No. S 66

HEALTH PRODUCTS ACT 2007

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

ARRANGEMENT OF PARAGRAPHS

Paragraph
1. Citation and commencement
2. Definitions
3. Exemption from manufacturer's licence requirements
4. Exemption from registration requirements

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;

"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.

(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.

[401:04/04-000; AG/LEGIS/SL/122D/2025/1]