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No. S 436

HEALTH PRODUCTS ACT 2007

HEALTH PRODUCTS (THERAPEUTIC 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 (Therapeutic Products) (Amendment) Regulations 2023 and, except for regulation 17, come into operation on 26 June 2023.

(2) Regulation 17 is deemed to have come into operation on 31 December 2021.

Amendment of regulation 2

2. In the Health Products (Therapeutic Products) Regulations 2016 (G.N. No. S 329/2016) (called in these Regulations the principal Regulations), in regulation 2(1) —

(*a*) before the definition of "administer", insert —

> "‘"acute hospital service", "ambulatory surgical centre service", "assisted reproduction service", "blood banking service", "community hospital service", "contingency care 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;";

(*b*) after the definition of "appropriate quantitative particulars", insert —

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

(*c*) after the definition of "Authority's website", 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;";

(*d*) replace the definition of "collaborative prescribing practitioner" with —

"‘"collaborative prescribing practitioner" has the meaning given by regulation 2 of the Healthcare Services (Collaborative Prescribing Service) Regulations 2023 (G.N. No. S 398/2023);";

(*e*) 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;";

(*f*) 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;";

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

(*h*) 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;

"outpatient dental service licensee" means a healthcare service licensee who is authorised to provide an outpatient dental service;

"outpatient medical service licensee" means a healthcare service licensee who is authorised to provide an outpatient medical service;

"outpatient renal dialysis service licensee" means a healthcare service licensee who is authorised to provide an outpatient renal dialysis service;

"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 a 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;";

(*i*) delete the definition of "private hospital";

(*j*) 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);";

(*k*) after the definition of "repacking", insert —

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

(*a*) an acute hospital service;

(*b*) an ambulatory surgical centre service;

(*c*) an assisted reproduction service;

(*d*) a blood banking service;

(*e*) a community hospital service;

(*f*) a contingency care service;

(*g*) a nuclear medicine service;

(*h*) an outpatient dental service;

(*i*) an outpatient medical service;

(*j*) an outpatient renal dialysis service;

(*k*) a radiological service;"; and

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

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

Amendment of regulation 5

3. In the principal Regulations, in regulation 5(1)(*b*), replace sub-paragraph (i) with —

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

Amendment of regulation 11

4. In the principal Regulations, in regulation 11, replace paragraph (*b*) with —

"(*b*) the supply is made by a nursing home licensee or a healthcare service licensee to a patient of the nursing home licensee or healthcare service licensee (as the case may be), and is in accordance with the written instructions of a qualified practitioner or collaborative prescribing practitioner who is a personnel of the nursing home licensee or healthcare service licensee, as the case may be;".

Amendment of regulation 13

5. In the principal Regulations, in regulation 13(1), replace sub-paragraph (*b*) with —

"(*b*) the supply is made by a nursing home licensee or a healthcare service licensee to a patient of the nursing home licensee or healthcare service licensee (as the case may be), and is in accordance with the written instructions of a qualified practitioner or collaborative prescribing practitioner who is a personnel of the nursing home licensee or healthcare service licensee, as the case may be; or".

Amendment of regulation 17

6. In the principal Regulations, in regulation 17(1), replace sub-paragraph (*b*) with —

"(*b*) where the 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 31

7. In the principal Regulations, in regulation 31(1), replace "healthcare institution licensee" with "nursing home licensee or a healthcare service licensee".

Amendment of regulation 32

8. In the principal Regulations, in regulation 32(1)(*b*), replace "58(1)(*a*), (*b*)" with "58(1)(*a*), (*b*), (*c*)".

Replacement of Division heading in Part 7

9. In the principal Regulations, in Part 7, in Division 1, replace the Division heading with —

"*Division 1 — Nursing homes licensees and specified healthcare service licensees*".

Amendment of regulation 46

10. In the principal Regulations, in regulation 46 —

(*a*) in the regulation heading, replace "**private hospitals and medical clinics**" with "**nursing homes, or approved permanent premises, etc., of specified healthcare service licensees**";

(*b*) in paragraph (1), replace "healthcare institution licensee for a private hospital or medical clinic" with "nursing home licensee or a specified healthcare service licensee";

(*c*) in paragraph (1), replace sub-paragraph (*c*) with —

"(*c*) the compounding is carried out —

(i) where the therapeutic product is compounded by a nursing home licensee —

(A) at the nursing home of the nursing home licensee or, in the case of a sterile therapeutic product, at a practice setting within the nursing home where standards established for the operation of clean rooms and the preparation of sterile products are in place and properly documented; and

(B) by or under the supervision of a qualified practitioner or a qualified pharmacist who is a personnel of the nursing home licensee; or

(ii) where the therapeutic product is compounded by a specified healthcare service licensee —

(A) at any approved permanent premises, temporary premises or approved conveyance of the specified healthcare service licensee or, in the case of a sterile therapeutic product, at a practice setting within the approved permanent premises, temporary premises or approved conveyance where standards established for the operation of clean rooms and the preparation of sterile

products are in place and properly documented; and

(B) by or under the supervision of a qualified practitioner or a qualified pharmacist who is a personnel of the specified healthcare service licensee; and";

(*d*) replace paragraphs (4) and (5) with —

"(4) It does not matter whether the patient mentioned in paragraph (2) is or is not a patient —

(*a*) at the nursing home at which the compounding is carried out; or

(*b*) at the approved permanent premises, temporary premises or approved conveyance of the specified healthcare service licensee at which the compounding is carried out.

(5) A therapeutic product compounded under paragraph (1) by a specified healthcare service licensee who is authorised to provide an outpatient dental service, outpatient medical service or outpatient renal dialysis service at any approved permanent premises, temporary premises or approved conveyance, must not be supplied to any of the following unless the approval of the Authority has been obtained for the supply:

(*a*) a nursing home;

(*b*) any approved permanent premises of the specified healthcare service licensee (other than the approved permanent premises at which the therapeutic product was compounded);

(*c*) any approved permanent premises of another specified healthcare service licensee."; and

(*e*) in paragraphs (7) and (9), replace "healthcare institution licensee" with "nursing home licensee or a specified healthcare service licensee".

Replacement of regulation 47

11. In the principal Regulations, replace regulation 47 with —

"**Transfer of therapeutic products by nursing homes licensees and specified healthcare service licensees without wholesaler's licence**

47.—(1) A nursing home licensee may, in the case of a therapeutic product compounded by the nursing home licensee under regulation 46(1) at a nursing home, transfer the nursing home licensee's stock of the therapeutic product at the nursing home to any of the following without holding a wholesaler's licence:

(*a*) another nursing home of the nursing home licensee;

(*b*) a nursing home of another nursing home licensee;

(*c*) any approved permanent premises, temporary premises or approved conveyance of a specified healthcare service licensee.

(2) A specified healthcare service licensee (other than an outpatient dental service licensee, outpatient medical service licensee or outpatient renal dialysis licensee) (called in this paragraph *A*) may, in the case of a therapeutic product compounded by *A* under regulation 46(1) at any approved permanent premises, temporary premises or approved conveyance, transfer *A*'s stock of the therapeutic product at the approved permanent premises, temporary premises or approved conveyance (as the case may be) to any of the following without holding a wholesaler's licence:

(*a*) a nursing home;

(*b*) another approved permanent premises, temporary premises or approved conveyance of *A*;

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

(3) A specified healthcare service licensee who is an outpatient dental service licensee, outpatient medical service licensee or outpatient renal dialysis service licensee (called in this paragraph *B*) may, in the case of a therapeutic product compounded by *B* under regulation 46(1) at any approved permanent premises, temporary premises or approved conveyance, transfer *B*'s stock of the therapeutic product at the approved permanent premises, temporary premises or approved conveyance (as the case may be) to any of the following without holding a wholesaler's licence, if the approval of the Authority has been obtained under regulation 46(5) for the transfer:

(*a*) a nursing home;

(*b*) any approved permanent premises of *B*;

(*c*) any approved permanent premises of another specified healthcare service licensee.

(4) A nursing home licensee or a specified healthcare service licensee (called in this paragraph *C*) may, in the case of a therapeutic product that is imported by *C* under regulation 51 or imported by a licensed importer under regulation 58(1)(*f*), transfer *C*'s stock of the therapeutic product to another nursing home licensee or specified healthcare service licensee without holding a wholesaler's licence.".

Amendment of regulation 48

12. In the principal Regulations, in regulation 48(2)(*b*), replace "practising at a private hospital or medical clinic" with "a personnel of a nursing home licensee or a specified healthcare service licensee".

Amendment of regulation 49

13. In the principal Regulations, in regulation 49, replace paragraph (*a*) with —

"(*a*) is to a nursing home licensee or a healthcare service licensee;".

Amendment of regulation 51

14. In the principal Regulations, in regulation 51, replace paragraph (1) with —

"(1) Subject to paragraph (3), a nursing home licensee or a specified healthcare service licensee may, without holding an importer's licence, import a therapeutic product that is not registered, if the therapeutic product —

(*a*) is required by, and on the written instructions of, a qualified practitioner who is a personnel of the nursing home licensee or specified healthcare service licensee; and

(*b*) is for the use of the qualified practitioner's patient.".

Amendment of regulation 58

15. In the principal Regulations, in regulation 58(1) —

(*a*) replace sub-paragraphs (*a*), (*b*) and (*c*) with —

"(*a*) the supply of a therapeutic product compounded under regulation 46 by a nursing home licensee at a nursing home of the nursing home to any of the following:

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

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

(iii) any approved permanent premises, temporary premises or approved conveyance of a specified

healthcare service licensee (other than an outpatient dental service licensee, outpatient medical service licensee or outpatient renal dialysis service licensee);

(*b*) the supply of a therapeutic product compounded under regulation 46 by a specified healthcare service licensee (other than an outpatient dental service licensee, outpatient medical service licensee or outpatient renal dialysis service licensee) at any approved permanent premises, temporary premises or approved conveyance of the specified healthcare service licensee to any of the following:

(i) a nursing home;

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

(iii) any approved permanent premises, temporary premises or approved conveyance of another specified healthcare service licensee (other than an outpatient dental service licensee, outpatient medical service licensee or outpatient renal dialysis service licensee);

(*c*) the supply of a therapeutic product compounded under regulation 46 by a nursing home licensee or a specified healthcare service licensee (other than an outpatient dental service licensee, outpatient medical service licensee or outpatient renal dialysis service licensee)

to a patient of a qualified practitioner, who is a personnel of any nursing home licensee or specified healthcare service licensee, as the case may be;

(*ca*) the supply of a therapeutic product compounded under regulation 46 by a specified healthcare service licensee who is an outpatient dental service licensee, outpatient medical service licensee or outpatient renal dialysis service licensee at any approved permanent premises, temporary premises or approved conveyance, for the use of a patient of a qualified practitioner and, if the supply for this purpose involves the supply by the specified healthcare service licensee to —

(i) a nursing home;

(ii) another approved permanent premises of the specified healthcare service licensee; or

(iii) any approved permanent premises of another specified healthcare service licensee,

the Authority's approval for the supply has been obtained under regulation 46(5);"; and

(*b*) replace sub-paragraphs (*f*) and (*g*) with —

"(*f*) the supply of a therapeutic product by a licensed importer to a nursing home licensee or a specified healthcare service licensee in accordance with the requirements in regulation 5(1)(*b*)(i);

(*g*) the supply by a nursing home licensee or a specified healthcare service licensee of a therapeutic product that is imported under regulation 51(1) to a patient of a qualified practitioner, who is a personnel of the nursing home licensee or specified healthcare service licensee;".

Replacement of regulation 59

16. In the principal Regulations, replace regulation 59 with —

"**Supply of therapeutic products compounded under contractual agreement with licensed manufacturer**

59.—(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 therapeutic product that is compounded in accordance with paragraph (2) and is supplied in any of the following cases:

(*a*) by a licensed manufacturer of the therapeutic product to —

(i) a nursing home licensee for the use of a patient of the nursing home licensee; or

(ii) a specified healthcare service licensee for the use of a patient of the specified healthcare service licensee;

(*b*) by a nursing home licensee to a patient of the nursing home licensee;

(*c*) by a specified healthcare service licensee to a patient of the specified healthcare service licensee.

(2) For the purposes of paragraph (1), the therapeutic product must be compounded —

(*a*) under an agreement between the licensed manufacturer of the therapeutic product and the nursing home licensee mentioned in

paragraph (1)(*a*)(i) or (*b*), or the specified healthcare service licensee mentioned in paragraph (1)(*a*)(ii) or (*c*);

(*b*) in accordance with the chemical composition and the written instructions of a qualified practitioner who is a personnel of —

(i) the nursing home licensee mentioned in paragraph (1)(*a*)(i) or (*b*) (as the case may be) for the use solely by or in connection with the patient mentioned in that paragraph; or

(ii) the specified healthcare service licensee mentioned in paragraph (1)(*a*)(ii) or (*c*) (as the case may be) for the use solely by or in connection with the patient mentioned in that paragraph;

(*c*) in premises approved by the Authority; and

(*d*) in accordance with the terms and conditions specified in the manufacturer's licence held by the licensed manufacturer of the therapeutic product.

(3) Paragraph (2)(*b*) does not apply to prohibit the supply of a therapeutic product that is not registered to any patient of a nursing home licensee mentioned in paragraph (1)(*a*)(i) or (*b*) or a specified healthcare service licensee mentioned in paragraph (1)(*a*)(ii) or (*c*), if the requirements mentioned in paragraph (2)(*a*), (*c*) and (*d*) are satisfied and the compounding consists only of repacking for the purpose of dispensing the therapeutic product.".

Miscellaneous amendments

17. In the principal Regulations —

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

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

(*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. 179, Rg 3)" with "(Rg 3)":

Regulation 5(1)(*b*)(iv)

Regulation 48(4)(*a*);

(*e*) in the following provisions, replace "(Cap. 6, O 2)" with "(O 2)":

Regulation 5(1)(*b*)(v)

Regulation 48(5)(*a*);

(*f*) in regulation 23(1), replace "(Cap. 221)" with "1994";

(*g*) in the following provisions, after "Patents Act" wherever it appears, insert "1994":

Regulation 23(2)(*a*), (5) and (8)(*a*)(ii)

Regulation 24(1)(*a*)(i);

(*h*) in regulation 58(2), replace "(Cap. 185)" with "1973";

(*i*) in regulation 60A(5), in the definition of "civil defence emergency", replace "(Cap. 42)" with "1986"; and

(*j*) in regulation 60A(5), in the definition of "infectious disease", replace "(Cap. 137)" with "1976".

[G.N. Nos. S 219/2017; S 119/2018; S 92/2019; S 969/2020; S 732/2021; S 1081/2021; S 458/2022]

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).