EXPLANATORY STATEMENT

Minute No. 16 of 2020 – Minister for Health

Subject - *Therapeutic Goods Act 1989*

Therapeutic Goods Amendment (Radiopharmaceuticals and Radiopharmaceutical Active Ingredients) Regulations 2020

The object of the *Therapeutic Goods Act 1989* (the Act) is to establish and maintain a national system of controls for the quality, safety, efficacy and timely availability of therapeutic goods that are used in Australia or exported from Australia. The Therapeutic Goods Administration (the TGA), which is part of the Department of Health, is responsible for administering the Act.

Subsection 63(1) of the Act provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing matters required or permitted to be prescribed by the Act or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

Subsection 34(1) of the Act provides that the regulations may exempt therapeutic goods or a class of therapeutic goods identified in the regulations from the operation of Part 3-3 of the Act, which provides the regulatory framework for the manufacture of certain therapeutic goods. Subregulation 17(1) of the *Therapeutic Goods Regulations 1990* (TG Regulations) provides that, for the purposes of subsection 34(1) of the Act, the therapeutic goods specified in Schedule 7 to the TG Regulations are exempt from the operation of Part 3-3 of the Act unless the goods are supplied as pharmaceutical benefits.

The principal purpose of the *Therapeutic Goods Amendment (Radiopharmaceuticals and Radiopharmaceutical Active Ingredients) Regulations 2020* (the Regulations) is to amend the TG Regulations to provide an exemption, in Schedule 7 to the TG Regulations, from the operation of Part 3-3 of the Act for certain radiopharmaceuticals and radiopharmaceutical active ingredients (RAI). This exemption is necessary to facilitate the continued supply of radiopharmaceuticals to patients around Australia which has been negatively impacted by the unforeseen reduction in commercial flights between Australian capital cities caused by the current outbreak of coronavirus disease (COVID-19).

Radiopharmaceuticals are used in the diagnosis and treatment of a number of medical conditions, including diagnosing congenital heart defects in newborn babies and diagnosing and treating certain cancers. The radioactive isotopes in a radiopharmaceutical or RAI decay at a rate, measured in half-life, which necessitates their use reasonably proximately to their manufacture. Where patients are located in a different State or Territory to where the radiopharmaceutical or RAI is manufactured by a manufacturer licensed under Part 3-3 of the Act, before the interruption to commercial flights, the radiopharmaceutical or RAI would be transported as quickly as possible from the manufacturer to the patient by direct flight between the relevant capital cities. With a significant reduction (and in some cases total absence) of direct flights between capital cities, in some situations it has not been possible for hospitals to obtain supplies of radiopharmaceuticals or of RAI manufactured by a licensed manufacturer for patients. The only option for affected patients would be to travel interstate for appropriate diagnosis or treatment.

The purpose of the Regulations is to enable public and private hospitals and public institutions that do not hold a manufacturing licence under the Act to manufacture radiopharmaceuticals or RAI for the treatment of a patient in another State or Territory, so that the radiopharmaceuticals or RAI can be transported to the patient in a timely manner. This, therefore, eliminates the need for patients to travel interstate for diagnosis or treatment.

The Regulations amend the TG Regulations to exempt from the operation of Part 3-3 of the Act the identified radiopharmaceuticals and RAI (including the requirement for their manufacture to be carried out by a licensed manufacturer). These medicines are manufactured by a registered medical practitioner, a radiochemist or a registered pharmacist, or a person under their professional supervision, when employed by a public or private hospital or a public institution. The exemptions only apply to radiopharmaceuticals and RAI that are supplied to a public or private hospital or public or private institution within Australia for, in the case of radiopharmaceuticals, the purposes of diagnosis or treatment of a medical condition for a patient of that hospital or institution or, in the case of RAI, for the manufacture of a radiopharmaceutical for that same purpose.

Where a hospital or institution is able to obtain sufficient supplies of radiopharmaceuticals or RAI from a manufacturer licensed under the Act, the radiopharmaceuticals or RAI should be obtained from that licensed manufacturer (instead of an unlicensed manufacturer in reliance on the new exemptions). This is to ensure that radiopharmaceuticals and RAI are preferably manufactured by those licensed under the Act as meeting all manufacturing requirements.

The exemptions address the current difficulties in obtaining supplies of radiopharmaceuticals and RAI from a licensed manufacturer in a timely manner during the COVID-19 outbreak. Reflecting the extraordinary circumstances necessitating the new exemptions, the exemptions are to be reviewed at an appropriate time when the current COVID-19 circumstances change. Accordingly, hospitals or public institutions should not seek to rely on the new exemptions as a long-term option for manufacturing radiopharmaceuticals or RAI without a licence under the Act.

Details of the Regulations are set out in Attachment A.

The Act specifies no conditions that need to be satisfied before the power to make the Regulations may be exercised.

The Regulations are a legislative instrument for the purposes of the *Legislation Act 2003*.

The Regulations commence on the day after they are registered.

Consultation

The Australasian Association of Nuclear Medicine Specialists (AANMS) and the Royal Darwin Hospital Positron Emission Tomography/Computed Tomography Unit were consulted about the proposed regulatory amendment and were generally supportive of the proposal.

Authority: Subsection 63(1) of the *Therapeutic Goods Act 1989*

ATTACHMENT A

Details of the *Therapeutic Goods Amendment (Radiopharmaceuticals and Radiopharmaceutical Active Ingredients) Regulations 2020*

Section 1 – Name

This section provides for the Regulations to be referred to as the *Therapeutic Goods Amendment (Radiopharmaceuticals and Radiopharmaceutical Active Ingredients) Regulations 2020.*

Section 2 – Commencement

This section provides for the commencement of the Regulations on the day after the Regulations are registered.

Section 3 – Authority

This section provides that the Regulations are made under the *Therapeutic Goods Act 1989* (the Act).

Section 4 – Schedules

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

Schedule 1 – Amendments

Therapeutic Goods Regulations 1990

Item 1 – Schedule 7 (at the end of the table)

This item amends the table in Schedule 7 to the *Therapeutic Goods Regulations 1990* to add two new items. New item 22 introduces an exemption to the operation of Part 3-3 of the Act for certain radiopharmaceuticals and new item 23 introduces an exemption to the operation of Part 3-3 of the Act for certain radiopharmaceutical active ingredients (RAI).

The new items enable hospitals or public institutions that do not hold a manufacturing license under the Act to manufacture radiopharmaceuticals or RAI for supply to a patient in another hospital or institution. Therefore, if a hospital or institution is unable to obtain supplies of radiopharmaceuticals or RAI from a licensed manufacturer in a timely manner, this exemption gives the hospital or institution the ability to source radiopharmaceuticals or RAI from a manufacturer that is not licensed.

New items 22 and 23 apply to radiopharmaceuticals and RAI (respectively) manufactured in public or private hospitals or public intuitions by a medical practitioner registered under a State or Territory law, a radiochemist or a pharmacist regulated under State or Territory law, when employed by a public or private hospital or a public institution. These items also apply

to a radiopharmaceutical or RAI manufactured by a person under the supervision of such a medical practitioner, radiochemist or pharmacist.

New items 22 and 23 also only apply to radiopharmaceuticals or RAI that are for supply to a public or private hospital or a public or private institution within Australia. In the case of radiopharmaceuticals, this is where the supply is for the purposes of diagnosing or treating a medical condition of a patient of that hospital or institution. In the case of a RAI, this is where the supply is for the purpose of manufacturing a radiopharmaceutical for diagnosing or treating a medical condition of a patient of the hospital or institution. The exemptions do not apply to supply for any other purpose.

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011.

Therapeutic Goods Amendment (Radiopharmaceuticals and Radiopharmaceutical Active Ingredient) Regulations 2020

The *Therapeutic Goods Amendment (Radiopharmaceuticals and Radiopharmaceutical Active Ingredient) Regulations 2020* (the Regulations) are compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of legislative instrument

The Regulations are made under subsection 63(1) of the *Therapeutic Goods Act 1989* (the Act). The principal purpose of the *Therapeutic Goods Amendment (Radiopharmaceuticals and Radiopharmaceutical Active Ingredients) Regulations 2020* (the Regulations) is to amend the TG Regulations to provide an exemption, in Schedule 7 to the TG Regulations, from the operation of Part 3-3 of the Act for certain radiopharmaceuticals and radiopharmaceutical active ingredients (RAI). This exemption is necessary to facilitate the continued supply of radiopharmaceuticals to patients around Australia which has been negatively impacted by the unforeseen reduction in commercial flights between Australian capital cities caused by the current outbreak of coronavirus disease (COVID-19).

Radiopharmaceuticals are used in the diagnosis and treatment of a number of medical conditions, including diagnosing congenital heart defects in newborn babies and diagnosing and treating certain cancers. The radioactive isotopes in a radiopharmaceutical or RAI decay at a rate, measured in half-life, which necessitates their use reasonably proximately to their manufacture. Where patients are located in a different State or Territory to where the radiopharmaceutical or RAI is manufactured by a manufacturer licensed under Part 3-3 of the Act, before the interruption to commercial flights, the radiopharmaceutical or RAI would be transported as quickly as possible from the manufacturer to the patient by direct flight between the relevant capital cities. With a significant reduction (and in some cases total absence) of direct flights between capital cities, in some situations it has not been possible for hospitals to obtain supplies of radiopharmaceuticals or of RAI manufactured by a licensed manufacturer, for patients. The only option for affected patients would be to travel interstate for appropriate diagnosis or treatment.

The purpose of the Regulations is to enable public and private hospitals and public institutions that do not hold a manufacturing licence under the Act to manufacture radiopharmaceuticals or RAI for the treatment of a patient in another State or Territory, so that the radiopharmaceuticals or RAI can be transported to the patient in a timely manner. This, therefore, eliminates the need for patients to travel interstate for diagnosis or treatment.

The Regulations amend the TG Regulations to exempt from the operation of Part 3-3 of the Act the identified radiopharmaceuticals and RAI (including the requirement for their manufacture to be carried out by a licensed manufacturer). These medicines are manufactured by a registered medical practitioner, a radiochemist or a registered pharmacist, or a person under their professional supervision, when employed by a public or private hospital or a public institution. The exemptions only apply to radiopharmaceuticals and RAI that are

supplied to a public or private hospital or public or private institution within Australia for, in the case of radiopharmaceuticals, the purposes of diagnosis or treatment of a medical condition for a patient of that hospital or institution or, in the case of RAI, for the manufacture of a radiopharmaceutical for that same purpose.

Human rights implications

The instrument engages the right to health in Article 12 of the International Covenant on Economic, Social and Cultural rights (ICESCR).

Article 12 of the ICESCR promotes the right of all individuals to enjoy the highest attainable standards of physical and mental health. 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 Regulations take positive steps to promote the right to health by facilitating the continued supply of radiopharmaceuticals to patients during the COVID-19 outbreak. The Regulations are intended to eliminate the need for patients to travel interstate for treatment or diagnosis of a medical condition if radiopharmaceuticals or RAI can be sourced from a manufacturer exempt from the requirement to be licensed under the Act and transported in a timely manner to the patient. Reflecting the extraordinary circumstances necessitating the new exemptions, the Regulations are to be reviewed at an appropriate time as the current circumstances change.

Conclusion

These Regulations are compatible with human rights because they promote and support the right to health in Article 12 of the ICESCR as outlined above, and do not raise any other human rights issues.

Greg Hunt, Minister for Health