

## INFORMATION SHEET TO HEALTH CARE PROFESSIONALS ON REGULATORY CONTROL OF THERAPEUTIC CHEWING GUM

1. This information sheet provides healthcare professionals with updated information on the regulatory control of chewing gum with therapeutic value in Singapore, as this may be of relevance to certain aspects of your practice.

### Background

2. Under the US-Singapore Free Trade Agreement (US-S FTA) coordinated by the Ministry of Trade and Industry (MTI), Singapore agreed to allow the importation and sale of chewing gum *with therapeutic value*, subject to laws relating to health products.
3. Hence new regulations and controls have been put in place by MTI to ensure that the original national policy of preventing chewed gum from being a public safety and environmental hazard is not circumvented through meeting the US-S FTA obligation on therapeutic chewing gum. The Health Sciences Authority (HSA) has been tasked with implementing the regulatory requirements for health products to support this policy.
4. HSA and other agencies including MTI and the Agri-food and Veterinary Authority (AVA) gazetted the necessary subsidiary legislation, which took effect from 1 January 2004 to govern the importation, distribution, advertisement and sale of therapeutic chewing gum. These are listed in Annex A for your reference.

### Classification

5. Under the legislative amendments, chewing gum with therapeutic value is classified into two categories:
- Medicinal Gums**, e.g. Nicotine gums; and
  - Oral Dental Gums**, e.g. gums for prevention of dental caries, tooth-whitening.
6. The classification of dental gums is illustrated in the chart at Annex A.

### Control of Medicinal Gums

7. Medicinal Gums are subject to all controls on medicinal products under the Medicines Act, including drug registration and medical advertisement control. Approved Medicinal Gums are classified as *Pharmacy-Only* or *Prescription-Only* medicines, and subject to the same controls as other health products in these categories. An example of a Medicinal Gum is nicotine chewing gum.

### Control of Oral Dental Gums

8. All sugarless Oral Dental Gums licensed by HSA are classified as *Prescription-Only* products, with the exception of products of the following two formulations which are classified as *Pharmacy-Only* products:
- Oral Dental Gums containing Xylitol 12% – 36% (w/w) and Calcium Lactate 2% – 5% w/w;
  - Oral Dental Gums containing Sodium Hexametaphosphate 1% to 2% w/w.
9. The import, wholesale dealing and manufacture of Oral Dental Gums are subjected to licensing requirements. Importation of chewing gum through parcel post remains prohibited.
10. Oral Dental Gums classified as *Prescription-Only* products, must be supplied only on the prescription of a registered medical or dental practitioner.
11. The two formulations specified in para. 8 are classified as *Pharmacy-Only* products. These are allowed to be sold in registered pharmacies, under the supervision of a pharmacist. Every sales transaction of Pharmacy-Only Oral Dental Gum must be recorded with the following information:
- Date of transaction
  - Name & NRIC of buyer
  - Name & quantity of product
12. Advertising is prohibited for all Prescription-Only Oral Dental Gums, while advertisement and sales promotion permits are required for Pharmacy-Only Oral Dental Gums.

### Enquiry/Clarification

13. Information on approved Medicinal Gums and Oral Dental Gums may be obtained at the following HSA website links:  
Oral Dental Gums: <http://www.hsa.gov.sg/prism/common/enquirepublic/SearchCCUProduct.do?action=load>  
Medicinal Gums: [http://app9.internet.gov.sg/scripts/hsa/CPA\\_databasesearch.asp](http://app9.internet.gov.sg/scripts/hsa/CPA_databasesearch.asp)

14. For further clarification on the regulation of chewing gum please contact the following:

<u>Medicinal Gums</u>	<u>Oral Dental Gums</u>
Mr Thomas Koh	Mrs Suzie Quek
Drug Registration Branch	Cosmetics Control Unit
Tel: 6325 5638	Tel: 6325 4737
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## ANNEX A

### 1. SUBSIDIARY LEGISLATION AMENDED OR INTRODUCED TO FACILITATE ENTRY OF THERAPEUTIC CHEWING GUM

- Medicines (Oral Dental Gums) (Specification) Order 2003;
- Medicines (Cosmetic Products) (Specification and Prohibition) (Amendment) Order 2003;
- Medicines (Registration of Pharmacies) (Amendment) Regulations 2003;
- Medicines (Oral Dental Gums) (Licensing) Regulations 2003;
- Medicines (Advertisements of Oral Dental Gums) Regulations 2003;
- Medicines (Prescription Oral Dental Gums) Order 2003;
- Medicines (Oral Dental Gums) (Labelling) Regulations 2003;
- Regulation of Imports and Exports (Chewing Gums) (Amendment No.2) Regulations 2003;
- Sale of Food (Prohibition of Chewing Gum) Regulations;
- Environmental Public Health (Composition of Offences) Rules;
- Rapid Transit System Regulations

### 2. CLASSIFICATION OF THERAPEUTIC CHEWING GUM

