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No. S 430

HEALTH PRODUCTS ACT 2007

HEALTH PRODUCTS
(CLINICAL RESEARCH MATERIALS)
(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 (Clinical Research Materials) (Amendment) Regulations 2023 and, except for regulation 4, come into operation on 26 June 2023.

(2) Regulation 4 is deemed to have come into operation on 31 December 2021.

Amendment of regulation 2

2. In the Health Products (Clinical Research Materials) Regulations 2016 (G.N. No. S 332/2016) (called in these Regulations the principal Regulations), in regulation 2(1) —

(*a*) after the definition of "appropriate non-proprietary name", insert —

> " "approved permanent premises", "approved conveyance" and "permanent premises" have the meanings given by section 2(1) of the Healthcare Services Act 2020;";

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

> " "business name", in relation to a healthcare service licensee, means the name under which the healthcare service licensee is authorised by a licence under the Healthcare

Services Act 2020 to carry on the business of providing a licensable healthcare service;";

(*c*) after the definition of "CTGTP Regulations", insert —

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

(*d*) 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;";

(*e*) after the definition of "licensed retail pharmacy", 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;";

(*f*) after the definition of "relevant fee", insert —

" "remote service kiosk" has the meaning given by regulation 2(1) of the Healthcare Services (Outpatient Medical Service) Regulations 2023 (G.N. No. S 410/2023);";

(*g*) after the definition of "subject", insert —

" "temporary premises" means any premises other than permanent premises;";

(*h*) in the definition of "traceability", replace paragraph (*d*) with —

"(*d*) the ability to identify the person who is —

(i) administered, dispensed or supplied the CTGT product at a nursing home, a licensed retail pharmacy or any approved permanent premises, temporary premises or approved

conveyance of a healthcare service licensee; or

(ii) dispensed or supplied the CTGT product by a healthcare service licensee using a remote service kiosk or by delivery to the person;"; and

(*i*) after the definition of "traceability", insert —

" "trial site" means a place where activities relating to a clinical trial are conducted.".

Amendment of Third Schedule

3. In the principal Regulations, in the Third Schedule, in paragraph 1 —

(*a*) in sub-paragraph (3), replace sub-paragraph (*d*) with —

"(*d*) where the clinical research material is supplied or dispensed —

(i) at a nursing home, licensed retail pharmacy, or a trial site that is not an approved permanent premises, temporary premises or an approved conveyance of a healthcare service licensee — the name, address and any identification number or logo of the nursing home, licensed retail pharmacy or trial site;

(ii) at any approved permanent premises by a healthcare service licensee under a business name — the business name, address of the approved permanent premises and any identification number or logo of the healthcare service licensee;

(iii) at any temporary premises or approved conveyance by a healthcare service licensee under a business name —

(A) if the healthcare service licensee is also approved under the Healthcare Services Act 2020 to provide the licensable healthcare service at any permanent premises under that business name — the business name, address of the approved permanent premises and any identification number or logo of the healthcare service licensee; or

(B) in any other case — the business name, address and any identification number or logo of the healthcare service licensee; or

(iv) by a healthcare service licensee using a remote service kiosk or by delivery under a business name —

(A) if the healthcare service licensee is also approved under the Healthcare Services Act 2020 to provide the licensable healthcare service at any permanent premises under that business name — the business name, address of the approved permanent premises and any identification number or logo of the healthcare service licensee; or

(B) in any other case — the business name, address and any identification number or logo of the healthcare service licensee;"; and

(*b*) in sub-paragraph (4), replace sub-paragraph (*b*) with —

"(*b*) where the clinical research material is supplied or dispensed —

(i) at a nursing home, licensed retail pharmacy, or a trial site that is not an approved permanent premises, temporary premises or an approved conveyance of a healthcare service licensee — the name, address and any identification number or logo of the nursing home, licensed retail pharmacy or trial site;

(ii) at any approved permanent premises by a healthcare service licensee under a business

name — the business name, address of the approved permanent premises and any identification number or logo of the healthcare service licensee;

(iii) at any temporary premises or approved conveyance by a healthcare service licensee of a healthcare service licensee under a business name —

(A) if the healthcare service licensee is also approved under the Healthcare Services Act 2020 to provide the licensable healthcare service at any permanent premises under that business name — the business name, address of the approved permanent premises and any identification number or logo of the healthcare service licensee; or

(B) in any other case — the business name, address and any identification number or logo of the healthcare service licensee; or

(iv) by a healthcare service licensee using a remote service kiosk or by delivery under a business name —

(A) if the healthcare service licensee is also approved under the Healthcare Services Act 2020 to provide the licensable healthcare service at any permanent premises under that business name — the business name, address of the approved permanent premises and any identification number or logo of the healthcare service licensee; or

(B) in any other case — the business name, address and any identification number or logo of the healthcare service licensee;".

Miscellaneous amendments

4. In the principal Regulations —

(*a*) in regulation 2(1), in the definition of "institutional review board", in paragraph (*b*), delete "(Act 29 of 2015)";

(*b*) in regulation 2(1), in the definition of "qualified pharmacist", in paragraph (*a*), replace "(Cap. 230)" with "2007";

(*c*) in regulation 2(1), in the definition of "qualified practitioner", in paragraph (*a*), replace "(Cap. 174)" with "1997";

(*d*) in regulation 2(1), in the definition of "qualified practitioner", in paragraph (*b*), replace "(Cap. 76)" with "1999";

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

Regulation 4(3)(*a*)(i)

Regulation 5(8); and

(*f*) in regulation 4(3)(*a*)(ii), replace "(Cap. 176, Rg 3)" with "(Rg 3)".

[G.N. Nos. S 94/2019; S 108/2021; S 730/2021; S 1078/2021; S 452/2022]

Made on 21 June 2023.

BENJAMIN ONG
Chairperson,
Health Sciences Authority,
Singapore.

[401:04/01-000.; MH 78:44/1; AG/LEGIS/SL/122D/2020/10 Vol. 1]

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