EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Standard for Tablets, Capsules and Pills) Amendment Order 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 Therapeutic Goods Administration ("the TGA"), which is part of the Department of Health, is responsible for administering the Act.

Subsection 10(1) of the Act provides that the Minister may, by legislative instrument, make an order determining that matters specified in the order constitute a standard for therapeutic goods or a class of therapeutic goods identified in the order. Offence and civil penalties may apply if therapeutic goods (other than medical devices) that do not comply with an applicable standard are imported, exported or supplied. The Secretary may, however, consent in writing to the import, supply or export of such goods notwithstanding their non-compliance (sections 14 and 14A of the Act refer).

Without limiting the generality of subsection 10(1), subsection 10(2) provides that an order establishing a standard for therapeutic goods may be specified by reference to a variety of matters including the quality of the goods, the procedures to be undertaken in the manufacture of the goods, or a monograph in the British or European Pharmacopoeia or in the United States Pharmacopeia-National Formulary. In addition, an order may require matters relating to the standard to be determined in accordance with particular tests.

The *Therapeutic Goods (Standard for Tablets, Capsules and Pills) (TGO 101) Order 2019* ("the Principal Order") is made under subsection 10(1) of the Act. The Principal Order establishes a ministerial standard for therapeutic goods that are tablets, capsules or pills for oral administration (principally, medicines). The Principal Order specifies the minimum requirements for the safety and quality of these therapeutic goods. In particular, section 16 of the Principal Order specifies requirements for elemental impurities and limits for residual solvents in tablets and capsules, and is due to commence on 31 March 2021 in accordance with item 2 of the table in subsection 2(1) of the Principal Order.

The *Therapeutic Goods (Standard for Tablets, Capsules and Pills) Amendment Order 2020* ("the Amendment Order") is made under subsection 10(3A) of the Act. The purpose of the Amendment Order is to amend the Principal Order to defer the commencement of section 16 from 31 March 2021 to 30 June 2021. A three-month extension to the commencement of the new requirements for elemental impurities and residual solvents is proposed in response to the increased pressures on the pharmaceuticals industry resulting from the impact of the public health emergency caused by the outbreak of the disease known as coronavirus disease 2019 (COVID-19). Disruptions to the operations and manufacturing processes of industry has meant that some manufacturers require additional time to finalise arrangements for the implementation of these requirements.

The new commencement date of 30 June 2021 aligns implementation of the new requirements for elemental impurities and residual solvents in section 16 with the transition to the new good manufacturing practice ("GMP") requirements under the Pharmaceutical Inspection Co-operation Scheme *Guide to Good Manufacturing Practice for Medicinal Products* (version PE 009-14, 1 July 2018) ("the PIC/S Guide to GMP"), as specified by the *Therapeutic Goods (Manufacturing Principles) Determination 2020*.

Consultation

The TGA consulted Complementary Medicines Australia ("CMA") and Consumer Healthcare Products Australia ("CHP Australia") about concerns related to the unforeseen impacts of the COVID-19 emergency on the pharmaceutical industry. Those concerns were first raised by CMA in May 2020. CMA is the peak industry body for the complementary medicines industry, representing manufacturers, raw material suppliers, distributors, consultants, retailers, allied health professionals and educators. CHP Australia is the peak body representing manufacturers and distributors of consumer healthcare products, including non-prescription medicines. The TGA was informed that due to the pressures of the COVID-19 emergency certain sponsors may be unable to ensure compliance with the requirements specified by section 16 by the commencement date of 31 March 2021.

In addition, the Office of Best Practice Regulation ("OBPR") advised that a regulation impact statement was not required in relation to remaking of the Principal Order in April 2019 (OBPR ID 24085). An extension to the commencement of section 16 of the Principal Order does not affect this original assessment. Further, the new commencement date aligns with the adoption of the new PIC/S Guide to GMP, which OBPR assessed as having minimal regulatory impact and not requiring a regulation impact statement (OBPR ID 42644).

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

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

The Amendment Order is a disallowable legislative instrument and commences on the day after it is registered on the Federal Register of Legislation.

Attachment A

Details of the *Therapeutic Goods (Standard for Tablets, Capsules and Pills) Amendment Order 2020*

Section 1 Name

This section provides that the name of the instrument is the *Therapeutic Goods (Standard for Tablets, Capsules and Pills) Amendment Order 2020* ("the Amendment Order").

Section 2 Commencement

This section provides that the Amendment Order 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 Order is section 10 of the *Therapeutic Goods Act 1989* ("the Act"). Specifically, subsection 10(3A) of the Act provides that the Minister may, by legislative instrument, vary or revoke an order made under subsection 10(1) of the Act.

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 that Schedule, and any other item in a Schedule to the Amendment Order has effect according to its terms.

Schedule 1 – Amendments

This Schedule amends the *Therapeutic Goods (Standard for Tablets, Capsules and Pills) (TGO 101) Order 2019* ("the Principal Order").

Item 1 of this Schedule repeals and replaces item 2 of the table in subsection 2(1) of the Principal Order to provide a new commencement date of 30 June 2021 for section 16 of the Principal Order.

Attachment B

Statement of Compatibility with Human Rights

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

Therapeutic Goods (Standard for Tablets, Capsules and Pills) Amendment Order 2020

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 the legislative instrument

The *Therapeutic Goods (Standard for Tablets, Capsules and Pills) (TGO 101) Order 2019* ("the principal instrument") is made under section 10 of the *Therapeutic Goods Act 1989* ("the Act"). The principal instrument establishes a ministerial standard for therapeutic goods that are tablets, capsules or pills for oral administration (principally, medicines). The principal instrument specifies the minimum requirements for the safety and quality of these therapeutic goods.

In particular, section 16 of the principal instrument specifies requirements for elemental impurities and limits for residual solvents in tablets and capsules, and is due to commence on 31 March 2021 in accordance with item 2 of the table in subsection 2(1) of the current principal instrument.

The *Therapeutic Goods (Standard for Tablets, Capsules and Pills) Amendment Order 2020* ("the amendment instrument") is made under section 10 of the Act. The purpose of the amendment instrument is to amend the principal instrument to defer the commencement of section 16 from 31 March 2021 to 30 June 2021. A three-month extension to the commencement of the new requirements for elemental impurities and residual solvents is proposed in response to the increased pressures on the pharmaceuticals industry resulting from the impact of the public health emergency caused by the outbreak of the disease known as coronavirus disease 2019 (COVID-19). Disruptions to the operations and manufacturing processes of industry has meant that some manufacturers require additional time to finalise arrangements for the implementation of these requirements.

The new commencement date of 30 June 2021 aligns implementation of the new requirements for elemental impurities and residual solvents in section 16 with the transition to the new good manufacturing practice ("GMP") requirements under the Pharmaceutical Inspection Co-operation Scheme *Guide to Good Manufacturing Practice for Medicinal Products* (version PE 009-14, 1 July 2018) ("the PIC/S Guide to GMP"), as specified by the *Therapeutic Goods (Manufacturing Principles) Determination 2020*.

Human rights implications

The principal 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 standard 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 supports steps taken by the principal instrument to promote the right to health by providing an extension of time for the commencement of section 16 of the principal instrument. The extension is appropriate in light of the COVID-19 emergency in order to afford industry with the necessary time to ensure that tablets and capsules comply with requirements relating to elemental impurities and residual solvents specified by section 16 of the principal instrument.

Conclusion

This instrument is compatible with human rights because it promotes the right to health in Article 12 of the ICESCR as outlined above, and otherwise does not raise any human rights issues.