Health Products (Licensing of Retail Pharmacies) Regulations 2016

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No. S 330

HEALTH PRODUCTS ACT
(CHAPTER 122D)

HEALTH PRODUCTS (LICENSING OF RETAIL PHARMACIES) REGULATIONS 2016

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 —

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

"collaborative prescribing practitioner" has the same meaning as in regulation 56C(6) of the Private Hospitals and Medical Clinics Regulations (Cap. 248, Rg 1);

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

"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;

"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;

"licensed healthcare institution" means —

(*a*) any premises or conveyance specified in a licence granted under the Healthcare Services Act 2020 for the provision of any licensable healthcare service; or

(*b*) a healthcare institution that is licensed under the Private Hospitals and Medical Clinics Act 1980;

[S 1079/2021 wef 03/01/2022]

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

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

"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 (Cap. 230);

(*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 (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;

"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]

"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*) a person authorised to supply a specified health product by retail sale in a