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No. S 66

HEALTH PRODUCTS ACT 2007

HEALTH PRODUCTS (AI STANDALONE MOBILE APPLICATION — EXEMPTION) ORDER 2026

ARRANGEMENT OF PARAGRAPHS

Paragraph

1. Citation and commencement
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In exercise of the powers conferred by section 70 of the Health Products Act 2007, the Health Sciences Authority makes the following Order:

Citation and commencement

1. This Order is the Health Products (AI Standalone Mobile Application — Exemption) Order 2026 and comes into operation on 13 February 2026.

Definitions

2. In this Order —

“AI standalone mobile application” means a medical device that is an artificial intelligence software, and a standalone mobile application as defined in regulation 26(5) of the Regulations;

“cluster HQ” means any of the following:

- (a) National Healthcare Group Pte Ltd;
- (b) National University Health System Pte. Ltd.;
- (c) Singapore Health Services Pte Ltd;

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- “HCSA” means the Healthcare Services Act 2020;
- “healthcare service” has the meaning given by section 3 of HCSA;
- “HPB” means the Health Promotion Board established under section 3 of the Health Promotion Board Act 2001;
- “medical device” means a health product that is a medical device as defined in item 1 of the First Schedule to the Act;
- “public healthcare entity” means any of the following:
- (a) a public healthcare institution;
 - (b) a cluster HQ;
 - (c) Synapxe Pte. Ltd.;
 - (d) MOH Office for Healthcare Transformation Pte. Ltd.;
- “public healthcare institution” means any of the following that holds a licence under HCSA:
- (a) a subsidiary of a cluster HQ;
 - (b) a business registered by a cluster HQ under the Business Names Registration Act 2014;
 - (c) an entity managed and controlled by a cluster HQ;
- “Regulations” means the Health Products (Medical Devices) Regulations 2010 (G.N. No. S 436/2010).

Exemption from manufacturer’s licence requirements

3. Section 12(1) of the Act does not apply to a public healthcare entity (*X*) that manufactures an AI standalone mobile application under all of the following conditions:

- (a) the AI standalone mobile application falls under Class A (low risk) or Class B (moderately low risk) of the Third Schedule to the Regulations;
- (b) the AI standalone mobile application is manufactured under the supervision of a clinician employed in a public

healthcare institution and holding the position of consultant or higher;

- (c) the AI standalone mobile application is intended for use —
 - (i) by *X*, if *X* holds a licence under HCSA, to provide a healthcare service that *X* is licensed under HCSA to provide; or
 - (ii) by another public healthcare entity that holds a licence under HCSA or by HPB (each *Y*), to provide a healthcare service that *Y* is licensed under HCSA to provide;
- (d) *X* notifies the Authority of its manufacture of the AI standalone mobile application prior to or at any time during its manufacture;
- (e) where the AI standalone mobile application is jointly manufactured with another person — that person is a public healthcare entity.

Exemption from registration requirements

4.—(1) Section 15(1) of the Act does not apply to a public healthcare entity (*X*) that supplies (whether by itself or jointly with one or more public healthcare entities) an AI standalone mobile application manufactured by *X* under all of the following conditions:

- (a) *X* manufactures the AI standalone mobile application by itself or jointly with one or more other public healthcare entities;
- (b) the common conditions in sub-paragraph (3) are satisfied.

(2) Section 15(1) of the Act does not apply to a public healthcare entity (*X*) that supplies (whether by itself or jointly with one or more public healthcare entities) an AI standalone mobile application not manufactured by *X* under all of the following conditions:

- (a) the AI standalone mobile application is manufactured by one or more other public healthcare entities;
- (b) the common conditions in sub-paragraph (3) are satisfied.

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- (3) The common conditions are —
- (a) the AI standalone mobile application falls under Class A (low risk) or Class B (moderately low risk) of the Third Schedule to the Regulations;
 - (b) the AI standalone mobile application is manufactured under the supervision of a clinician employed in a public healthcare institution and holding the position of consultant or higher;
 - (c) *X* supplies the AI standalone mobile application —
 - (i) by way of administration to or application in any person in the course of any diagnosis, treatment or test, if *X* holds a licence under HCSA to provide such healthcare service;
 - (ii) to another public healthcare entity (*Y*), for *Y* to supply the AI standalone mobile application to another public healthcare entity that holds a licence under HCSA or to HPB (*Z*), for *Z* to provide a healthcare service that *Z* is licensed under HCSA to provide; or
 - (iii) directly to *Z*, for *Z* to provide a healthcare service that *Z* is licensed under HCSA to provide;
 - (d) *X* notifies the Authority of *X* or *Z*'s deployment (as the case may be) for use of the AI standalone mobile application prior to such deployment; and
 - (e) the AI standalone mobile application is, prior to its deployment under sub-paragraph (d), endorsed for use in *X* or *Z* (as the case may be) by —
 - (i) if *X* or *Z* has both a medical board and a chief executive officer — either the chairman of the medical board, or the chief executive officer, of *X* or *Z*;
 - (ii) if *X* or *Z* has a medical board and no chief executive officer — the chairman of the medical board of *X* or *Z*;

- (iii) if *X* or *Z* has a chief executive officer and no medical board — the chief executive officer of *X* or *Z*; or
- (iv) if *X* or *Z* is HPB — the Chief Executive of HPB.

Made on 5 February 2026.

BENJAMIN ONG
Chairperson,
Health Sciences Authority,
Singapore.

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