Health Products (Oral Dental Gums) Regulations 2016

Table of Contents

No. S 539

HEALTH PRODUCTS ACT
(CHAPTER 122D)

HEALTH PRODUCTS (ORAL DENTAL GUMS) 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:

PART 1

PRELIMINARY

Citation and commencement

1. These Regulations are the Health Products (Oral Dental Gums) 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;

"container", in relation to any oral dental gum, means an article or packaging immediately covering the oral dental gum, including any bottle, bubble pack, blister pack, strip pack, wrapper or other similar article, but does not include —

(*a*) an article for ingestion; or

(*b*) an outer package or other packaging in which the container is further enclosed;

"expiry date", for any oral dental gum, means the date after which, or the month and year after the end of which, the oral dental gum should not be used;

"licensed healthcare institution" means a medical clinic or private hospital that is licensed under the Private Hospitals and Medical Clinics Act (Cap. 248);

"licensed retail pharmacy" means premises specified in a pharmacy licence issued under the Health Products (Licensing of Retail Pharmacies) Regulations 2016 (G.N. No. S 330/2016);

"licensee", in relation to any oral dental gum, means the holder of a manufacturer's licence, an importer's licence or a wholesaler's licence for the oral dental gum;

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

"prescription-only oral dental gum" means an oral dental gum that is registered under the classification of "prescription-only oral dental gum" in the Register of Health Products;

"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;

"sales promotion" means any advertisement of an oral dental gum in the form of —

(*a*) a sales campaign (including door-to-door sales and price discounts);

(*b*) an exhibition;

(*c*) a competition; or

(*d*) any other activity meant to introduce, publicise or raise the profile, public awareness or visibility of, the oral dental gum,

for the purpose of promoting the sale or use of the oral dental gum;

"supply by retail sale" means sale by retail and includes exposure or display as an invitation to treat.

PART 2

SUPPLY OF ORAL DENTAL GUMS

Supply by retail sale of oral dental gums

3.—(1) For the purposes of section 17(1) of the Act, a person must not supply by retail sale an oral dental gum unless —

(*a*) the supply is made at or from a licensed retail pharmacy in accordance with regulation 3(1) of the Health Products (Licensing of Retail Pharmacies) Regulations 2016 (G.N. No. S 330/2016);

(*b*) the supply is made at or from a licensed healthcare institution supplying the oral dental gum to a patient of that healthcare institution, and in accordance with the written instructions of a qualified practitioner practising in that healthcare institution; or

(*c*) the person is a qualified practitioner or a person acting in accordance with the oral or written instructions of a qualified practitioner, and the supply is made to a patient under the care of the qualified practitioner.

(2) In addition to the requirements in paragraph (1)(*a*), a person who supplies by