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

I, John Skerritt, as delegate of the Minister for Health, make the following determination.

Dated 13 January 2021

Adjunct Professor John Skerritt
Deputy Secretary
Health Products Regulation Group
Department of Health

Contents

1 Name

This instrument is the *Therapeutic Goods (Excluded Goods) Amendment (Software-based Products) Determination 2021*.

2 Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	**Column 2**	**Column 3**
Provisions	**Commencement**	**Date/Details**
1. The whole of this instrument	25 February 2021.	25 February 2021

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under section 7AA of the *Therapeutic Goods Act 1989*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

Therapeutic Goods (Excluded Goods) Determination 2018

1 Section 4

Insert:

health professional has the same meaning as in the Medical Devices Regulations.

Medical Devices Regulations means the *Therapeutic Goods (Medical Devices) Regulations 2002*.

serious, for a condition, ailment or defect, has the same meaning as in the Medical Devices Regulations.

serious disease has the same meaning as in the Medical Devices Regulations.

2 Schedule 1 (after table item 14)

Insert:

14A	software that is: (a) intended by its manufacturer to be used by a consumer for the self-management of an existing disease, condition, ailment or defect that is not a serious disease or serious condition, ailment or defect; and (b) not intended by its manufacturer to be used: (i) in clinical practice; or (ii) in relation to a serious disease or serious condition, ailment or defect; or (iii) for the purpose of diagnosis, treatment, or making a specific recommendation or decision about the treatment, of a disease, condition, ailment or defect that is not a serious disease or serious condition, ailment or defect
14B	software, or a combination of software and non-invasive hardware, that is: (a) intended by its manufacturer to be used by a consumer to promote or facilitate general health or wellness by measuring or monitoring (through non-invasive means) a physical parameter, such as movement, sleep, heart rate, heart rhythm, temperature, blood pressure or oxygen saturation; and (b) not intended by its manufacturer to be used: (i) in clinical practice; or (ii) for the purpose of diagnosis, screening, prevention, monitoring, prediction, prognosis, alleviation, treatment, or making a recommendation or decision about the treatment, of a serious disease or a serious condition, ailment or defect
14C	software that is: (a) intended by its manufacturer to be used by a consumer to improve general health or wellness by coaching, or encouraging behavioural change, in relation to personal or environmental factors, such as weight, exercise, sun exposure or dietary intake; and (b) not intended by its manufacturer to be used:

	(i) in clinical practice or to provide information to the consumer that would generally be accepted to require the interpretation of a health professional; or (ii) for the purpose of diagnosis, prognosis, or making a decision about the treatment, of a disease, condition, ailment or defect
14D	software that is: (a) intended by its manufacturer to be used as a patient reported outcome measures (PROMs) questionnaire or patient survey; and (b) not intended by its manufacturer to diagnose, screen for, monitor, predict, make a prognosis of, alleviate, treat, or make a recommendation or decision about the treatment of, a disease, condition, ailment or defect
14E	software that is a digital mental health tool (including a cognitive behaviour therapy tool) based on established clinical practice guidelines that are referenced and displayed in the software in a manner that is reviewable by the user
14F	software that is: (a) intended by its manufacturer to enable communications, including the transmission of patient information, for the purposes of supporting the delivery of health services; and (b) not intended by its manufacturer to diagnose, screen for, prevent, monitor, predict, make a prognosis of, alleviate, treat, or make a recommendation or decision about the treatment of, a disease, condition, ailment or defect
14G	software that is: (a) intended by its manufacturer to be used for the administration or management of health processes or facilities (including financial records, claims, billing, appointments, operating theatre management, hospital bed management, schedules, business analytics, admissions, inventory and workflow); and (b) not intended by its manufacturer to be used for the purpose of diagnosis, screening, prevention, monitoring, prediction, prognosis, alleviation, treatment, or making a recommendation or decision about the treatment, of a disease, condition, ailment or defect
14H	software that is intended by its manufacturer to be used for the sole purpose of storing or transmitting patient images
14I	software that is: (a) intended by its manufacturer to be used for the sole purpose of providing alerts to health professionals in relation to patient care; and (b) not intended by its manufacturer to: (i) replace the clinical judgement of a health professional; or (ii) diagnose, screen for, prevent, alleviate, treat, or make a decision about the treatment of, a disease, condition, ailment or defect
14J	software that is: (a) intended by its manufacturer to be used for clinical workflow management; and (b) not intended by its manufacturer to diagnose, screen for, prevent, monitor, predict, make a prognosis of, alleviate, treat, or make a recommendation or decision about the treatment of, a disease, condition, ailment or defect
14K	software that is middleware and is: (a) intended by its manufacturer to connect or interface applications to an

	underlying operating system or another application, including by communicating or transmitting information; and (b) not intended by its manufacturer to: (i) control medical devices; or (ii) perform analysis, computation or logic that relates to the intended purpose of a medical device; or (iii) be used for the purpose of diagnosis, screening, prevention, monitoring, prediction, prognosis, alleviation, treatment, or making a recommendation or decision about the treatment, of a disease, condition, ailment or defect
14L	software that is a calculator and: (a) either: (i) uses relevant published clinical standards or authoritative sources to make calculations; or (ii) displays calculations and outputs in a manner that may be validated by the user; and (b) is not intended by its manufacturer to control the administration of a calculated dosage
14M	software, or a combination of software and hardware, that is an electronic health record (however named or described) and is: (a) intended by its manufacturer to be used in clinical practice by healthcare providers to collect, use, disclose and otherwise manage patient clinical data within or between healthcare facilities; and (b) not intended by its manufacturer to diagnose, screen for, prevent, monitor, predict, make a prognosis of, alleviate, treat, or make a recommendation or decision about the treatment of, a disease, condition, ailment or defect
14N	software that is data analytics and is: (a) intended by its manufacturer to be used for the collection and analysis of class, group or population data; and (b) not intended by its manufacturer to be used for the purpose of diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation, of a disease, condition, ailment or defect in relation to individuals
14O	software that is a laboratory information management system (however named or described) and is not intended by its manufacturer to: (a) manipulate information or data to change, or generate new, diagnostic outputs (other than automating simple calculations or generating report comments); or (b) prevent, monitor, predict, make a prognosis of, treat or alleviate a disease, condition, ailment or defect