

Medicines (Cosmetic Products) (Licensing) Regulations 1996

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No. S 271

MEDICINES ACT (CHAPTER 176)

MEDICINES (COSMETIC PRODUCTS) (LICENSING) REGULATIONS 1996

In exercise of the powers conferred by section 74 of the Medicines Act, the Minister for Health hereby makes the following Regulations:

Citation and commencement

1. These Regulations may be cited as the Medicines (Cosmetic Products) (Licensing) Regulations 1996 and shall come into operation on 1st June 1997.

Definition

2. In these Regulations, “cosmetic product” has the same meaning as in the Medicines (Cosmetic Products) (Specification and Prohibition) Order 1996.

[G.N. No.]

[S 272/96]

Standard provisions for licences

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

- (a) for a product licence, the provisions set out in the First Schedule; and
- (b) for an import licence or a manufacturer’s licence, the provisions set out in the Second Schedule.

Duration of licence

4. A licence granted under Part II of the Act shall be valid for a period of 3 years or such other duration as the licensing authority may determine.

Fees

5.—(1) The fees set out in the Third Schedule shall be payable to the licensing authority in respect of applications for, and the granting of, licences and for any variations or amendments of the licences.

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

Penalty

6. Any person who contravenes any of the provisions of these Regulations shall be guilty of an offence and shall be liable on conviction to a fine not exceeding \$5,000 or to imprisonment for a term not exceeding 2 years or to both.

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 and address and 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, in relation to any cosmetic product to which the licence relates as follows:

- (a) in the specification of any of the constituents of the cosmetic product;
- (b) in the composition of the cosmetic product or of any of the constituents of the cosmetic product; and
- (c) in the contents of any label affixed to or displayed on the container or package of the cosmetic product, or in the contents of any leaflet relating to the cosmetic product enclosed in the container or package of the cosmetic product.

(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. The holder of the licence shall inform the licensing authority within 7 days upon receipt of any report of which he is aware which indicates that the product 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 or animals.

5. 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.

6. The holder of the licence shall keep such records as will facilitate the withdrawal or recall from sale or supply any cosmetic product to which the licence relates.

7. 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, such records.

8. 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 cosmetic product was authorised by or on behalf of the holder of the licence.

9. The holder of the licence shall, if so directed and as far as may be reasonably practicable, withhold the cosmetic product 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 the regulations made thereunder or does not conform to any of the requirements in paragraph 4.

10. The holder of the licence shall notify the licensing authority immediately of any decision to