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No. S 434

HEALTH PRODUCTS ACT 2007

HEALTH PRODUCTS (MEDICAL DEVICES) (AMENDMENT) REGULATIONS 2023

In exercise of the powers conferred by section 72 of the Health Products Act 2007, the Health Sciences Authority, with the approval of the Minister for Health, makes the following Regulations:

Citation and commencement

1.—(1) These Regulations are the Health Products (Medical Devices) (Amendment) Regulations 2023 and, except for regulation 8, come into operation on 26 June 2023.

(2) Regulation 8 is deemed to have come into operation on 31 December 2021.

Amendment of regulation 2

2. In the Health Products (Medical Devices) Regulations 2010 (G.N. No. S 436/2010) (called in these Regulations the principal Regulations), in regulation 2 —

(*a*) after the definition of "active medical device", insert —

> " "acute hospital service", "ambulatory surgical centre service", "assisted reproduction service", "blood banking service", "community hospital service", "cord blood banking service", "human tissue banking service", "nuclear medicine service", "outpatient dental service", "outpatient medical service", "outpatient renal dialysis service" and "radiological service" have the meanings given by paragraph 2 of the First Schedule to the Healthcare Services Act 2020;

"approved permanent premises" has the meaning given by section 2(1) of the Healthcare Services Act 2020;";

(*b*) after the definition of "hazard", insert —

" "healthcare service licensee" means a person who holds a licence under the Healthcare Services Act 2020 to provide a licensable healthcare service;";

(*c*) replace the definition of "licensed healthcare institution" with —

" "licensable healthcare service" has the meaning given by section 3(1) of the Healthcare Services Act 2020;";

(*d*) after the definition of "non-viable", insert —

" "nursing home" means a nursing home within the meaning of the Private Hospitals and Medical Clinics Act 1980 that is licensed under that Act;

"nursing home licensee" means a person who holds a licence issued under the Private Hospitals and Medical Clinics Act 1980 to operate a nursing home;";

(*e*) after the definition of "objective evidence", insert —

" "personnel" means —

(*a*) in relation to a healthcare service licensee providing a licensable healthcare service — any individual employed or engaged by the healthcare service licensee to assist the licensee in providing the licensable healthcare service; and

(*b*) in relation to a nursing home licensee operating a nursing home — any individual employed or engaged by

the nursing home licensee to assist in the operation of the nursing home;"; and

(*f*) after the definition of "serious deterioration in the state of health", insert —

" "specified healthcare service licensee" means a healthcare service licensee who is authorised to provide any of the following licensable healthcare services:

(*a*) acute hospital service;

(*b*) ambulatory surgical centre service;

(*c*) assisted reproduction service;

(*d*) blood banking service;

(*e*) community hospital service;

(*f*) cord blood banking service;

(*g*) human tissue banking service;

(*h*) nuclear medicine service;

(*i*) outpatient dental service;

(*j*) outpatient medical service;

(*k*) outpatient renal dialysis service;

(*l*) radiological service;".

Amendment of regulation 2B

3. In the principal Regulations, in regulation 2B(1)(*b*)(ii) and (iii), replace sub-paragraphs (B) and (C) with —

"(B) a nursing home licensee;

(C) a healthcare service licensee;".

Amendment of regulation 3

4. In the principal Regulations, in regulation 3 —

(*a*) replace paragraph (1) with —

"(1) A nursing home licensee may manufacture a medical device without holding a manufacturer's licence under section 12(1) of the Act if the medical device —

(*a*) is manufactured —

(i) at the nursing home of the nursing home licensee;

(ii) at the request of a qualified practitioner who is a personnel of the nursing home licensee; and

(iii) in accordance with the specifications of the qualified practitioner regarding the design characteristics or construction of the medical device; and

(*b*) is intended for the use of a particular patient of the nursing home.

(1A) A specified healthcare service licensee may manufacture a medical device without holding a manufacturer's licence under section 12(1) of the Act if the medical device —

(*a*) is manufactured —

(i) at the approved permanent premises of the specified healthcare service licensee;

(ii) at the request of a qualified practitioner who is the specified healthcare service licensee's personnel; and

(iii) in accordance with the specifications of the qualified practitioner regarding the design characteristics or construction of the medical device; and

(*b*) is intended for the use of a particular patient of the specified healthcare service licensee."; and

(*b*) replace paragraph (3) with —

"(3) The following persons are subject to the duties and obligations of a manufacturer of a medical device under regulations 33(*a*), 38, 39, 41, 42, 44, 45, 46 and 47:

(*a*) a nursing home licensee mentioned in paragraph (1);

(*b*) a specified healthcare service licensee mentioned in paragraph (1A);

(*c*) a person mentioned in paragraph (2).".

Amendment of regulation 3D

5. In the principal Regulations, in regulation 3D, replace paragraph (5) with —

"(5) This regulation does not apply to the manufacture of specified dental medical devices in accordance with —

(*a*) regulation 3(1) by a nursing home licensee; or

(*b*) regulation 3(1A) by a specified healthcare service licensee.".

Amendment of regulation 4

6. In the principal Regulations, in regulation 4(3), replace sub-paragraph (*a*) with —

"(*a*) a nursing home licensee;

(*aa*) a healthcare service licensee; or".

Amendment of regulation 8

7. In the principal Regulations, in regulation 8(1), replace sub-paragraphs (*b*) and (*c*) with —

"(*b*) a nursing home licensee for the use of a patient of that nursing home licensee; or

(*c*) a healthcare service licensee for the use of a patient of that healthcare service licensee,".

Miscellaneous amendments

8. In the principal Regulations —

(*a*) in regulation 2, in the definition of "institutional review board", in paragraph (*b*), delete "(Act 29 of 2015)";

(*b*) in the following provisions, replace "(Cap. 176)" with "1975":

Regulation 2, definition of "medicinal product"

Regulation 4C(*b*)(ii)

Regulation 11(1)(*a*)(ii) and (*b*)(iii)

Third Schedule, in Part II, in paragraph 2(*g*)(ii);

(*c*) in regulation 2, in the definition of "qualified practitioner", in paragraph (*a*), replace "(Cap. 174)" with "1997";

(*d*) in regulation 2, in the definition of "registered midwife", replace "(Cap. 209)" with "1999";

(*e*) in regulation 2, in the definition of "registered nurse", after "Act", insert "1999";

(*f*) in regulation 2, in the definition "registered pharmacist", replace "(Cap. 230)" with "2007";

(*g*) in regulation 2B(1)(*b*)(v), replace "(Cap. 179, Rg 3)" with "(Rg 3)";

(*h*) in regulation 2B(1)(*b*)(vi), replace "(Cap. 6, O 2)" with "(O 2)";

(*i*) in the following provisions, replace "(Cap. 262)" with "2007":

Regulation 4B(*a*)

Regulation 5A(*a*);

(*j*) in regulation 11(1)(*c*)(ii), replace "section 5 or 6 of the Radiation Protection Act (Cap. 262)" with "section 6 or 7 of the Radiation Protection Act 2007";

(*k*) in regulation 13C(5), in the definition of "civil defence emergency", replace "(Cap. 42)" with "1986"; and

(*l*) in the following provisions, replace "(Cap. 137)" with "1976":

Regulation 13C(5), definition of "infectious disease"

Regulation 26(6), definition of "infectious disease".

Saving and transitional provision

9.—(1) An approval by the Authority referred to in regulation 8(2)(*b*) of the principal Regulations that is granted before 26 June 2023 for a private hospital or medical clinic licensed under the Private Hospitals and Medical Clinics Act 1980 to supply an unregistered medical device is, on or after that date, treated as an approval granted to the healthcare service licensee providing a licensable healthcare service at the premises of the private hospital or medical clinic to supply that unregistered medical device.

(2) An approval by the Authority referred to in regulation 8(3)(*b*) of the principal Regulations that is granted before 26 June 2023 for a person (*P*) to supply an unregistered medical device to a private hospital or medical clinic licensed under the Private Hospitals and Medical Clinics Act 1980 is, on or after that date, treated as an approval granted to *P* to supply that unregistered medical device to the healthcare service licensee providing a licensable healthcare service at the premises of that private hospital or medical clinic.

[G.N. Nos. S 542/2011; S 140/2012; S 169/2012; S 370/2012; S 426/2012; S 646/2012; S 334/2016; S 538/2016; S 444/2017; S 318/2018; S 319/2018; S 90/2019; S 968/2020; S 111/2021; S 1080/2021; S 456/2022; S 950/2022]

Made on 21 June 2023.

BENJAMIN ONG
Chairperson,
Health Sciences Authority,
Singapore.

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(To be presented to Parliament under section 72(5) of the Health Products Act 2007).