

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Tocilizumab) Amendment Instrument 2021

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 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.

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) (Tocilizumab) Instrument 2021* (“the Principal Instrument”) is a legislative instrument made under subsection 30EK(1) of the Act. It declares two medicines as scarce medicines, ACTEMRA tocilizumab (rch) 162mg/0.9mL solution for injection pre-filled syringe, and ACTEMRA tocilizumab (rch) 162g/0.9mL solution for injection pre-filled pen, ACTPen Autoinjector, and has the effect that each are specified as being substitutable for the other in the relevant permitted circumstances.

The *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Tocilizumab) Amendment Instrument 2021* (“the Amendment Instrument”) is made in the context of the ongoing shortage of medicines containing the active ingredient tocilizumab. The purpose of the Amendment Instrument is to extend the period of time for which the Principal Instrument remains in force, from 31 December 2021 to 30 April 2022.

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.

There are currently shortages, or anticipated to be shortages, across Australia of multiple presentations of medicines containing the active ingredient tocilizumab, due to global demand for these products in connection with the COVID-19 pandemic. The active ingredient tocilizumab is principally used to treat rheumatoid arthritis, giant cell arthritis, systemic juvenile idiopathic arthritis, polyarticular idiopathic arthritis and cytokine release syndrome. Its use in connection with COVID-19 principally relates to administration of intravenous tocilizumab to assist with the treatment of ventilated COVID-19 patients.

Supplies of these medicines for COVID-19 patients are being managed by state and territory health departments and hospitals. The Principal Instrument is not designed to safeguard supplies for this purpose but rather to support access to the limited quantities of the subcutaneous medicines (being, the pre-filled pen and pre-filled syringe) that are, or will be, present in pharmacies in Australia for persons in the community who suffer from the other conditions for which these medicines are used, particularly giant cell arthritis or rheumatoid arthritis.

The Principal 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 Principal Instrument:

- ACTEMRA tocilizumab (rch) 162mg/0.9mL solution for injection pre-filled syringe (registration number 234034); and
- ACTEMRA tocilizumab (rch) 162mg/0.9mL solution for injection pre-filled pen, ACTPen Autoinjector (registration number 296808).

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

The making of the Amendment 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 patients could not access the substitutable medicine before having a further appointment with their specialist prescriber.

The Principal 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 tocilizumab 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 Principal Instrument remains in force until 31 December 2021. However, as shortages of tocilizumab continue and supply is not expected to normalise until late February or March, the purpose of the Amendment Instrument is to extend the

period of time for which the Principal Instrument remains in force, being until 30 April 2022. If the shortage of the scarce medicines is resolved sooner or if safety concerns are identified, the Principal 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 Amendment Instrument as it is unlikely to have more than a minor regulatory impact (OBPR ID 44306).

In developing the Amendment Instrument, during the period 10 to 16 December 2021, the TGA consulted with the Australian Rheumatology Association, 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, the Pharmacy Board of Australia, and Arthritis Australia to ensure the substitution protocol and associated permitted circumstances are appropriate.

The TGA has also consulted with the sponsor of the substitutable medicines throughout November and December 2021, to ensure that overall supply of subcutaneous presentations will be available, although the quantities of each may vary across Australia.

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

The Amendment Instrument is compatible with human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in **Attachment B**.

The Amendment Instrument is a disallowable legislative instrument for the purposes of the *Legislation Act 2003* and commences on the day after it is registered on the Federal Register of Legislation.

Details of the *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Tocilizumab) Amendment Instrument 2021*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Tocilizumab) Amendment Instrument 2021* (“the Amendment Instrument”).

Section 2 – Commencement

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

Subsection 33(3) of the *Acts Interpretation Act 1901* relevantly provides that, where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character, the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument. This Amendment Instrument is made in accordance with that provision.

Section 4 – Schedules

This section provides that each instrument that is specified in a Schedule to the Amendment Instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and that any other item in a Schedule to the Amendment Instrument has effect according to its terms.

Schedule 1—Amendments

Schedule 1 amends the *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Tocilizumab) Instrument 2021* (“the Principal Instrument”).

Item 1 repeals and replaces section 7 of the Principal Instrument to provide that the Principal Instrument remains in force until 30 April 2022.

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) (Tocilizumab) Amendment Instrument 2021

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. 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 tocilizumab, due to global demand for these products in connection with the COVID-19 pandemic.

The active ingredient tocilizumab is principally used to treat rheumatoid arthritis, giant cell arthritis, systemic juvenile idiopathic arthritis, polyarticular idiopathic arthritis and cytokine release syndrome. Its use in connection with COVID-19 principally relates to assisting with the treatment of severe COVID-19 and mitigating the effects of a patient’s immune system experiencing a cytokine storm following infection.

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The purpose of the *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Tocilizumab) Amendment Instrument 2021* (“the Amendment Instrument”) is to extend the period of time for which the Principal Instrument remains in force, from 31 December 2021 to 30 April 2022.

Human rights implications

The amendment 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 amendment instrument takes positive steps to promote the right to health by facilitating improved access to the substitutable medicines, each of which are also scarce medicines under the principal instrument and able to be used as an alternative medicine for the other, and to ameliorate the effects of their uneven availability across the Australian market. By enabling pharmacists to substitute these important products, the amendment 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 giant cell arthritis or rheumatoid arthritis.

Conclusion

The amendment 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.