No. S 000

HEALTH PRODUCTS ACT
(CHAPTER 122D)

HEALTH PRODUCTS (LICENSING OF RETAIL PHARMACIES) REGULATIONS 2015

ARRANGEMENT OF REGULATIONS

Regulation

In exercise of the powers conferred by sections 71(1) and 72 of the Health Products Act, the Health Sciences Authority, with the approval of the Minister for Health, hereby makes the following Regulations:

Citation and commencement

1. These Regulations may be cited as the Health Products (Licensing of Retail Pharmacies) Regulations 2015 and shall come into operation on 2015.

Definitions

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

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

"controlled drug" has the same meaning as in section 2 of the Misuse of Drugs Act (Cap. 185);

"general sale list medicine" means a therapeutic product that is registered by the Authority and entered into the Register of Health Products under the classification of "general sale list medicine";

"licensed healthcare institution" means a healthcare institution, as defined in the Private Hospitals and Medical Clinics Act (Cap. 248), that is licensed under that Act;

"pharmacy department" means the part of the premises of a licensed healthcare institution set aside for the supply, dispensing or compounding of medicines on order or prescription to patients or staff of the licensed healthcare institution;

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

"qualified practitioner" means —

(*a*) a registered medical practitioner under the Medical Registration Act (Cap. 174); or

(*b*) a registered dentist under the Dental Registration Act (Cap. 76) whose name appears in the first division of the Register of Dentists maintained and kept under section 13(1)(*a*) of that Act;

"registered pharmacist" has the same meaning as in section 2 of the Pharmacists Registration Act (Cap. 230);

"retail pharmacy" means any premises in or from which a retail pharmacy business is or is to be carried on, and excludes a pharmacy department;

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

"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 registered pharmacist at a retail pharmacy through a computer, or video or audio link, to a person other than a registered pharmacist at another retail pharmacy;

"therapeutic product" means a product falling within the category of health products called therapeutic products in the First Schedule to the Act.

Requirements for supply by retail of specified health products

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

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

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

(i) by a registered pharmacist at the retail pharmacy or under the personal supervision of the registered pharmacist; or

(ii) by any other means approved by the Authority if the registered pharmacist is absent or in special circumstances;

(*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 registered pharmacist or the person acting under the personal supervision of the registered pharmacist;

(*e*) the record made under paragraph (*d*) is kept for a period of 2 years from the date of the supply of the specified health product;

(*f*) the person ensures that only a registered pharmacist, a person under the personal supervision of a registered pharmacist or a person supplying a health product through telepharmacy services may have access to any health product which is a specified health product; and

(*g*) the person ensures that only a registered pharmacist may have access to any controlled drug.

(2) Paragraph (1) does not apply to a qualified practitioner supplying a specified health product in connection with the practice of his profession.

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

(*a*) in such form and manner as the Authority may require; and

(*b*) accompanied by the application fee specified in the Second Schedule.

Telepharmacy services

4.—(1) A holder of a pharmacy licence must obtain the Authority's approval before the holder may provide telepharmacy services in and from the retail pharmacy specified in the pharmacy licence.

(2) The Authority may grant its approval for the holder of a pharmacy licence to provide telepharmacy services in and from the retail pharmacy specified in the pharmacy licence, if 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; and

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

(3) An application for the Authority's approval under paragraph (2) must be —

(*a*) in such form and manner as the Authority may require; and

(*b*) accompanied by the application fee specified in the Second Schedule.

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

(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 in and from which the telepharmacy services are to be provided.

(6) Any holder of a pharmacy licence who contravenes paragraph (1) 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.

(7) Without prejudice to section 27(1)(*b*)(i) and (ii) of the Act, any holder of a pharmacy licence endorsed with the Authority's approval to provide telepharmacy services who fails to comply with any condition attached to the approval 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.

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 the specified health products to be supplied or dispensed by retail in 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 in or from the retail pharmacy and to prevent unauthorised access to the specified health products 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 registered pharmacist; and

(*h*) the applicant has paid the application fee specified in the Second Schedule.

Suspension and revocation of pharmacy licence

6. For the purposes of section 27(1)(*b*)(iii) of the Act, the Authority may suspend or revoke any pharmacy licence, if the holder of the pharmacy licence is convicted of an offence under any of the following Acts or subsidiary legislation made under such Act:

(*a*) the Medicines Act (Cap. 176);

(*b*) the Poisons Act (Cap. 234);

(*c*) the Pharmacists Registration Act (Cap. 230);

(*d*) the Misuse of Drugs Act (Cap. 185).

Changes affecting pharmacy licence

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

(*a*) make any change to the particulars on the pharmacy licence;

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

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

(2) Despite paragraph (1), a holder of a pharmacy licence who has been granted approval by the Authority to provide telepharmacy services under regulation 4 may make any change to the procedures for providing the telepharmacy services referred to in regulation 4(2)(*c*), if the holder has given prior notice to the Authority of the change.

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

(*a*) in such form and manner as the Authority may require; and

(*b*) accompanied by the application fee specified in the Second Schedule.

(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.

Fees

9.—(1) The fees specified in the second column of the Second Schedule are payable in respect of the matters specified opposite in the first column.

(2) The Authority may, in any particular case, waive or refund the whole or any part of any fee payable or paid under these Regulations.

FIRST SCHEDULE

Regulation 2

SPECIFIED HEALTH PRODUCTS

1. Therapeutic products except general sale list medicines.

SECOND SCHEDULE

Regulations 3(3), 4(3), 5, 7(3) and 9

FEES

	First column	*Second column*
1.	Application fee for a pharmacy licence	$500
2.	Renewal fee for a pharmacy licence	$500
3.	Application fee for the Authority's approval under regulation 3(1)(*b*)(ii) or 4(2) in relation to a retail pharmacy if made on a separate occasion as an application for a pharmacy licence for that same retail pharmacy	$300
4.	Application fee for the Authority's approval under regulation 7(1) —	
	(*a*) with site inspection	$300
	(*b*) without site inspection	$50