EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Insulin Degludec and Insulin Aspart) Instrument 2023

The *Therapeutic Goods Act 1989* ("the Act") provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy, and timely availability of therapeutic goods that are used in, or exported from, Australia. The Act also provides for a scheme allowing pharmacists to substitute certain medicine for other medicine if the Minister has declared there is a serious scarcity of the other medicine. The Act is administered by the Therapeutic Goods Administration ("the TGA") within the Australian Government Department of Health and Aged Care ("the Department").

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) (Insulin Degludec and Insulin Aspart) Instrument 2023* ("the Instrument") is a legislative instrument made under subsection 30EK(1) of the Act in relation to insulin degludec in combination with insulin aspart, that is in the form of a solution for injection. It declares that there is a serious scarcity across Australia of specified medicines ("the scarce medicines"), specifies the medicine that pharmacists are permitted to dispense in substitution for the scarce medicines ("the substitutable medicine"), and the circumstances in which they may do so.

The Instrument declares one registered medicine, being RYZODEG 70/30 FLEXTOUCH 70% insulin degludec (rys) / 30% insulin aspart (rys) 100 U/mL solution for injection cartridge, Australian Register of Therapeutic Goods ("ARTG") registration number 280432, to be a scarce medicine. 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. To this end, the substitutable medicine that is specified in the Instrument is RYZODEG 70/30 PENFILL 70% insulin degludec (rys) / 30% insulin aspart (rys) 100 U/mL solution for injection cartridge, ARTG registration number 280433.

Background

Medicine shortages continue to occur for a number of reasons, including manufacturing issues, such as shortages of raw materials, as well as logistics problems and increases in demand. The TGA receives approximately 110 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.

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; 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 is currently a shortage across Australia of RYZODEG 70/30 FLEXTOUCH 70% insulin degludec (rys) / 30% insulin aspart (rys) 100 U/mL solution for injection cartridge, ARTG registration number 280432 ("RYZODEG 70/30 FLEXTOUCH"). The medicine is expected to be in shortage until 5 June 2024. This is primarily due to manufacturing issues resulting from an unprecedented global demand for other medicines using the FlexTouch delivery system.

RYZODEG 70/30 FLEXTOUCH is a soluble insulin product consisting of insulin degludec (ultra-long acting basal insulin) and insulin aspart (rapid acting mealtime insulin) administered in one injection. It is used to treat diabetes mellitus in patients aged 6 years and older. The scarcity of this medicine is having, and is anticipated to have, a significant impact on the health and wellbeing of many patients in Australia. As such, there is a significant risk of adverse health consequences for patients in Australia if they are unable to take the scarce medicine.

The specified substitutable medicine is RYZODEG 70/30 PENFILL 70% insulin degludec (rys) / 30% insulin aspart (rys) 100 U/mL solution for injection cartridge, ARTG registration number 280433 ("RYZODEG 70/30 PENFILL"). The scarce medicine and the substitutable medicine contain the same active ingredients, in the same strength, and are both administered by subcutaneous injection. However, the insulin delivery system to administer each medicine is different - RYZODEG 70/30 FLEXTOUCH is supplied in the form of a pre-filled pen that is ready for injection, whereas RYZODEG 70/30 PENFILL is supplied in the form of a cartridge that needs to be used with a separate insulin delivery system for administration.

The making of the Instrument enables pharmacists to substitute the specified substitutable medicine for the relevant 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 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. These include that the pharmacist must ensure that the patient, or person acting on behalf of the patient, has, or is given, a suitable insulin delivery system to administer the substitutable medicine. The pharmacist must also advise the patient, or person acting on behalf of the patient, of suitable instructions for administering the substitutable medicine, including using the insulin delivery system. Where the pharmacist is unable to provide suitable instructions, the pharmacist must advise the patient, or person acting on behalf of the patient, to obtain suitable instructions for administering the substitutable medicine, including using the insulin delivery system, from their prescriber, a suitably qualified health practitioner or a credentialed diabetes educator.

Further, the pharmacist must advise the patient, or person acting on behalf of the patient, of the number of dose units of substitutable medicine that must be administered to the patient in substitution for the prescribed dose of scarce medicine, based on the dose unit equivalence specified in the Instrument, and of the differences between the scarce and 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, medicines that contain insulin degludec are 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 5 June 2024, unless sooner revoked. This reflects the period that the scarce medicine is 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.

Unless repealed earlier, this Instrument will be automatically repealed at the start of 6 June 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.

The TGA consulted with 20 stakeholders in late June 2023, including the Royal Australian College of General Practitioners, the Royal Australasian College of Physicians, the Australian Diabetes Society, the Australia and New Zealand Society for Paediatric Endocrinology and Diabetes, the Endocrine Society of Australia, the Australian Medical Association, state and territory Chief Pharmacists or health departments, the Pharmaceutical Society of Australia, the Pharmacy Guild of Australia, the Society of Hospital Pharmacists of Australia, the National Aboriginal Community Controlled Health Organisation, Diabetes Australia and the Australian Diabetes Educators Association. Consultation was undertaken to ensure the substitution protocol and associated permitted circumstances are appropriate. The TGA received 9 responses that were all supportive of the proposed Instrument, and feedback was incorporated into the Instrument. The TGA has also consulted with the sponsor of the substitutable medicine to alert them to the potential change in demand.

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

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

The Instrument is a disallowable legislative instrument for the purposes of the *Legislation Act 2003* and commences on 6 July 2023. The Instrument will be repealed at the start of 6 June 2024, unless it is repealed earlier.

Attachment A

Details of the *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Insulin Degludec and Insulin Aspart) Instrument 2023*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Insulin Degludec and Insulin Aspart) Instrument 2023* ("the Instrument").

Section 2 – Commencement

This section provides that the Instrument commences on 6 July 2023.

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' 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 5 June 2024.

Section 8 – Repeals

This section provides that, unless repealed earlier, the Instrument is repealed at the start of 6 June 2024.

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 medicine as being RYZODEG 70/30 FLEXTOUCH 70% insulin degludec (rys) / 30% insulin aspart (rys) 100 U/mL solution for injection cartridge (ARTG registration number 280432); and
- the substitutable medicine as being RYZODEG 70/30 PENFILL 70% insulin degludec (rys) / 30% insulin aspart (rys) 100 U/mL solution for injection cartridge (ARTG registration number 280433).

Column 4 of the table 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. In particular, it specifies that one 3mL cartridge of the substitutable medicine (containing 300 units) is equivalent to one 3mL pre-filled pen of the scarce medicine (containing 300 units).

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

The specific permitted circumstances are that the pharmacist has:

- ensured that the patient, or person acting on behalf of the patient, has, or is given, a suitable insulin delivery system to administer the substitutable medicine. As the substitutable medicine is a cartridge of insulin that must be loaded into a re-usable device before administration, this ensures that the patient has the appropriate insulin delivery system needed to administer the substitutable medicine; and
- advised the patient, or person acting on behalf of the patient, of suitable instructions for administering the substitutable medicine, including using the insulin delivery system. This requires the pharmacist to explain that the patient, or person acting on behalf of the patient, is required to load a cartridge into a re-usable insulin delivery system prior to administration. Where the pharmacist is unable to provide suitable instructions, the pharmacist must advise the patient, or person acting on behalf of the patient, to obtain suitable instructions for administering the substitutable medicine, including using the insulin delivery system, from their prescriber, a suitably qualified health practitioner or a credentialed diabetes educator; and
- 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 of the table in Schedule 1. 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
- advised the patient, or person acting on behalf of the patient, of the differences between the scarce medicine and substitutable medicine. This ensures that the patient, or person acting on behalf of the patient, understands that the insulin delivery system to administer each of the medicines is different.

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) (Insulin Degludec and Insulin Aspart) Instrument 2023

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.

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) (Insulin Degludec and Insulin Aspart) Instrument 2023* ("the Instrument") is a legislative instrument made under subsection 30EK(1) of the Act in relation to insulin degludec in combination with insulin aspart, that is in the form of a solution for injection. It declares that there is a serious scarcity across Australia of specified medicines ("the scarce medicines"), specifies the medicine that pharmacists are permitted to dispense in substitution for the scarce medicines ("the substitutable medicine"), and the circumstances in which they may do so.

The Instrument declares one registered medicine, being RYZODEG 70/30 FLEXTOUCH 70% insulin degludec (rys) / 30% insulin aspart (rys) 100 U/mL solution for injection cartridge, Australian Register of Therapeutic Goods ("ARTG") registration number 280432, to be a scarce medicine. 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. To this end, the substitutable medicine that is specified in the Instrument is RYZODEG 70/30 PENFILL 70% insulin degludec (rys) / 30% insulin aspart (rys) 100 U/mL solution for injection cartridge, ARTG registration number 280433.

Background

Medicine shortages continue to occur for a number of reasons, including manufacturing issues, such as shortages of raw materials, as well as logistics problems and increases in demand. The TGA receives approximately 110 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.

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; 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 is currently a shortage across Australia of RYZODEG 70/30 FLEXTOUCH 70% insulin degludec (rys) / 30% insulin aspart (rys) 100 U/mL solution for injection cartridge, ARTG registration number 280432 ("RYZODEG 70/30 FLEXTOUCH"). The medicine is expected to be in shortage until 5 June 2024. This is primarily due to manufacturing issues resulting from an unprecedented global demand for other medicines using the FlexTouch delivery system.

RYZODEG 70/30 FLEXTOUCH is a soluble insulin product consisting of insulin degludec (ultra-long acting basal insulin) and insulin aspart (rapid acting mealtime insulin) administered in one injection. It is used to treat diabetes mellitus in patients aged 6 years and older. The scarcity of this medicine is having, and is anticipated to have, a significant impact on the health and wellbeing of many patients in Australia. As such, there is a significant risk of adverse health consequences for patients in Australia if they are unable to take the scarce medicine.

The specified substitutable medicine is RYZODEG 70/30 PENFILL 70% insulin degludec (rys) / 30% insulin aspart (rys) 100 U/mL solution for injection cartridge, ARTG registration number 280433 ("RYZODEG 70/30 PENFILL"). The scarce medicine and the substitutable medicine contain the same active ingredients, in the same strength, and are both administered by subcutaneous injection. However, the insulin delivery system to administer each medicine is different - RYZODEG 70/30 FLEXTOUCH is supplied in the form of a pre-filled pen that is ready for injection, whereas RYZODEG 70/30 PENFILL is supplied in the form of a cartridge that needs to be used with a separate insulin delivery system for administration.

The making of the Instrument enables pharmacists to substitute the specified substitutable medicine for the relevant 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 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. These include that the pharmacist must ensure that the patient, or person acting on behalf of the patient, has, or is given, a suitable insulin delivery system to administer the substitutable medicine. The pharmacist must also advise the patient, or person acting on behalf of the patient, of suitable instructions for administering the substitutable medicine, including using the insulin delivery system. Where the pharmacist is unable to provide suitable instructions, the pharmacist must advise the patient, or person acting on behalf of the patient, to obtain suitable instructions for administering the substitutable medicine, including using the insulin delivery system, from their prescriber, a suitably qualified health practitioner or a credentialed diabetes educator.

Further, the pharmacist must advise the patient, or person acting on behalf of the patient, of the number of dose units of substitutable medicine that must be administered to the patient in substitution for the prescribed dose of scarce medicine, based on the dose unit equivalence specified in the Instrument, and of the differences between the scarce and 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, medicines that contain insulin degludec are 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 5 June 2024, unless sooner revoked. This reflects the period that the scarce medicine is 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.

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.