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No. S 437

HEALTH PRODUCTS ACT 2007

HEALTH PRODUCTS (CELL, TISSUE AND GENE THERAPY PRODUCTS) (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 (Cell, Tissue and Gene Therapy Products) (Amendment) Regulations 2023 and, except for regulation 13, come into operation on 26 June 2023.

(2) Regulation 13 is deemed to have come into operation on 31 December 2021.

Amendment of regulation 2

2. In the Health Products (Cell, Tissue and Gene Therapy Products) Regulations 2021 (G.N. No. S 104/2021) (called in these Regulations the principal Regulations), in regulation 2(1) —

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

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

(*b*) after the definition of "autologous", 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*) replace the definitions of "healthcare institution licence" and "healthcare institution licensee" with —

" "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*) delete the definition of "medical clinic";

(*f*) after the definition of "non-clinical purpose", 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 under the Private Hospitals and Medical Clinics Act 1980 to operate a nursing home;";

(*g*) replace the definition of "private hospital" with —

" "personnel" means —

(*a*) 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

(*b*) 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 healthcare service licensee in providing the licensable healthcare service;";

(*h*) 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);";

(*i*) after the definition of "supply by retail sale", insert —

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

(*j*) 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;".

Amendment of regulation 9

3. In the principal Regulations, in regulation 9(*a*) —

(*a*) replace sub-paragraph (i) with —

"(i) in the case of an unregistered CTGT product, the product is imported on behalf of a nursing home licensee or healthcare service licensee pursuant to a valid prescription given by a qualified practitioner (who is a personnel of the nursing home licensee or healthcare service licensee, as the case may be) for administration to a patient of the nursing home licensee or healthcare service licensee, as the case may be;"; and

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

"(A) by a nursing home licensee or healthcare service licensee on the written instructions of a qualified practitioner (who is a personnel of the nursing home licensee or healthcare service licensee, as the case may be) for administration to a patient of the nursing home licensee or healthcare service licensee, as the case may be; or".

Replacement of regulation 12

4. In the principal Regulations, replace regulation 12 with —

"**Class 2 CTGT products transferred by nursing home licensees and healthcare service licensees**

12.—(1) For the purposes of section 14(1) of the Act, a wholesaler's licence is not required for the transfer of an unregistered Class 2 CTGT product under the following circumstances if the conditions in paragraph (2) are satisfied:

(*a*) the transfer of the unregistered Class 2 CTGT product by a nursing home licensee from a nursing home of the nursing home licensee to —

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

(ii) a nursing home of another nursing home licensee; or

(iii) any approved permanent premises, temporary premises or approved conveyance of a healthcare service licensee;

(*b*) the transfer of the unregistered Class 2 CTGT product by a healthcare service licensee from any approved permanent premises, temporary premises or approved conveyance of the healthcare service licensee to —

(i) a nursing home;

(ii) another approved permanent premises, temporary premises or approved conveyance of the healthcare service licensee; or

(iii) any approved permanent premises, temporary premises or approved conveyance of another healthcare service licensee.

(2) For the purposes of paragraph (1), the conditions are —

(*a*) the unregistered Class 2 CTGT product is —

(i) imported under regulation 7(1)(*c*) or 9(*a*)(i) or (ii) for a qualified practitioner to administer it to a patient; or

(ii) manufactured for administration to a patient; and

(*b*) the unregistered Class 2 CTGT product is intended for administration to a patient at the nursing home, approved permanent premises, temporary premises or approved conveyance to which the unregistered Class 2 CTGT product is transferred.".

Amendment of regulation 15

5. In the principal Regulations, in regulation 15(1), replace sub-paragraphs (*b*) to (*e*) with —

"(*b*) the supply of a CTGT product that —

(i) is imported in accordance with regulation 9(*a*)(i) by a licensed importer; and

(ii) is supplied by the licensed importer to a nursing home licensee or healthcare service licensee;

(*c*) the supply of a CTGT product that —

(i) is imported in accordance with regulation 7(1)(*c*) by a known importer that is also a nursing home licensee or healthcare service licensee; and

(ii) is pursuant to the written instructions of a qualified practitioner who is a personnel of the nursing home licensee or healthcare service licensee (as the case may be), and is for administration to a patient of the nursing home licensee or healthcare service licensee, as the case may be;

(*d*) the supply by a nursing home licensee or healthcare service licensee of a CTGT product that is imported in accordance with regulation 7(1)(*c*) or 9(*a*)(ii), to a patient of the nursing home licensee or healthcare service licensee, as the case may be;

(*e*) the supply of a CTGT product that is imported in accordance with regulation 7(1)(*c*) or 9(*a*)(i) or (ii), and is supplied —

(i) by a nursing home licensee from a nursing home of the nursing home licensee to —

(A) another nursing home of the nursing home licensee;

(B) a nursing home of another nursing home licensee; or

(C) any approved permanent premises, temporary premises or approved conveyance of a healthcare service licensee; or

(ii) by a healthcare service licensee from any approved permanent premises, temporary premises or approved conveyance of the healthcare service licensee to —

(A) a nursing home;

(B) another approved permanent premises, temporary premises or approved conveyance of the healthcare service licensee; or

(C) any approved permanent premises, temporary premises or approved conveyance of another healthcare service licensee;

(*ea*) the supply of a CTGT product that —

(i) is manufactured by a nursing home licensee or healthcare service licensee; and

(ii) is for the administration to a patient of the nursing home licensee or healthcare service licensee, or another nursing home licensee or healthcare service licensee, as the case may be;

(*eb*) the supply by a nursing home licensee of a CTGT product that is manufactured by the nursing home licensee, to —

(i) a nursing home of the nursing home licensee or another nursing home licensee; or

(ii) any approved permanent premises, temporary premises or approved conveyance of a healthcare service licensee;

(*ec*) the supply by a healthcare service licensee of a CTGT product that is manufactured by the healthcare service licensee, to —

(i) a nursing home; or

(ii) any approved permanent premises, temporary premises or approved conveyance of the healthcare service licensee or another healthcare service licensee;".

Amendment of regulation 16

6. In the principal Regulations, in regulation 16(1), after "(*e*)", insert ", (*ea*), (*eb*), (*ec*)".

Amendment of regulation 18

7. In the principal Regulations, in regulation 18 —

(*a*) replace paragraph (1) with —

"(1) Without limiting any other provision in these Regulations, the prohibition in section 15(1) of the Act against the supply of a health product unless the health product is registered, does not apply to a CTGT product that is manufactured in accordance with paragraph (2) or (3) and is supplied in any of the following cases:

(*a*) by a licensed manufacturer or known manufacturer to a nursing home licensee for the use of the CTGT product by a patient of the nursing home licensee;

(*b*) by a licensed manufacturer or known manufacturer to a healthcare service licensee for the use of the CTGT product by a patient of the healthcare service licensee;

(*c*) by a nursing home licensee for the use of the CTGT product by a patient of the nursing home licensee;

(*d*) by a healthcare service licensee for the use of the CTGT product on a patient of the healthcare service licensee.";

(*b*) in paragraphs (2) and (3)(*a*), replace "healthcare institution licensee" with "nursing home licensee mentioned in paragraph (1)(*a*) or (*c*) or healthcare service licensee mentioned in paragraph (1)(*b*) or (*d*), as the case may be";

(*c*) in paragraph (3), replace sub-paragraph (*b*) with —

"(*b*) in accordance with its formulation and specifications, and the written instructions of a qualified practitioner, who is a personnel of the nursing home licensee mentioned in paragraph (1)(*a*) or (*c*) or healthcare service licensee mentioned in paragraph (1)(*b*) or (*d*) (as the case may be), and for the use solely by or in connection with the patient mentioned in that paragraph;"; and

(*d*) in paragraph (4), replace "at the private hospital or medical clinic" with "of the nursing home licensee mentioned in paragraph (1)(*a*) or (*c*) or healthcare service licensee mentioned in paragraph (1)(*b*) or (*d*), as the case may be".

Amendment of regulation 21

8. In the principal Regulations, in regulation 21, replace paragraph (*b*) with —

"(*b*) the supply is made by a nursing home licensee to a patient of that nursing home licensee, and in accordance with the written instructions of a qualified practitioner who is a personnel of the nursing home licensee;

(*ba*) the supply is made by a healthcare service licensee to a patient of the healthcare service licensee, and in accordance with the written instructions of a qualified

practitioner who is a personnel of the healthcare service licensee; or".

Amendment of regulation 26

9. In the principal Regulations, in regulation 26(1), replace sub-paragraph (*b*) with —

"(*b*) where the CTGT product is supplied or dispensed —

(i) at a nursing home or licensed retail pharmacy — the name, address and any identification number or logo of the nursing home or licensed retail pharmacy;

(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;".

Amendment of regulation 33

10. In the principal Regulations, in regulation 33(1)(*b*), replace "(*b*) or (*e*)" with "(*b*), (*c*), (*ea*), (*eb*) or (*ec*)".

Amendment of regulation 34

11. In the principal Regulations, in regulation 34 —

(*a*) in paragraph (2), replace sub-paragraph (*h*) with —

"(*h*) delivery to the nursing home, licensed retail pharmacy, the approved permanent premises, temporary premises, approved conveyance or remote service kiosk of a healthcare service licensee (as the case may be), where the CTGT product is used, administered, supplied or disposed of, as the case may be."; and

(*b*) in paragraph (3), replace "a licensed healthcare institution or a licensed retail pharmacy" with "the nursing home or licensed retail pharmacy or the approved permanent premises, temporary premises, approved conveyance or remote service kiosk of a healthcare service licensee".

Amendment of regulation 40

12. In the principal Regulations, in regulation 40(*a*), replace sub-paragraph (iii) with —

"(iii) is imported on behalf of a nursing home licensee or healthcare service licensee pursuant to a valid prescription given by a qualified practitioner (who is a personnel of the nursing home licensee or healthcare service licensee (as the case may be)) for the use of a patient of the nursing home licensee or healthcare service licensee;".

Miscellaneous amendments

13. In the principal Regulations, in regulation 2(1), in the definition of "qualified practitioner" —

(*a*) in paragraph (*a*), replace "(Cap. 174)" with "1997"; and

(*b*) in paragraph (*b*), replace "(Cap. 76)" with "1999".

[G.N. Nos. S 1076/2021; S 451/2022]

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).