Medicines (Oral Dental Gums) (Licensing) Regulations

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MEDICINES ACT
(CHAPTER 176, SECTIONS 14, 54 AND 74)

MEDICINES (ORAL DENTAL GUMS) (LICENSING) REGULATIONS

Rg 18

G.N. No. S 660/2003

[1st January 2004]

Citation

1. These Regulations may be cited as the Medicines (Oral Dental Gums) (Licensing) Regulations.

Definition

2. In these Regulations, unless the context otherwise requires, "oral dental gum" shall have the same meaning as in the Medicines (Oral Dental Gums) (Specification) Order (O 19).

Standard provisions for licences

3. The standard provisions for licences to be granted under Part II of the Act in respect of oral dental gum shall be as follows:

(*a*) for a product licence, the provisions set out in the First Schedule;

(*b*) for an import licence, the provisions set out in the Second Schedule;

(*c*) for a wholesale dealer's licence, the provisions set out in the Third Schedule; and

(*d*) for a manufacturer's licence, the provisions set out in the Fourth Schedule.

Duration of licence

4. A licence granted under Part II of the Act in respect of oral dental gum shall be valid for a period of one year or such other duration as the licensing authority may determine.

Fees

5.—(1) The fees specified in the Fifth Schedule shall be payable to the licensing authority on application for, or the grant of, licences in respect of oral dental gum and for any variation of the licences.

(2) No refund shall be made in respect of any fee paid under these Regulations.

FIRST SCHEDULE

Regulation 3(*a*)

STANDARD PROVISIONS FOR A PRODUCT LICENCE

1. The holder of the licence shall immediately report to the licensing authority any change in his name or address, or in any address at which there is carried on a business to which the licence relates.

2.—(1) The holder of the licence shall immediately inform the licensing authority of any material change that has been made or that he proposes to make in the particulars contained in his application for a product licence, in relation to any oral dental gum to which the licence relates, as follows:

(*a*) in the specification of any of the ingredients of the oral dental gum;

(*b*) in the composition of the oral dental gum or of any of the ingredients of the oral dental gum; and

(*c*) in the contents of any label affixed to or displayed on the container or package of the oral dental gum, or in the contents of any leaflet relating to the oral dental gum enclosed in the container or package of the oral dental gum.

(2) The holder of the licence shall immediately inform the licensing authority of any change to a material extent in the licence that he proposes to make.

3. The holder of the licence shall immediately inform the licensing authority of any information received by him that casts doubt on the continued validity of the data which was submitted with, or in connection with, the application for the product licence.

4.—(1) The holder of the licence shall inform the licensing authority within 7 days upon receipt of any report which indicates that the oral dental gum to which the licence relates or any ingredient in the product is unsafe for human use or is liable to cause damage to human health when it is applied under the normal conditions of use or will cause adverse effects to human beings.

(2) The report shall be open to inspection by a person authorised by the licensing authority, who may make copies of the report and, if the licensing authority so directs, the holder of the licence shall furnish the licensing authority with a copy of any such report of which he has a record or of which he is or subsequently becomes aware.

5.—(1) The holder of the licence shall keep such records as will facilitate the withdrawal or recall from sale or supply of any oral dental gum to which the licence relates.

(2) The records shall be readily available for inspection by a person authorised by the licensing authority and the holder of the licence shall permit the person authorised to take copies of, or to make extracts from, the records.

(3) The records shall not be destroyed without the consent of the licensing authority for a period of 2 years from the date when the importation, sale, supply or exportation of the relevant batch of the oral dental gum was authorised by or on behalf of the holder of the licence.

6. The holder of the licence shall, if so directed and as far as may be reasonably practicable, withhold the oral dental gum to which the licence relates from sale and supply and withdraw the product from the market if he has received information referred to in paragraph 4 or has been informed by the licensing authority that the product does not comply with the provisions of the Act or any regulations made thereunder or does not conform to any of the requirements in paragraph 4.

7. The holder of the licence shall notify the licensing authority immediately of any decision to withdraw from sale, supply or exportation any oral dental gum to which the licence relates, and shall state

the reason for that decision.

8. The holder of the licence shall, at any time as may be required by the licensing authority, submit samples of the oral dental gum to which the licence relates to the testing laboratory approved by the licensing authority and any expenses incurred in or arising out of the sampling, testing or analysis shall be borne by the holder of the licence.

9. The holder of the licence shall not use the licence for advertising purposes.

SECOND SCHEDULE

Regulation 3(*b*)

STANDARD PROVISIONS FOR AN IMPORT LICENCE

1. The holder of the licence shall immediately report to the licensing authority any change in his name or address, or in any address at which there is carried on a business to which the licence relates.

2.—(1) The holder of the licence shall immediately inform the licensing authority of any material change that has been made in the particulars contained in his application for an import licence, in relation to any oral dental gum to which the licence relates as follows:

(*a*) in the specification of any of the ingredients of the oral dental gum;

(*b*) in the composition of the oral dental gum, or of any of the ingredients of the oral dental gum; and

(*c*) in the contents of any label affixed to or displayed on the container or package of the oral dental gum, or in the contents of any leaflet relating to the oral dental gum enclosed in the container or package of the oral dental gum.

(2) The holder of the licence shall immediately inform the licensing authority of any change to a material extent in the licence that he proposes to make.

3. The holder of the licence shall immediately inform the licensing authority of any information received by him that casts doubt on the continued validity of the data which was submitted with, or in connection with, the application for the import licence.

4.—(1) The holder of the licence shall inform the licensing authority within 7 days upon receipt of any report which indicates that the oral dental gum to which the licence relates or any ingredient in the product is unsafe for human use or is liable to cause damage to human health when it is applied under the normal conditions of use or will cause adverse effects in human beings.

(2) The report shall be open to inspection by a person authorised by the licensing authority, who may make copies of the report and, if the licensing authority so directs, the holder of the licence shall furnish the licensing authority with a copy of any such report of which he has a record or of which he is or subsequently becomes aware.

5.—(1) The holder of the licence shall keep such records as will facilitate the withdrawal or recall from sale or supply of any oral dental gum to which the licence relates.

(2) The records shall be readily available for inspection by a person authorised by the licensing authority and the holder of the licence shall permit the person authorised to take copies of, or to make