EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020

Therapeutic Goods Amendment (Excluded Goods) Determination (No. 1) 2020

Therapeutic Goods Amendment (Declared Goods) Order (No. 1) 2020

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 is administered by the Therapeutic Goods Administration ("the TGA") within the Department of Health.

Subsection 3(1) of the Act defines 'therapeutic goods' as goods that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be for therapeutic use, and includes biologicals and medical devices. The Act provides a number of mechanisms, principally under sections 7, 7AA, 32A and 41BD, to determine or clarify whether particular goods are or are not therapeutic goods, biologicals, or medical devices, and therefore subject to the national system of controls established by the Act, including the requirement for those goods to be included in the Australian Register of Therapeutic Goods ("the Register").

Section 7 of the Act provides that the Secretary may declare that particular goods or classes of goods, or those goods when used, advertised, or presented for supply in a particular way, are or are not therapeutic goods for the purposes of the Act. In making a declaration that goods are or are not therapeutic goods, the Secretary must first be satisfied that the goods are or are not therapeutic goods as defined in subsection 3(1) of the Act.

Section 7AA of the Act provides that the Minister may determine that specified goods (other than goods declared to be therapeutic goods under an order in force under section 7 of the Act) are excluded goods for the purposes of the Act, or are excluded goods for the purposes of the Act when used, advertised or presented for supply in a specified manner. Before making a determination under section 7AA, the Minister must have regard to certain matters specified in subsection 7AA(3) of the Act, and any other matter the Minister considers relevant in accordance with subsection 7AA(4) of the Act.

The matters that the Minister must have regard to before making a determination, in accordance with subsection 7AA(3) of the Act, are:

(a) whether it is likely that the specified goods might harm the health of members of the public if not regulated under the Act;

(b) whether it is appropriate in all the circumstances to apply the national system of controls established by the Act to regulate the specified goods; and

(c) whether the kinds of risks that members of the public might be exposed to from the specified goods could be more appropriately dealt with under another regulatory scheme.

Section 41BD of the Act provides the definition of a medical device. Relevantly, paragraph 41BD(1)(a) of the Act provides that a medical device is any instrument, apparatus, appliance, material or other article that is intended, by the person under whose name it is or is to be supplied, to be used for human beings for one or more of the purposes in subparagraphs 41BD(1)(a)(i)–(iv), including for example, the diagnosis, prevention, monitoring, treatment or alleviation of disease.

Further, paragraph 41BD(1)(ab) of the Act provides that an instrument, apparatus, appliance, material or other article that is included in a class of instruments, apparatus, appliances, materials or other articles specified under subsection 41BD(2B), is also a medical device.

Instruments made under section 7, section 7AA and subsection 41BD(2B) of the Act are disallowable legislative instruments within the meaning of section 8(4) of the *Legislation Act 2003* ("the Legislation Act"). In accordance with subsection 56(1) of the Legislation Act, the requirement for an instrument made under section 7 of the Act to be published in the *Gazette* is satisfied by registration of the instrument as a legislative instrument.

Purpose

The *Therapeutic Goods (Declared Goods) Order 2019* ("the Principal Order") is made under section 7 of the Act. The Principal Order declares particular goods or classes of goods, or those goods when used, advertised, or presented for supply in a particular way, to be therapeutic goods, or not to be therapeutic goods, for the purposes of the Act.

The *Therapeutic Goods (Excluded Goods) Determination 2018* ("the Principal Determination") is made under section 7AA of the Act. The Principal Determination determines specified goods, including specified goods when used, advertised or presented for supply in a specified manner, to be excluded goods for the purposes of the Act.

The *Therapeutic Goods (Articles that are Medical Devices) Specification 2014* ("the former Specification") is made under subsection 41BD(2B) of the Act. The former Specification specifies that particular classes of instruments, apparatus, appliances, materials or other articles are medical devices for the purposes of the Act.

The *Therapeutic Goods Amendment (Declared Goods) Order (No. 1) 2020* ("the Amendment Order"), the *Therapeutic Goods Amendment (Excluded Goods) Determination (No. 1) 2020* ("the Amendment Determination"), and the *Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020* ("the Principal Instrument"), are made under section 7, section 7AA, and subsection 41BD(2B) of the Act, respectively. The Amendment Order amends the Principal Order, the Amendment Determination amends the Principal Determination, and the Principal Instrument repeals and replaces the former Specification. The Amendment Order, Amendment Determination, and Principal Instrument (together, "the Amendment Instruments") are made in the context of the public health emergency caused by the outbreak of the disease known as coronavirus disease 2019 ("COVID-19") with the principal purpose of providing greater clarity with respect to the long-standing regulatory status of certain non-sterile personal protective equipment or safety apparel ("non-sterile PPE") in Australia.

To date, item 5 of Part 2 of Schedule 2 to the Principal Order has been relied on to determine the regulatory status of non-sterile PPE, and whether particular non-sterile PPE are, or are not, therapeutic goods requiring inclusion in the Register. Item 5 relevantly provides that '*non-sterile protective or safety apparel or equipment*" are ***not*** therapeutic goods "*when used: (a) in the home; or (b) for occupational or recreational use*'. In short, the intention of item 5, and the TGA's implementation of that item in practice, has been to exclude from the operation of the Act non-sterile PPE other than non-sterile PPE intended by the manufacturer to be used in health care services to prevent the transmission of disease. In the present circumstances — as the Australian Government, medical device manufacturers, and the health services industry intensify efforts to facilitate the availability of critical PPE in response to COVID-19 — it has become apparent that the terms of item 5 are not helpful in clearly and easily determining whether particular non-sterile PPE are or are not therapeutic goods subject to the requirements of the Act. This uncertainty ultimately has implications for the importation, supply and timely availability of these critical devices in Australia.

The purpose of the Amendment Instruments are to more clearly and accurately provide for the regulation of non-sterile PPE as intended by item 5 of Part 2 of Schedule 2 to the Principal Order. By providing greater clarity and certainty around the regulatory status of particular non-sterile PPE, the Amendment Instruments support efforts to ensure the availability and appropriate use of non-sterile PPE in Australia, in particular during the COVID-19 public health emergency. The effect and operation of the Amendment Instruments are detailed below.

Most importantly, the Principal Instrument positively specifies a particular class of non-sterile PPE to be medical devices, thereby ensuring those articles are appropriately regulated as medical devices under the Act. Namely, item 1 of Schedule 1 to the Principal Instrument specifies articles that are non-sterile PPE intended, by the person under whose name the articles are or are to be supplied, to be used for the prevention of the transmission of disease between persons, including where that intention may be ascertained from the articles being represented as suitable for use in surgery, or clinical, medical or other health services. As explained above, this item does not introduce substantive changes to existing regulatory arrangements for non-sterile PPE.

Further, the Principal Instrument reproduces the class of articles covered by the former Specification made under subsection 41BD(2B) of the Act, to be medical devices, without any substantive changes. The Principal Instrument thus renders the former Specification redundant and accordingly repeals and replaces the former Specification. The replacement and consolidation of the former Specification enables the medical devices previously specified under section 41BD(2B) of the Act to be housed in the new consolidated Principal Instrument. Moreover, the drafting of the Principal Instrument reflects contemporary drafting standards and practices on matters relating to style and form, such as the use of plain English and compliance with the Office of Parliamentary Counsel's Drafting Directions. As such, the Principal Instrument improves readability, accessibility and presentation for stakeholders, without making substantive changes to the particular class of articles that is the subject of the former Specification.

The Amendment Determination amends the Principal Determination by adding a new item 2A in Schedule 1, in order to exclude from the operation of the Act all non-sterile PPE other than non-sterile PPE specified in the Principal Instrument. That item provides that articles that are non-sterile PPE other than articles specified in item 1 of Schedule 1 to the Principal Instrument are excluded goods for the purposes of the Act. In accordance with the matters to be taken into account under subsection 7AA(3) of the Act, the exclusion of the non-sterile PPE specified in the Amendment Determination is not likely to harm public health, given the negligible public health or personal risk associated with use of the goods. On the contrary, these goods are intended principally to prevent injury and to otherwise protect persons in other occupational, sporting or domestic settings. Further, it would not be appropriate to apply the national system of controls established by the Act, in circumstances where the benefits associated with the timely availability of the goods significantly outweighs the negligible risks associated with excluding the goods from regulation under the Act. Moreover, while the goods specified in the Amendment Determination are excluded goods for the purposes of the Act, the goods will continue to be regulated as they are presently, principally under consumer protection legislation and work place health and safety laws.

Finally, the Amendment Order amends the Principal Order to repeal the existing declaration for non-sterile PPE under item 5 of Part 2 of Schedule 2 to the Principal Order, as a consequence of the making of the Principal Instrument and the Amendment Determination in the manner described above.

Background

On 11 March 2020, the World Health Organization ("WHO") declared the outbreak of COVID-19 caused by the pathogen virus known as severe acute respiratory syndrome coronavirus ("SARS-CoV-2") a pandemic. On 18 March 2020, the Governor-General made a declaration, acting with the advice of the Federal Executive Council, that a human biosecurity emergency exists in Australia.

COVID-19 represents a severe and immediate threat to public health, both in Australia and globally, placing significant pressure on health care systems and causing economic disruption. In order to respond to the COVID-19 outbreak effectively, appropriate clinical management and infection control in conjunction with implementation of community mitigation measures are necessary. This includes the appropriate use of PPE, particularly in the provision of clinical, medical, surgical or other health services.

Consultation

Given the Amendment Instruments do not alter existing regulatory arrangements for non-sterile PPE, the rule-maker considers that, in accordance with section 17 of the Legislation Act, consultation was not necessary or appropriate in the circumstances. The Amendment Instruments merely provide necessary clarity in relation to the regulatory status of non-sterile PPE and otherwise have no measurable impact on businesses, community organisations, individuals or any combination of them.

Moreover, the Prime Minister has granted an exemption from the requirement to complete regulatory impact analysis in the form of a Regulation Impact Statement for all Australian Government measures made in response to COVID-19 (OBPR reference: 26445). The Amendment Instruments are similarly made in response to the public health emergency.

Details of the Amendment Order, Amendment Determination, and Principal Instrument are set out in **Attachment A**, **Attachment B**, and **Attachment C**, respectively.

The Amendment Instruments are 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 D.**

The Amendment Instruments are disallowable legislative instruments for the purposes of the *Legislation Act 2003* and commence on the day after the Principal Instrument is registered on the Federal Register of Legislation.

This explanatory statement has been prepared in relation to the Amendment Instruments in accordance with subsection 15J(4) of the Legislation Act.

Attachment A

Details of the *Therapeutic Goods Amendment (Declared Goods) Order (No. 1) 2020*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods Amendment (Declared Goods) Order (No. 1) 2020* ("the Amendment Order").

Section 2 – Commencement

This section provides that the Amendment Order commences at the commencement of the *Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020*.

Section 3 – Authority

This section provides that the legislative authority for making the Amendment Order is section 7 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 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 Order 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 instrument has effect according to its terms.

Schedule 1 – Amendments

This Schedule amends the *Therapeutic Goods (Declared Goods) Order 2019* ("the Principal Order").

Item 1 of this Schedule omits "(other than apparel specified in item 5)," after reference to "non-sterile apparel" in item 4 of Part 2 of Schedule 2 to the Principal Order. This is a consequential amendment to remove reference to item 5 of Part 2 of Schedule 2 to the Principal Order, which is repealed by the Amendment Order.

Item 2 of this Schedule repeals item 5 of Part 2 of Schedule 2 to the Principal Order, which declared non-sterile protective or safety apparel or equipment not to be therapeutic goods when used, advertised, or presented for supply in a particular way.

Attachment B

Details of the *Therapeutic Goods Amendment (Excluded Goods) Determination (No. 1) 2020*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods Amendment (Excluded Goods) Determination (No. 1) 2020* ("the Amendment Determination").

Section 2 – Commencement

This section provides that the Amendment Determination commences at the commencement of the *Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020*.

Section 3 – Authority

This section provides that the legislative authority for making the Amendment Determination is section 7AA 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 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 Determination 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 instrument has effect according to its terms.

Schedule 1 – Amendments

This Schedule amends the *Therapeutic Goods (Excluded Goods) Determination 2018* ("the Principal Determination").

Item 1 of this Schedule adds a new item 2A to the end of the table in Schedule 1 to the Principal Determination, to exclude from the operation of the Act articles that are non-sterile personal protective equipment or safety apparel other than articles specified in item 1 of Schedule 1 to the *Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020*.

Attachment C

Details of the *Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020* ("the Principal Instrument").

Section 2 – Commencement

This section provides that the Principal 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 Principal Instrument is subsection 41BD(2B) 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. Part of this instrument is made in accordance with that provision.

Section 4 – Definitions

This section provides the definitions of terms used in the Principal Instrument. Some terms are defined in the Act and therefore, as explained in the note, have the same meaning as given in the Act.

Section 5 – Classes of articles specified to be medical devices

This section provides that the classes of instruments, apparatus, appliances, materials and other articles mentioned in Schedule 1 are specified to be medical devices for the purposes of paragraph 41BD(1)(ab) of the Act.

Section 6 – Repeals

This section provides that instruments specified in Schedule 2 are repealed as set in that Schedule.

Schedule 1 – Specified classes of articles that are medical devices

This Schedule specifies classes of articles to be medical devices.

Item 1 of this Schedule specifies particular articles that are non-sterile personal protective equipment or safety apparel to be medical devices.

Item 2 of this Schedule specifies articles already specified to be medical devices under the *Therapeutic Goods (Articles that are Medical Devices) Specification 2014* ("the former Specification").

Schedule 2 – Repeals

This Schedule repeals the former Specification.

Attachment D

Statement of Compatibility with Human Rights

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

Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020

Therapeutic Goods Amendment (Excluded Goods) Determination (No. 1) 2020

Therapeutic Goods Amendment (Declared Goods) Order (No. 1) 2020

These disallowable legislative instruments 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 instruments

The *Therapeutic Goods Amendment (Declared Goods) Order (No. 1) 2020*, the *Therapeutic Goods Amendment (Excluded Goods) Determination (No. 1) 2020*, and the *Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020* (together, "the amendment instruments"), are made under section 7, section 7AA and subsection 41BD(2B) of the *Therapeutic Goods Act 1989* ("the Act").

Section 7 of the Act provides that the Secretary may declare that particular goods or classes of goods, or those goods when used, advertised, or presented for supply in a particular way, are or are not therapeutic goods for the purposes of the Act. In making a declaration that goods are or are not therapeutic goods, the Secretary must first be satisfied that the goods are or are not therapeutic goods as defined in subsection 3(1) of the Act.

Section 7AA of the Act provides that the Minister may determine that specified goods (other than goods declared to be therapeutic goods under an order in force under section 7 of the Act) are excluded goods for the purposes of the Act, or are excluded goods for the purposes of the Act when used, advertised or presented for supply in a specified manner. Before making a determination under section 7AA, the Minister must have regard to certain matters specified in subsection 7AA(3) of the Act, and any other matter the Minister considers relevant in accordance with subsection 7AA(4) of the Act.

Section 41BD of the Act provides the definition of a medical device. Relevantly, paragraph 41BD(1)(a) of the Act provides that a medical device is any instrument, apparatus, appliance, material or other article that is intended, by the person under whose name it is or is to be supplied, to be used for human beings for one or more of the purposes in subparagraphs 41BD(1)(a)(i)–(iv), including for example, the diagnosis, prevention, monitoring, treatment or alleviation of disease.

Further, paragraph 41BD(1)(ab) of the Act provides that an instrument, apparatus, appliance, material or other article that is included in a class of instruments, apparatus, appliances, materials or other articles specified under subsection 41BD(2B), is also a medical device.

Purpose

The *Therapeutic Goods Amendment (Declared Goods) Order (No. 1) 2020* ("the Amendment Order"), the *Therapeutic Goods Amendment (Excluded Goods) Determination (No. 1) 2020* ("the Amendment Determination"), and the *Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020* ("the Principal Instrument"), are made under section 7, section 7AA, and subsection 41BD(2B) of the Act, respectively. The Amendment Order amends the *Therapeutic Goods (Declared Goods) Order 2019*, the Amendment Determination amends the *Therapeutic*

Goods (Excluded Goods) Determination 2018, and the Principal Instrument repeals and replaces the *Therapeutic Goods (Articles that are Medical Devices) Specification 2014*. The Amendment Order, Amendment Determination, and Principal Instrument (together, "the Amendment Instruments") are made in the context of the public health emergency caused by the outbreak of the disease known as coronavirus disease 2019 ("COVID-19") with the principal purpose of providing greater clarity with respect to the long-standing regulatory status of certain non-sterile personal protective equipment or safety apparel ("non-sterile PPE") in Australia.

To date, item 5 of Part 2 of Schedule 2 to the *Therapeutic Goods (Declared Goods) Order 2019* has been relied on to determine the regulatory status of non-sterile PPE, and whether particular non-sterile PPE are, or are not, therapeutic goods requiring inclusion in the Register. Item 5 relevantly provides that '*non-sterile protective or safety apparel or equipment*" are ***not*** therapeutic goods "*when used: (a) in the home; or (b) for occupational or recreational use*'. In short, the intention of item 5, and the TGA's implementation of that item in practice, has been to exclude from the operation of the Act non-sterile PPE other than non-sterile PPE intended by the manufacturer to be used in health care services to prevent the transmission of disease. In the present circumstances — as the Australian Government, medical device manufacturers, and the health services industry intensify efforts to facilitate the availability of critical PPE in response to COVID-19 — it has become apparent that the terms of item 5 are not helpful in clearly and easily determining whether particular non-sterile PPE are or are not therapeutic goods subject to the requirements of the Act. This uncertainty ultimately has implications for the importation, supply and timely availability of these critical devices in Australia.

The purpose of the Amendment Instruments are to more clearly and accurately provide for the regulation of non-sterile PPE as intended by item 5 of Part 2 of Schedule 2 to the current *Therapeutic Goods (Declared Goods) Order 2019*. By providing greater clarity and certainty around the regulatory status of particular non-sterile PPE, the Amendment Instruments support efforts to ensure the availability and appropriate use of non-sterile PPE in Australia, in particular during the COVID-19 public health emergency. The effect and operation of the Amendment Instruments are detailed below.

Most importantly, the Principal Instrument positively specifies a particular class of non-sterile PPE to be medical devices, thereby ensuring those articles are appropriately regulated as medical devices under the Act. Namely, item 1 of Schedule 1 to the Principal Instrument specifies articles that are non-sterile PPE intended, by the person under whose name the articles are or are to be supplied, to be used for the prevention of the transmission of disease between persons, including where that intention may be ascertained from the articles being represented as suitable for use in surgery, or clinical, medical or other health services. As explained above, this item does not introduce substantive changes to existing regulatory arrangements for non-sterile PPE.

Further, the Principal Instrument reproduces the class of articles covered by the *Therapeutic Goods (Articles that are Medical Devices) Specification 2014* made under subsection 41BD(2B) of the Act, to be medical devices, without any substantive changes.

The Amendment Determination amends the *Therapeutic Goods (Excluded Goods) Determination 2018* by adding a new item 2A in Schedule 1, in order to exclude from the operation of the Act all non-sterile PPE other than non-sterile PPE specified in the Principal Instrument. That item provides that articles that are non-sterile PPE other than articles specified in item 1 of Schedule 1 to the Principal Instrument are excluded goods for the purposes of the Act. In accordance with the matters to be taken into account under subsection 7AA(3) of the Act, the exclusion of the non-sterile PPE specified in the Amendment Determination is not likely to harm public health, given the negligible public health or personal risk associated with use of the goods. On the contrary, these goods are intended principally to prevent injury and to otherwise protect persons in other occupational, sporting or domestic settings. Further, it would not be appropriate to apply the national system of controls established by the Act, in circumstances where the benefits associated with the timely availability of the goods significantly outweighs the negligible risks associated with

excluding the goods from regulation under the Act. Moreover, while the goods specified in the Amendment Determination are excluded goods for the purposes of the Act, the goods will continue to be regulated as they are presently, principally under consumer protection legislation and work place health and safety laws.

Finally, the Amendment Order amends the *Therapeutic Goods (Declared Goods) Order 2019* to repeal the existing declaration for non-sterile PPE under item 5 of Part 2 of Schedule 2, as a consequence of the making of the Principal Instrument and the Amendment Determination in the manner described above.

Human rights implications

The Amendment Instruments engage 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 Amendment Instruments promote and support the right to health by reducing uncertainty in relation to the way non-sterile PPE is to be regulated under the therapeutic goods framework. The regulation of PPE has become an increasingly important and critical issue due to the public health emergency caused by the outbreak of COVID-19.

One of the Australian Government's highest priorities in responding to this public health emergency is to ensure access to masks and other PPE for frontline acute health service and primary care staff. This includes in settings where people are most likely to present with COVID-19, such as public hospitals, general practices and pharmacies, and also residential aged care facilities in the event of an outbreak.

By more clearly and accurately providing for the regulation of non-sterile PPE, the Amendment Instruments support efforts to ensure the timely availability and appropriate use of non-sterile PPE in Australia, particularly in relation to health care and other medical settings during the current public health emergency.

Conclusion

The Amendment Instruments are compatible with human rights because they promote the right to health in Article 12 of the ICESCR and otherwise do not raise any other human rights issues.