EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Excluded Goods) Amendment (Software-based Products) Determination 2021

The *Therapeutic Goods Act 1989* ("the Act") provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy and timely availability of therapeutic goods that are used in or exported from Australia. The Act is administered by the Therapeutic Goods Administration ("the TGA") within the Department of Health.

Section 7AA of the Act provides that the Minister may, by legislative instrument, 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), 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.

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 (Excluded Goods) Amendment (Software-based Products) Determination 2021* ("the Amendment Determination") is made under section 7AA of the Act, read together with subsection 33(3) of the *Acts Interpretation Act 1901*. The Amendment Determination amends the Principal Determination by inserting 15 new items (items 14A to 14O) in Schedule 1. The new items specify certain low risk software-based products ("relevant software products") that are excluded goods for the purposes of the Act. The relevant software products can be broadly described as follows:

- consumer-facing software products that typically perform prevention, management or follow up functions in relation to general health or wellness (items 14A to 14E);
- enabling technologies for the delivery of health services, including telehealth, remote diagnosis, dispensing and healthcare facility management (items 14F to 14K);
- software that digitises paper-based (or other published) clinical rules or data (items 14L and 14M);
- software that performs population-based analytics (item 14N); and
- laboratory information management systems (item 14O).

The effect of these items is to exclude the relevant software products from the operation of the Act.

The TGA takes a risk-based approach to regulation, ensuring that the degree of regulatory oversight corresponds to the level of risk associated with particular therapeutic goods. Relevantly, in accordance with subsection 7AA(3) of the Act, a determination to exclude specified goods from the operation of the Act must take into account the risks to members of the public associated with not regulating the specified goods as therapeutic goods, and whether the specified goods could be more appropriately dealt with under other regulatory schemes.

The Amendment Determination is made on the basis that the relevant software products are low risk and unlikely to harm the health of members of the public if not regulated as therapeutic goods.

Accordingly, the relevant software products are described in the Amendment Determination in a manner that ensures only software that is sufficiently low risk is necessarily excluded. For example, some of the relevant software products (such as new items 14A and 14B) are described so as not to exclude software that is used in relation to serious diseases, conditions, ailments or defects. Further, some of the relevant software products (such as new items 14C and 14I) are described so as not to exclude software in circumstances that would require the involvement of a health professional.

Importantly, the relevant software products would continue to be appropriately regulated as consumer goods under the Australian Consumer Law. In the event of any safety issues or false or misleading statements in advertising for those products, provisions of the Australian Consumer Law would continue to afford protection to the public. Some of the relevant software products are also sufficiently regulated by other regulatory schemes. For example, laboratory information management systems (new item 14O) are used in laboratories in Australia of which many are accredited by the National Association of Testing Authorities ("NATA") and the Royal College of Pathologists of Australia ("RCPA") for compliance with standards set by the National Pathology Accreditation Advisory Council ("NPAAC").

Further, while aspects of the relevant software products involve the collection and handling of personal information, the Amendment Determination does not itself authorise or require the collection of such information, or alter the application of Australian privacy laws. The Amendment Determination merely excludes the relevant software products from regulation as therapeutic goods under the Act, and, consequently, the collection and handling of personal information by the relevant software products would continue (where applicable) to be regulated by the *Privacy Act 1988* as well as applicable state or territory privacy laws.

In addition to easing unnecessary regulatory burden associated with such low risk software, the Amendment Determination is also intended to provide clarity in relation to the regulatory status of certain software that does not, or is unlikely to, meet the definition of a medical device under the Act. This includes software that simply enables communications (such as new item 14F) or facilitates administrative processes (such as new item 14G).

Background

Medical devices are regulated in Australia as therapeutic goods by the TGA. Section 41BD of the Act provides a definition of 'medical device' which includes software that is intended by the person under whose name the software is supplied to be used for the purpose of diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease (among other purposes). The definition of medical device also extends to software that is necessary for the proper application of medical devices. As such, the TGA regulates software-based medical devices, including software that functions as a medical device in its own right, and software that controls or interacts with a medical device either from within the device or externally. If a product is a medical device, it must as a general rule be included in the Australian Register of Therapeutic Goods ("the Register") before it can be legally supplied in Australia.

Rapid innovation in technology in recent years has lowered costs and enabled widespread consumer access to the internet and powerful computing platforms. These advancements have increased the number and diversity of software applications in the health field, including software that is able to inform, drive or replace clinical decisions, or directly provide therapy to individuals. Personal devices such as smartphones, wearables and tablets have become ubiquitous, together with lower cost and enormously increased communications bandwidth, which have established digital technology as an essential part of everyday infrastructure.

The increasing use of software and digital technology in the health sector has accelerated during the COVID-19 pandemic. Healthcare professionals and consumers have benefited from the significant investment and development of virtual and connected technologies that have enabled the delivery of health services in a COVID safe way. A report released in 2020 by ANDHealth titled '*Digital Health: the sleeping giant of Australia's health technology industry*' confirms that the COVID-19 pandemic has led to greater adoption of digital health, increased acceptance among patients of new technologies, and more favourable regulatory and reimbursement environments. ANDHealth's survey of more than 300 high growth potential companies in the digital health sector indicated that many would need specialised support to navigate and enter the market, including in relation to regulatory approval of software-based medical devices and other 'digital medicines' and 'digital therapeutics'.

The digital health environment continues to evolve rapidly and the emergence of new software often crosses or blends traditional definitions or understandings of medical devices and therapeutic goods. As a consequence, the boundary for regulated software is becoming more difficult to identify, and there is a need for regulators of therapeutic goods around the world, including the TGA, to be more agile in considering or implementing changes to address this uncertainty.

The Amendment Determination seeks to provide greater clarity around the regulatory boundary for software-based products by clearly demarcating and excluding the relevant software products from the operation of the Act. However, given the dynamic nature of the digital health environment, the TGA will continue to monitor developments in software-based products to ensure Australia's regulatory settings are appropriate and adapted to managing those developments.

Consultation

The TGA conducted extensive consultation in relation to the changes proposed by the Amendment Determination over the course of 2019 and 2020. Consultation was conducted in the form of public consultation papers, targeted meetings and discussions with key stakeholders. In March 2020, the most recent consultation paper titled '*Scope of regulated software-based products*' was released by the TGA for public comment. The consultation paper sought feedback on the proposal to exclude certain software-based products from regulation under the Act.

Following release of the consultation paper, the TGA held 12 meetings with key industry members and representative bodies (including the Medical Software Industry Association and Telstra Health), four meetings with other bodies responsible for regulatory oversight (including the Australian Commission for Safety and Quality in Health Care), and received 48 written submissions. The majority of respondents were supportive of the proposal to exclude the relevant software products from regulation under the Act on the basis that those products carried no significant potential for harm. Industry members in particular welcomed the proposal to the extent that it represented greater regulatory clarity, a reduction in unnecessary or duplicative regulatory burden, and closer alignment with international approaches. A detailed summary and analysis of the submissions is published on the TGA website (www.tga.gov.au).

The TGA also consulted the Office of Best Practice Regulation ("OBPR") in relation to the regulatory impacts of the changes proposed by the Amendment Determination and whether the

preparation of a regulation impact statement was required. OBPR assessed that the impacts of the proposal were minor and that a regulation impact statement was not required (OBPR ID: 42873).

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

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

The Amendment Determination is a disallowable legislative instrument for the purposes of the *Legislation Act 2003*, and commences on 25 February 2021.

Attachment A

Details of the *Therapeutic Goods (Excluded Goods) Amendment (Software-based Products) Determination 2021*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Excluded Goods) Amendment (Software-based Products) Determination 2021* ("the Amendment Determination").

Section 2 – Commencement

This section provides that the Amendment Determination commences on 25 February 2021.

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* 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 Amendment Determination 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 inserts a number of definitions in the Principal Determination, including 'health professional', 'serious' and 'serious disease'.

Item 2 of this Schedule inserts fifteen new items (items 14A to 14O) in the table in Schedule 1 to the Principal Determination. These new items specify certain low risk software-based products ("relevant software products"). The effect of these new items is to exclude the relevant software products from the operation of the Act.

Attachment B

Statement of Compatibility with Human Rights

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

Therapeutic Goods (Excluded Goods) Amendment (Software-based Products) Determination 2021

This disallowable legislative instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of legislative instrument

The *Therapeutic Goods (Excluded Goods) Amendment (Software-based Products) Determination 2021* ("the amendment instrument") is made under section 7AA of the *Therapeutic Goods Act 1989* ("the Act"), read together with subsection 33(3) of the *Acts Interpretation Act 1901*. The amendment instrument amends the *Therapeutic Goods (Excluded Goods) Determination 2018* ("the principal instrument") by inserting 15 new items (items 14A to 14O) in Schedule 1. The new items specify certain low risk software-based products ("the relevant software products") that are excluded goods for the purposes of the Act. The relevant software products can be broadly described as follows:

- consumer-facing software products that typically perform prevention, management or follow up functions in relation to general health or wellness (items 14A to 14E);
- enabling technologies for the delivery of health services, including telehealth, remote diagnosis, dispensing and healthcare facility management (items 14F to 14K);
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- software that performs population-based analytics (item 14N); and
- laboratory information management systems (item 14O).

The effect of these items is to exclude the relevant software products from the operation of the Act.

The amendment instrument is made on the basis that the relevant software products are low risk and unlikely to harm the health of members of the public if not regulated as therapeutic goods. Accordingly, the relevant software products are described in the amendment instrument in a manner that ensures only software that is sufficiently low risk is necessarily excluded. Importantly, the relevant software products would continue to be appropriately regulated as consumer goods under the Australian Consumer Law. In the event of any safety issues or false or misleading statements in advertising for these products, provisions of the Australian Consumer Law would continue to afford protection to the public. Some of the relevant software products are also sufficiently regulated by other regulatory schemes, including for example, by the National Association of Testing Authorities ("NATA") and the Royal College of Pathologists of Australia ("RCPA").

Further, while aspects of the relevant software products involve the collection and handling of personal information, the amendment instrument does not itself authorise or require the collection of such information or alter the application of Australian privacy laws. The amendment instrument merely excludes the relevant software products from regulation as therapeutic goods under the Act, and consequently, the collection and handling of personal information by the relevant software products would continue (where applicable) to be regulated by the *Privacy Act 1988* as well as applicable state or territory privacy laws.

In addition to easing unnecessary regulatory burden associated with low risk software, the amendment instrument is also intended to provide clarity in relation to the regulatory status of certain software that does not, or is unlikely to, meet the definition of medical device under the Act.

Human rights implications

The amendment 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 that provides equal opportunity for people to enjoy the highest attainable level of health.

The amendment instrument takes positive steps to promote the right to health by excluding the relevant software products from regulation as therapeutic goods in circumstances where those products are low risk and more appropriately regulated by other regulatory schemes, including under the Australian Consumer Law. As a consequence, the amendment instrument provides certainty for industry and consumers, and enables the Department of Health and industry to appropriately focus valuable resources on regulating higher risk software-based medical devices. The prioritisation of resources in this way promotes enhanced regulation of the quality, safety and efficacy of higher risk therapeutic goods available to the Australian public.

Conclusion

The amendment instrument is compatible with human rights because it promotes the right to health in Article 12 of the ICESCR and otherwise does not raise any other human rights issues.