the day after it is registered on the Federal Register of Legislation.

Attachment A

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

Section 1 – Name

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

Section 2 – Commencement

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

Section 3 – Authority

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

Section 4 – Definitions

This section provides the definitions of terms used in the Instrument. This section also notes that some expressions used in the Instrument, for example, 'Register' and 'medicine', have the same meaning as in the Act.

Section 5 – Declaration of serious scarcity

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 mentioned in the tables in Part 1 and Part 2 of Schedule 1, the 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 30 April 2022.

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.

Columns 2 and 3 of the table in Part 1 of Schedule 1 specify ORENCIA abatacept (rch) 125 mg single dose syringe subcutaneous injection ultrasafe passive needle guard and flange extender, Australian Register of Therapeutic Goods ("ARTG") registration number 206764, as the scarce medicine under that Part, with ORENCIA abatacept (rch) 125 mg single dose ClickJect prefilled autoinjector, ARTG registration number 236039, as the corresponding substitutable medicine.

Columns 2 and 3 of the table in Part 2 of Schedule 1 specify ORENCIA abatacept (rch) 125 mg single dose ClickJect prefilled autoinjector, ARTG registration number 236039, as the scarce medicine under that Part, with ORENCIA abatacept (rch) 125 mg single dose syringe subcutaneous injection ultrasafe passive needle guard and flange extender, ARTG registration number 206764, as the corresponding substitutable medicine.

Column 4 of the tables in Part 1 and Part 2 of Schedule 1 specifies the equivalent dose of each scarce medicine and substitutable medicine for the purposes of the permitted circumstances in column 5 of the two tables.

Column 5 of the tables in Part 1 and Part 2 of Schedule 1 sets out the same specific permitted circumstances for each of the substitutable medicines, being that the patient is at least 18 years of age and that the pharmacist must advise the patient (or person acting on behalf of the patient):

- on the 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 or rheumatologist) in relation to the administration process of the substitutable medicine; and
- 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 the Instrument (i.e. that one prefilled autoinjector of the substitutable medicine containing abatacept (rch) 125mg is equivalent to one single dose syringe of the scarce medicine containing abatacept (rch) 125mg, and vice versa).

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 2022

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

Overview of legislative instrument

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

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

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

Medicine shortages have become an increasing problem in recent years for a number of reasons, including a decrease in local manufacturing, logistics problems and increases in demand. The Therapeutic Goods Administration receives notifications of approximately 105 new medicine shortages every month. The problem of medicines shortages has been amplified as a result of the COVID-19 pandemic.

There are currently shortages, or anticipated to be shortages, across Australia of multiple presentations of medicines containing the active ingredient abatacept, due to manufacturing issues. Abatacept is principally used to treat rheumatoid arthritis, psoriatic arthritis, and polyarticular juvenile idiopathic arthritis, and therefore the scarcity has a significant impact on the health and wellbeing of many patients in Australia. There is a significant risk of adverse health consequences for patients in Australia if they are not able to access the scarce medicine.

The *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Abatacept) 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.

The purpose of the instrument is to declare that there is a serious scarcity across Australia of two medicines, with the effect that each is specified as being substitutable for the other in the circumstances permitted in the instrument:

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

The making of this instrument reflects that, while both of these medicines are the subject of a serious scarcity, small but variable quantities of each are likely to be intermittently available in the market. Allowing pharmacists to substitute one for the other is designed to alleviate the effects of this variability and ensure that patients with the conditions outlined above are able to access suitable treatments without delay. This reduces the risk of interrupted treatment for affected patients, which would otherwise occur if patients could not access the substitutable medicine before having a further appointment with their specialist prescriber.

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

In accordance with subsection 30EK(2) of the Act, the rule-maker is satisfied that there is an imminent risk that supplies of each of these medicines will not, or will not be likely to, meet the demand for them for all of the patients in Australia who take, or who may need to take, each of them, 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 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 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 remains in force until 30 April 2022, 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.

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 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 conditions, such as rheumatoid arthritis.

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.