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No. S 440

MEDICINES ACT 1975

MEDICINES (CLINICAL TRIALS) (AMENDMENT) REGULATIONS 2023

In exercise of the powers conferred by section 18 of the Medicines Act 1975, the Minister for Health makes the following Regulations:

Citation and commencement

1.—(1) These Regulations are the Medicines (Clinical Trials) (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 Medicines (Clinical Trials) Regulations 2016 (G.N. No. S 335/2016) (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 medicinal product", 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 "clinical trial in an emergency situation", 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 "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 "minor", 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 institutional review board", 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);"; and

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

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

Amendment of Second Schedule

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

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

"(*d*) where the licensed investigational medicinal product is supplied or dispensed —

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

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

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 the following provisions, replace "(Cap. 174)" with "1997":

Regulation 2(1), definition of "qualified practitioner", paragraph (*a*)

Regulation 17(8);

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

(*d*) in the following provisions, replace "(Cap. 177A)" with "2008":

Regulation 2(2)(*a*)

Regulation 18(7); and

(*e*) in regulation 2(3)(*a*)(i) and (*b*)(i), after "Mental Capacity Act", insert "2008".

[G.N. No. S 1047/2021]

Made on 19 June 2023.

CHAN YENG KIT
Permanent Secretary,
Ministry of Health,
Singapore.

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