

# 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

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### 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Note:	This table relates only to the provisions of the	his instrument as originally made. It will not

This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 a

- (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:
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:

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<ul> <li>generally be accepted to require the interpretation of a health profession of (ii) for the purpose of diagnosis, prognosis, or making a decision about the treatment, of a disease, condition, ailment or defect</li> <li>software that is:         <ul> <li>(a) intended by its manufacturer to be used as a patient reported outcome mean (PROMs) questionnaire or patient survey; and</li> <li>(b) not intended by its manufacturer to diagnose, screen for, monitor, predict, a prognosis of, alleviate, treat, or make a recommendation or decision about the transmission of patient information, ailment or defect</li> </ul> </li> <li>software that is a digital mental health tool (including a cognitive behaviour therapp tool) based on established clinical practice guidelines that are referenced and displa in the software in a manner that is reviewable by the user</li> <li>software that is:         <ul> <li>(a) intended by its manufacturer to enable communications, including the transmission of patient information, for the purposes of supporting the delio of health services; and</li> <li>(b) not intended by its manufacturer to be used for the administration or manager health processes or facilities (including financial records, claims, billing, appointments, operating theatre management, hospital bed management, schedules, business analytics, admissions, inventory and workflowy), and</li> <li>(b) not intended by its manufacturer to be used for the sole purpose of storit transmitting patient images</li> </ul> </li> <li>software that is:         <ul> <li>(a) intended by its manufacturer to be used for the sole purpose of storit transmitting patient images</li> <li>(b) not intended by its manufacturer to be used for the sole purpose of storit transmitting patient images</li> </ul> </li> <li>14G software that is:         <ul> <li>(a) intended by its manufacturer to be used</li></ul></li></ul>		
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<ul> <li>or transmitting information; and</li> <li>(b) not intended by its manufacturer to: <ul> <li>(i) control medical device; or</li> <li>(ii) perform analysis, computation or logic that relates to the intended purpo of a medical device; or</li> <li>(iii) be used for the purpose of diagnosis, screening, prevention, monitoring, prediction, prognosis, alleviation, treatment, or making a recommendati or decision about the treatment, of a disease, condition, ailment or defect</li> </ul> 14L software that is a calculator and: <ul> <li>(a) either:</li> <li>(i) uses relevant published clinical standards or authoritative sources to ma calculations; or</li> <li>(ii) displays calculations and outputs in a manner that may be validated by its user; and</li> <li>(b) is not intended by its manufacturer to control the administration of a calculat dosage</li> </ul> 14M software, or a combination of software and hardware, that is an electronic health record (however named or described) and is: <ul> <li>(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</li> <li>(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</li> </ul> 14N software that is data analytics and is: <ul> <li>(a) intended by its manufacturer to be used for the collection and analysis of clargroup or population data; and</li> <li>(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</li> </ul></li></ul>		
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<ul> <li>(i) control medical devices; or</li> <li>(ii) perform analysis, computation or logic that relates to the intended purpor of a medical device; or</li> <li>(iii) be used for the purpose of diagnosis, screening, prevention, monitoring prediction, prognosis, alleviation, treatment, or making a recommendation decision about the treatment, of a disease, condition, ailment or defect</li> <li>14L software that is a calculator and:         <ul> <li>(a) either:</li> <li>(i) uses relevant published clinical standards or authoritative sources to macalculations; or</li> <li>(ii) displays calculations and outputs in a manner that may be validated by user, and</li> <li>(b) is not intended by its manufacturer to control the administration of a calculat dosage</li> </ul> </li> <li>14M software, or a combination of software and hardware, that is an electronic health record (however named or described) and is:         <ul> <li>(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</li> <li>(b) not intended by its manufacturer to be used for the collection and analysis of clar group or population data; and</li> <li>(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</li> </ul> </li> <li>14N software that is a laboratory information management system (however named or described) and is:         <ul> <li>(a) intended by its manufacturer to:</li> <li>(b) not intended by its manufacturer to:</li> <li>(a) an anipulate information or data to change, or generate new, diagnostic output (other than automating simple calculations or generating report comments);</li> <li></li></ul></li></ul>		
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