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No. S 330

HEALTH PRODUCTS ACT
(CHAPTER 122D)

HEALTH PRODUCTS (LICENSING OF RETAIL PHARMACIES) REGULATIONS 2016

ARRANGEMENT OF REGULATIONS

In exercise of the powers conferred by sections 71 and 72 of the Health Products Act, the Health Sciences Authority, with the approval of the Minister for Health, makes the following Regulations:

Citation and commencement

1. These Regulations are the Health Products (Licensing of Retail Pharmacies) Regulations 2016 and come into operation on 1 November 2016.

Definitions

2. In these Regulations, unless the context otherwise requires —

"application fee" means the applicable application fee specified in the Fifth Schedule to the Health Products (Fees) Regulations 2022 (G.N. No. S 450/2022);

[S 455/2022 wef 01/07/2022]

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

[S 433/2023 wef 26/06/2023]

"Authority's website" means the Authority's Internet website at http://www.hsa.gov.sg;

"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);

[S 433/2023 wef 26/06/2023]

"CTGT product" means a health product categorised as a cell, tissue or gene therapy product in the First Schedule to the Act;

[S 106/2021 wef 01/03/2021]

"dispense", in relation to a therapeutic product, means to prepare and supply the therapeutic product to a patient, where the preparation and supply is made by —

(*a*) a qualified practitioner or collaborative prescribing practitioner, or a person acting under the supervision of a qualified practitioner or collaborative prescribing practitioner; or

[S 120/2018 wef 01/03/2018]

(*b*) a qualified pharmacist or a person acting under the supervision of a qualified pharmacist;

"general sale list medicine" means a therapeutic product registered under the classification of "general sale list medicine" in the Register of Health Products;

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

[S 433/2023 wef 26/06/2023]

"in-store pharmaceutical officer" means —

(*a*) a qualified pharmacist engaged or employed to provide pharmacy services at or from a retail pharmacy specified in a pharmacy licence; or

(*b*) a person acting under the supervision of the qualified pharmacist mentioned in paragraph (*a*), when providing pharmacy services at or from the retail pharmacy mentioned in that paragraph;

[*Deleted by S 433/2023 wef 26/06/2023*]

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

[S 433/2023 wef 26/06/2023]

[*Deleted by S 808/2023 wef 18/12/2023*]

[*Deleted by S 808/2023 wef 18/12/2023*]

"oral dental gum" means a health product categorised as an oral dental gum in the First Schedule to the Act;

"personnel", in relation to a healthcare service licensee providing a licensable healthcare service, means any individual employed or engaged by the healthcare service licensee to assist the licensee in providing the licensable healthcare service;

[S 808/2023 wef 18/12/2023]

"pharmacy department", in relation to a healthcare service licensee, means the part of any approved permanent premises, approved conveyance or temporary premises of the healthcare service licensee set aside for the supply, dispensing or compounding of therapeutic products on order or prescription to patients at the approved permanent premises, approved conveyance or temporary premises;

[S 808/2023 wef 18/12/2023]

"pharmacy licence" means a licence, issued by the Authority under these Regulations, to carry on a retail pharmacy business at or from the retail pharmacy specified in the licence;

"qualified pharmacist" means a person who —

(*a*) is registered as a pharmacist under the Pharmacists Registration Act 2007;

[S 433/2023 wef 31/12/2021]

(*b*) holds a valid practising certificate granted under section 23 of that Act; and

(*c*) is in active practice as defined in regulation 2 of the Pharmacists Registration (Practising Certificates) Regulations 2008 (G.N. No. S 438/2008);

"qualified practitioner" means —

(*a*) a registered medical practitioner under the Medical Registration Act 1997; or

[S 433/2023 wef 31/12/2021]

(*b*) a registered dentist under the Dental Registration Act 1999 whose name appears in the first division of the Register of Dentists maintained and kept under section 13(1)(*a*) of that Act;

[S 433/2023 wef 31/12/2021]

"retail pharmacy" means any premises at or from which a retail pharmacy business is or is to be conducted, and excludes a pharmacy department;

"retail pharmacy business" means a business (not being a professional practice carried out by a qualified practitioner or collaborative prescribing practitioner) that consists of or includes the provision of retail pharmacy services to the general public;

[S 120/2018 wef 01/03/2018]

"retail pharmacy services" means the sale or dispensing of one or more specified health products, whether or not accompanied by advice or counselling on the effective and safe use of those products;

"specified health product" means a health product specified in the First Schedule;

"telepharmacy services" means the provision of retail pharmacy services by a qualified pharmacist at a retail pharmacy, through a computer, or video or audio link;

[S 106/2021 wef 01/03/2021]

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

[S 433/2023 wef 26/06/2023]

"therapeutic product" means a health product categorised as a therapeutic product in the First Schedule to the Act.

Requirements for supply by retail sale of specified health products

3.—(1) For the purposes of section 17 of the Act, a person (*P*) must not supply by retail sale any specified health product, unless —

(*a*) *P* is the holder of a pharmacy licence;

(*b*) the supply of the specified health product is carried out at or from the retail pharmacy specified in the pharmacy licence —

(i) by an in-store pharmaceutical officer; or

(ii) in the absence of that officer, by a special mode with the prior approval of the Authority;

(*c*) the supply of the specified health product is carried out under, and in accordance with the conditions of, the pharmacy licence;

(*d*) a proper record of every supply of the specified health product is made by the in-store pharmaceutical officer mentioned in sub-paragraph (*b*)(i), or using that special mode of supply mentioned in sub-paragraph (*b*)(ii);

(*e*) *P* keeps the record made under sub-paragraph (*d*) for at least 2 years after the date of the supply of the specified health product to which the record relates;

(*f*) *P* ensures that only an in-store pharmaceutical officer may have access to specified health products (other than a controlled drug) stored at the retail pharmacy; and

(*g*) *P* ensures that only a qualified pharmacist may have access to any controlled drug stored at the retail pharmacy.

(2) In addition to the requirements in paragraph (1), *P* must not supply by retail sale any prescription-only medicine, unless —

(*a*) the prescription-only medicine is supplied —

(i) to a patient in accordance with a valid prescription given by a qualified practitioner or collaborative prescribing practitioner; or

[S 120/2018 wef 01/03/2018]

(ii) in accordance with the oral or written instructions of a qualified practitioner or collaborative prescribing practitioner who undertakes, when giving the instructions, to give a valid prescription within 24 hours after giving the instructions; or

[S 120/2018 wef 01/03/2018]

(*b*) in the case of therapeutic products only, the prescription-only medicine supplied —

(i) is specified in the list of prescription-only medicines exempted for limited sale and supply;

(ii) is labelled to show a maximum daily dose not exceeding that specified in the list of prescription-only medicines exempted for limited sale and supply;

(iii) does not exceed the maximum supply specified in the list of prescription-only medicines exempted for limited sale and supply;

(iv) is to a person who is of or above any minimum age specified in the list of prescription-only medicines exempted for limited sale and supply,

and a record of the supply is made in accordance with regulation 16 of the Health Products (Therapeutic Products) Regulations 2016 (G.N. No. S 329/2016).

[S 106/2021 wef 01/03/2021]

(3) To avoid doubt, paragraphs (1) and (2) do not apply to —

(*a*) [*Deleted by S 808/2023 wef 18/12/2023*]

(*aa*) any of the following persons who supplies a specified health product by retail sale to a patient of a healthcare service licensee in accordance with the written instructions of a qualified practitioner or collaborative prescribing practitioner, who is a personnel of the healthcare service licensee:

(i) the healthcare service licensee;

(ii) a person who is authorised by the healthcare service licensee to make that supply; or

[S 433/2023 wef 26/06/2023]

(*b*) a qualified practitioner or collaborative prescribing practitioner, or a person acting in accordance with the oral or written instructions of a qualified practitioner or collaborative prescribing practitioner, supplying a specified health product to a patient under the care of the qualified practitioner or collaborative prescribing practitioner.

[S 120/2018 wef 01/03/2018]

(4) An application for the Authority's approval under paragraph (1)(*b*)(ii) must —

(*a*) be made in the form and manner specified on the Authority's website; and

(*b*) be accompanied by the application fee.

[S 455/2022 wef 01/07/2022]

(5) In this regulation —

"controlled drug" has the same meaning as in section 2 of the Misuse of Drugs Act 1973;

[S 433/2023 wef 31/12/2021]

"list of prescription-only medicines exempted for limited sale and supply" means the list, as published on the Authority's website, of therapeutic products classified as prescription-only medicines that may be supplied at or from a retail pharmacy without the need for a valid prescription;

"prescription-only medicine" means a therapeutic product or a CTGT product registered under the classification of "prescription-only medicine" in the Register of Health Products;

[S 106/2021 wef 01/03/2021]

"valid prescription" means a prescription that is valid within the meaning in regulation 2(2) of the Health Products (Therapeutic Products) Regulations 2016 or regulation 2(2) of the Health Products (Cell, Tissue and Gene Therapy Products) Regulations 2021 (G.N. No. S 104/2021), as the case may be.

[S 106/2021 wef 01/03/2021]

(6) In relation to a collaborative prescribed practitioner mentioned in paragraphs (2)(*a*) and (3), references to prescription-only medicine in paragraph (2)(*a*) and specified health product in paragraph (3) are references to a therapeutic product only.

[S 106/2021 wef 01/03/2021]

Telepharmacy services

4.—(1) For the purposes of section 17 of the Act, a person must not supply any specified health product through telepharmacy services, unless the person —

(*a*) is the holder of a pharmacy licence;

(*b*) has obtained the Authority's prior approval to provide telepharmacy services at or from the retail pharmacy specified in the pharmacy licence; and

(*c*) complies with the conditions imposed by the Authority under paragraph (4).

(2) The Authority may grant its approval for the holder of a pharmacy licence to supply specified health products through telepharmacy services at or from the retail pharmacy specified in the pharmacy licence, if all of the following requirements are satisfied:

(*a*) the holder has the necessary technological set-up and capability for the delivery of the telepharmacy services;

(*b*) the holder ensures there are adequately trained personnel to provide the telepharmacy services;

(*c*) there are written procedures detailing how the telepharmacy services are to be provided.

(3) An application for the Authority's approval under paragraph (1)(*b*) must —

(*a*) be made in the form and manner specified on the Authority's website; and

(*b*) be accompanied by the application fee.

[S 455/2022 wef 01/07/2022]

(4) The Authority may grant its approval under paragraph (2), subject to any conditions that the Authority may impose, and the Authority's approval and the conditions are to be endorsed on the pharmacy licence of the holder.

(5) In determining whether to grant its approval under paragraph (2) for any telepharmacy service, the Authority may carry out an inspection of the retail pharmacy at or from which the telepharmacy services are to be provided.

Application for pharmacy licence

5. For the purposes of section 24(2)(*a*)(i) of the Act, the Authority may issue a pharmacy licence in respect of a retail pharmacy to an applicant if all of the following requirements are satisfied:

(*a*) the applicant has obtained all necessary approvals for the applicant's retail pharmacy business from the relevant authorities, other than the Authority;

(*b*) the retail pharmacy has a designated dispensing area which is sufficiently secure to prevent unauthorised access to the dispensing area during operating hours;

(*c*) the layout of the retail pharmacy allows for the orderly arrangement of specified health products which are to be supplied or dispensed by retail at or from the retail pharmacy;

(*d*) the retail pharmacy is sufficiently secure to ensure the safekeeping of the specified health products to be supplied or dispensed by retail at or from the retail pharmacy and to prevent unauthorised access to any specified health product at all times;

(*e*) the retail pharmacy has appropriate storage facilities to store each specified health product in accordance with the conditions approved by the Authority for the storage of the specified health product;

(*f*) an adequate system is in place for proper safekeeping and maintenance of records in respect of the specified health products stored at the retail pharmacy, including arrangements to audit the records to ensure their integrity;

(*g*) the retail pharmacy will at all times be under the control and management of a qualified pharmacist;

(*h*) the applicant has paid the application fee.

[S 455/2022 wef 01/07/2022]

Suspension and revocation of pharmacy licence and cancellation of approval

6. For the purposes of section 27(1)(*b*)(iii) of the Act, the Authority may suspend or revoke any pharmacy licence issued to a person, or cancel any approval granted to a person, if the person is convicted, whether before, on or after 1 November 2016, of an offence under any of the following Acts or subsidiary legislation made under those Acts:

(*a*) the Medicines Act 1975;

[S 433/2023 wef 31/12/2021]

(*b*) the Misuse of Drugs Act 1973;

[S 433/2023 wef 31/12/2021]

(*c*) the Pharmacists Registration Act 2007;

[S 433/2023 wef 31/12/2021]

(*d*) the Poisons Act 1938.

[S 433/2023 wef 31/12/2021]

Changes affecting pharmacy licence

7.—(1) Subject to paragraph (2), a holder of a pharmacy licence in respect of a retail pharmacy must not, without the prior approval of the Authority —

(*a*) make any change to any matter the particulars of which are contained in the pharmacy licence or the holder's application for the pharmacy licence;

(*b*) make or cause any change to the layout or infrastructure of the retail pharmacy; or

(*c*) make or cause any change in the conduct of the holder's retail pharmacy business that the holder is approved to conduct at or from the retail pharmacy.

(2) Despite paragraph (1), a holder of a pharmacy licence who is approved by the Authority to provide telepharmacy services under regulation 4 may make any change to the procedures for providing the telepharmacy services mentioned in regulation 4(2)(*c*), if the holder gives prior notice to the Authority of that change.

(3) An application for the Authority's approval under paragraph (1) must —

(*a*) be made in the form and manner specified on the Authority's website; and

(*b*) be accompanied by the application fee.

[S 455/2022 wef 01/07/2022]

(4) In determining whether to grant its approval under paragraph (1), the Authority may carry out an inspection of the retail pharmacy specified in the pharmacy licence.

(5) Any holder of a pharmacy licence who contravenes paragraph (1) or (2) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

Routine inspections

8. The Authority may conduct routine inspections of any retail pharmacy to ensure that the provisions of the Act and these Regulations are complied with.

9. [*Deleted by S 455/2022 wef 01/07/2022*]

FIRST SCHEDULE

Regulation 2

SPECIFIED HEALTH PRODUCTS

1. Therapeutic products except general sale list medicines
2. Oral dental gums
3. CTGT products

[S 106/2021 wef 01/03/2021]

SECOND SCHEDULE

[*Deleted by S 455/2022 wef 01/07/2022*]

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KANDIAH SATKUNANANTHAM
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