Suppliment tal-Gazzetta tal-Gvern ta' Malta Nru. 21,136, 20 ta' Ottubru, 2023
Taqsima B

L.N. 249 of 2023

MEDICINES ACT
(CAP. 458)

Permission for the supply of medicines for use in the National Health Services in exceptional circumstances Regulations, 2023

IN EXERCISE of the powers conferred by article 106 of the Medicines Act, the Minister responsible for public health, after consultation with the Licensing Authority, has made the following regulations:-

Citation and scope.

1. The title of these regulations is the Permission for the supply of medicines for use in the National Health Services in exceptional circumstances Regulations, 2023.

Interpretation.

2. In these regulations, unless the context otherwise requires:

Cap. 458.

"Act" means the Medicines Act;

"Licensing Authority" means the Licensing Authority established in accordance with article 3 of the Act;

"Minister" means the Minister responsible for public health;

"permission" means the permit to place medicinal products on the market in Malta in accordance with the provisions of article 20 of the Act and these regulations;

"permission holder" means the person holding a permission issued under these regulations;

"importer" means any person who supplies medicinal products within the National Health Services.

Permission.

3. (1) When the Central Procurement and Supplies Unit does not have access to any medicinal product, intended to be used in the National Health Service, which is registered or may be registered under the Act or any other legislation within the applicable time frame, and subsequent to a request made under the first proviso of article 20 of the Act, it may request permission to the Licensing Authority to procure and place an unauthorised medicinal product on the market within the National Health Services in accordance with these regulations.

(2) Permission to place an unauthorised medicinal product on the market within the National Health Services may also be requested by an importer.

(3) The Licensing Authority may grant permission to place such unauthorised medicinal product on the market within the National Health Services after an evaluation is carried out by the said Licensing Authority, under exceptional circumstances of inherent public health need.

Request for permission.

4. (1) The Central Procurement and Supplies Unit and, or an importer may, upon confirming that no medicinal product from alternative sources is available, present to the Licensing Authority an application in writing, requesting that the unauthorised medicinal product is permitted to be procured and placed on the market within the National Health Services.

(2) Each application shall be accompanied by the prescribed fee in the Schedule and shall include:

(a) the full name of the medicinal product, its active ingredients, strength, dosage form and country of origin;

(b) the full name, address and contact details of the supplier and the manufacturer;

(c) the detailed reasons for the request;

(d) information, documentation, or evidence proving that no offers were received for a registered medicinal product or a medicinal product which may be registered within the applicable time frame; and

(e) any other information, documentation, or evidence as may be requested by the Licensing Authority:

Provided that seventy-five percent (75%) of the prescribed fee shall be refunded if the application is rejected.

Conditions of permission.

5. (1) Any permission granted shall only apply to the medicinal product listed on the application and shall not be transferable to a similar product.

(2) Permission may be subject to conditions as may be determined by the Licensing Authority.

Validity of permission.

6. (1) Permission shall be granted for a period of up to one (1) year provided that all the conditions set out by the Licensing

Authority are satisfied.

(2) The application for permission shall be subject to the payment of fees in the Schedule.

Responsibilities of permission holder.

7. At the time of application and during the period of validity of the permission, the permission holder shall:

(a) bear full responsibility of the medicinal product;

(b) declare that it does not have access to any equivalent medicinal product which is registered or may be registered under the Act or any other legislation within the applicable time frame;

(c) declare that the permission is being requested due to a justified public health need and that the patient would remain without the medicinal product if permission is not granted:

Provided that a public health need includes but is not limited to accessibility, excessive pricing, seriousness of the circumstances of the case and product risk.

Rights pertaining to the Licensing Authority.

8. (1) The Licensing Authority shall have the right to amend, suspend or revoke the permission at any time:

(a) if any information in the application on which the permission was granted is found to be either false or incomplete;

(b) if a material change of circumstances has occurred in relation to the application which was not duly reported by the applicant;

(c) if the permission holder does not adhere to all the conditions as established by these regulations or under the Act; or

(d) for any other circumstances which the Licensing Authority considers fit.

(2) Furthermore, the Licensing Authority has the right to request the applicant for any relevant additional information at any time.

SCHEDULE (regulations 4 and 6)	
For each application for the first year	€4,000
For each application for subsequent years	€6,000

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