L.N. 437 of 2004

MEDICINES ACT, 2003
(ACT NO. III OF 2003)

Parallel Importation of Medicinal Products Regulations, 2004

IN exercise of the powers conferred by article 106 of the Medicines Act, 2003, the Minister of Health, the Elderly and Community Care has made the following regulations:-

Title.

1. The title of these regulations is the Parallel Importation of Medicinal Products Regulations, 2004.

Interpretation.

2. For the purpose of these regulations-

"the Act" means the Medicines Act, 2003

"the Commission" means the Commission of the European Union;

"Maltese-market product" means the medicinal product for which a marketing authorisation has been granted with which the parallel imported medicinal product is compared;

"Member State" means a State which is a member of the European Union;

"parallel distribution" means the importation from a Member State or a country within the European Economic Area of a centrally authorised medicinal product, by an importer who is someone other than the importer authorised and appointed by the marketing authorisation holder of the product on the Maltese market;

"parallel importation" means the importation from a Member State or a country within the European Economic Area of a medicinal product which is already authorised on the Maltese market, by an importer who is someone other than the importer authorised and appointed by the marketing authorisation holder of the product on the Maltese market;

"parallel importer" means a person engaged in the activities of parallel importation;

"parallel imported product" means a product authorised in a Member State or a country within the European Economic Area imported by parallel importation;

"repackaging" includes the removal of blister packs from the original packaging and their insertion into new external packaging or addition of new user instructions or information or the fixing of self-stick labels;

"source country" means the Member State country from which the parallel imported product is imported.

Licence requirement.

3. (1) No person shall engage in the parallel importation of medicinal product unless he is in possession of a parallel import licence in respect of each medicinal product, hereinafter referred to as the licence.

(2) No person shall engage in the parallel importation of medicinal products unless such a person is in possession of:

(a) wholesale dealer's licence in accordance with the provisions of the Importation and Wholesale Distribution of Medicinal Products Regulations, and

(b) parallel import licence issued by the Authority.

(3) When the holder of the manufacturing licence for repackaging of a parallel imported product is also the holder of the parallel import licence in respect of the product, he shall have the right to distribute by wholesale the repackaged parallel imported product in respect of which the manufacturing licence has been issued.

Application for granting of a licence.

4. (1) Any application for the granting of a parallel import licence shall be made to the Licensing Authority and shall contain such information, documents any other material in accordance with the provisions of this regulation.

(2) Such application as is mentioned in sub-regulation (1) shall indicate the following:

(a) name, address and contact person of the proposed parallel import licence holder;

(b) name and address of the applicant, if different from that of the licence holder;

(c) parallel import licence holder's trading style on labels and leaflets;

(d) name, pharmaceutical form, any active ingredient, strength, pack size details, marketing authorisation holder, marketing authorisation number of the medicinal product for which a parallel import licence is being applied for;

(e) name, pharmaceutical form, strength, name and address of the marketing authorisation holder and marketing authorisation number of the Maltese-market product;

(f) copy of the wholesale dealer's licence and, if the parallel imported product is to be repackaged, of the manufacturer's licence; provided that if the holder of the manufacturer's licence is responsible for both repackaging and distribution of the parallel imported product, then only a copy of the manufacturer's licence shall be required; and

(g) basis on which the applicant makes a presumption of essential similarity between the local and imported product.

(3) The Authority shall process an application for a parallel import license within forty-five working days of validation of the application. Such period shall be suspended in those cases where the applicant is requested to furnish additional data.

Granting for a licence.

5. (1) A parallel import licence shall only be granted for parallel imported products that fulfill the following criteria:

(a) Maltese-market product shall have a valid marketing authorisation in Malta;

(b) parallel imported product shall be imported from a Member State or a country of the European Economic Area and it must have a valid marketing authorisation in that country;

(c) parallel imported product shall have the same pharmaceutical form and be identical to, or have no significant therapeutic difference from, the Maltese-market product.

(2) A parallel import licence shall cease to be valid if the marketing authorisation is withdrawn for reasons directly related to the protection of public health.

Validity and renewal.

6. A parallel import licence is granted for a period of five years. An application for the renewal of the parallel import licence shall be submitted to the Licensing Authority no later than three months before expiry of the previous licence.

Duties of parallel importer.

7. It shall be the duty of a parallel importer to:

(a) ensure that there is a clear audit trail from the authorised distributor or manufacturer in the source country;

(b) submit to the Licensing Authority a declaration that the supplier is going to keep him informed of any Pharmacovigilance issues;

(c) provide, in the case of repackaging of a medicinal product, a written declaration stating that the marketing authorisation holder of the original product marketed in Malta has been notified about the repackaged product being put on sale in Malta, one month prior to submitting the application to the Medicines Authority. A copy of the letter sent to the marketing authorisation holder shall also be submitted together with the application for a parallel import licence;

(d) ensure, in the case of repackaged products, that the parallel import licence number assigned by the Licensing Authority is present on the outer packaging of the medicinal products. In the case where the medicinal product with the parallel import licence is identical to the Maltese market product, the same requirements for numbering apply as for the Maltese market product.

Keeping of records.

8. (1) A parallel importer shall at all times keep records of the origin, imported quantities, and batch numbers of the parallel imported medicinal products.

(2) Upon request, such information as is referred to in sub-regulation (1) hereof shall be submitted to the Licensing Authority without delay.

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