

SUBSIDIARY LEGISLATION 458.37

**WHOLESALE DISTRIBUTION AND BROKERING
OF MEDICINAL PRODUCTS AND ACTIVE
SUBSTANCES REGULATIONS**

24th December, 2012

*LEGAL NOTICE 478 of 2012, as amended by Legal Notices 350 of 2013
and 234 of 2022.*

1. (1) The title of these regulations is the Wholesale Distribution and Brokering of Medicinal Products and Active Substances Regulations. Citation and scope.

(2) The scope of these regulations is to transpose Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use as amended by Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products, and Article 85a of Directive 2001/83/EC, as the said Article has been amended by Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012 amending Directive 2001/83/EC as regards pharmacovigilance.

2. For the purposes of these regulations - Interpretation.

"the Agency" means the European Medicines Agency established by Regulation (EC) No. 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency;

"applicant" includes a holder or licensee;

"the Commission" means the Commission in accordance with Council Decision 1999/468/EC of the 28th June, 1999;

"Member State" means a State which is a member of the European Union and includes Iceland, Norway and Liechtenstein;

"responsible person" means a person registered as a pharmacist with the Pharmacy Council and recognised as suitable by the Medicines Authority since such person possesses adequate knowledge of the conditions required for the storage and distribution of medicinal products in order to avoid their deterioration or damage, has adequate knowledge of the regulations concerning the distribution of medicinal products, and has knowledge and understanding of good distribution practice.

3.(1) (a) Only products in respect of which a marketing authorisation has been granted by the Licensing Authority, hereinafter referred to as "the Authority", or the Agency shall be distributed or brokered in Malta. Distribution of medicinal products.

- (b) In the case of brokering, wholesale distribution and storage, medicinal products shall be covered by a marketing authorisation granted by the Agency or by the competent authority of a Member State:

Provided that in the case where medicinal products are stored but not distributed in Malta and in the case of wholesale distribution of medicinal products to third countries, only the licence laid down in regulation 4 shall be required.

(2) Any distributor, not being the marketing authorisation holder, who brings into Malta a product from another Member State, shall notify the marketing authorisation holder and the Authority of each product he intends to bring into Malta. In the case of products which have not been granted an authorisation pursuant to Regulation (EC) No 726/2004, the notification to the Authority shall be without prejudice to additional procedures provided for in the law at the time and to fees payable to the Authority for examining the notification:

Provided that where the distributor intends to place the product on the market in Malta, he shall notify the Authority of each batch he brings into Malta.

(3) In the case of medicinal products which have been granted an authorisation pursuant to Regulation (EC) No. 726/2004, the distributor shall submit the notification in accordance with sub-regulation (2) to the marketing authorisation holder and the Agency. A fee shall be payable to the Agency for checking that the conditions laid down in European Union legislation on medicinal products and in the marketing authorisations are observed.

(4) Persons brokering medicinal products established in Malta shall have a permanent address and contact details, so as to ensure accurate identification, location, communication and supervision of their activities by the Licensing Authority.

Wholesale dealer's
licence.

4. No person shall engage in the wholesale distribution of medicinal products unless he is in possession of a wholesale dealer's licence, hereinafter referred to as "the licence", to that effect.

Registering of
activity with the
Authority.

5. (1) Distributors of active substances who are established in Malta shall register their activity with the Licensing Authority.

(2) The registration form shall include, at least, the following information:

- (a) name or corporate name and permanent address;
- (b) the active substances which are to be distributed;
- (c) particulars regarding the premises and the technical equipment for their activity.

The persons referred to in sub-regulation (1) shall submit the registration form to the Licensing Authority at least sixty days prior to the intended commencement of their activity.

(3) The Licensing Authority may, based on a risk assessment, decide to carry out an inspection. If the Licensing Authority

notifies the applicant within sixty days of the receipt of the registration form that an inspection will be carried out, the activity shall not begin before the Licensing Authority has notified the applicant that he may commence the activity. If within sixty days of the receipt of the registration form the Licensing Authority has not notified the applicant that an inspection will be carried out, the applicant may commence the activity.

(4) The persons referred to in sub-regulation (1) shall communicate annually to the Licensing Authority an inventory of the changes which have taken place as regards the information provided in the registration form. Any changes that may have an impact on the quality or safety of the active substances that are distributed shall be notified immediately.

(5) Persons referred to in sub-regulation (1) who had commenced their activity before 2 January 2013 shall submit the registration form to the competent authority by 2 March 2013.

(6) Member States shall enter the information provided in accordance with sub-regulation (2) in the European Union database referred to in Article 111(6) of Directive 2001/83/EC as amended.

(7) This regulation shall be without prejudice to articles 101 and 102 of the Medicines Act, hereinafter referred to as "the Act".

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6. (1) The Licensing Authority, hereinafter referred to as "the Authority", may inspect any premises and check any person authorised to engage in the activity of wholesaler in medicinal products and of active substances, including active substances that are intended for export.

Inspection of
premises.

(2) If the Authority deems that any of the conditions of the licence issued by it has not been met, it shall suspend or revoke such licence.

(3) If a licence has been granted in another Member State and the Authority deems that the licensee is not fulfilling the conditions set therein, it shall inform the Commission and the Member State concerned.

7. (1) The Authority shall process an application for a wholesale dealer's licence within ninety days of receipt of the application. This period shall be suspended in those cases where the applicant is requested to furnish additional data.

Processing of
applications.

(2) The application shall, apart from the particulars listed under article 55(1) of the Act, also include the pharmaceutical forms of the products to be distributed, in particular any sterile products and products requiring storage below 8° Centigrade, and details of narcotic or psychotropic substances, blood, immunological medicinal products, or radiopharmaceuticals.

8. (1) A wholesale distribution licence shall only be granted if the Authority is satisfied that the applicant has at least -

Granting of
licence.
Amended by:
L.N. 350 of 2013;
L.N. 234 of 2022.

- (a) suitable and adequate premises, installations and equipment, so as to ensure proper conservation and distribution of the medicinal products;

(b) adequate staff, and in particular, a responsible person.

(2) A licence shall not be granted or renewed unless the applicant:

(a) makes the premises, installations and equipment accessible at all times for inspection;

(b) obtains the supplies of medicinal products from persons who are themselves in possession of a distribution licence, or who are exempt from obtaining such authorisation under the terms of regulation 3(4) of the Manufacture and Importation of Medicinal Products for Human Use Regulations, and verifies that the medicinal products received are not falsified by checking the safety features on the outer packaging, in accordance with the requirements as may be adopted by the Commission:

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Provided that the requirements of this paragraph shall not apply where a medicinal product is directly received from a third country but not imported, that is to say, not to be placed on any Member State market. However, in that case wholesale distributors shall ensure that the medicinal products are obtained only from persons who are authorised or entitled to supply medicinal products in accordance with the applicable legal and administrative provisions of the third country concerned. The wholesale distributor should also exercise all necessary caution and precautions in order to ensure that these medicinal products not intended to be imported, remain in quarantine and do not in any way end up on any Member State market:

Provided further that the requirements of the above proviso shall not apply to the import of a medicinal product meeting the conditions laid down in regulation 11B of the Manufacture and Importation of Medicinal Products for Human Use Regulations;

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(c) supplies medicinal products to persons who are themselves in possession of a wholesale distribution licence or who are otherwise authorised or entitled to supply medicinal products to the public:

Provided that in the case of distribution of medicinal products to third countries this shall not apply. However, when wholesale distributors supply medicinal products to persons in third countries, they shall ensure that such supplies are only made to persons who are authorised or entitled to receive medicinal products for wholesale distribution or supply to the public in accordance with the applicable legal and administrative provisions of the third country concerned;

(d) has an emergency plan which ensures effective implementation of any recall of medicinal products from the market as ordered by the Authority or carried out in co-operation with the manufacturer or marketing

authorization holder for the medicinal product concerned;

- (e) keeps records, either in the form of purchase/sales invoices, or on computer, or in any other form, available for inspection by the Authority, for a period of five years of any transaction in medicinal products received, dispatched or brokered, containing at least the following information:
 - (i) date;
 - (ii) name and pharmaceutical form of the medicinal product;
 - (iii) quantity received, supplied or brokered;
 - (iv) name and address of the supplier or consignee, as appropriate;
 - (v) batch number of the medicinal product;
- (f) complies with the principles and guidelines of good distribution practice for medicinal products as published by the Commission;
- (g) maintains a quality system setting out responsibilities, processes and risk management measures in relation to their activities;
- (h) immediately informs the Authority and, where applicable, the marketing authorisation holder, of medicinal products he receives or are offered which he identifies as falsified or suspect to be falsified.

(3) For the purposes of sub-regulation (2)(e), where the medicinal product is obtained from another wholesale distributor, the wholesale distribution authorisation holder must verify compliance with the principles and guidelines of good distribution practices by the supplying wholesale distributor. This includes verifying whether the supplying wholesale distributor holds a wholesale distribution authorisation.

Where the medicinal product is obtained from the manufacturer or importer, wholesale distribution authorisation holders shall verify that the manufacturer or importer holds a manufacturing authorisation. Where the medicinal product is obtained through brokering, the wholesale distribution authorisation holder shall verify that the broker involved fulfils the requirements set out in these regulations and in the Act.

(4) The requirements set out in paragraphs (a) and (d) to (h) of sub-regulation (2) shall apply *mutatis mutandis* to the brokering of medicinal products.

(5) The Authority shall enter the information relating to the licence referred to in sub-regulation (1) in the European Union database as may be established by the Commission. At the request of the Commission or any Member State, the Authority shall provide all appropriate information concerning the individual licences which were granted under sub-regulation (1).

Duty of wholesale
dealer.

9. (1) It shall be the duty of the wholesale dealer, when supplying medicinal products to a person authorised or entitled to supply them to the public, to enclose a document thereby making it possible to ascertain the date, name and pharmaceutical form of the medicinal product, quantity supplied, batch number of the medicinal products and the name and address of the supplier or consignee:

Provided that the requirements of this sub-regulation shall also apply to the supply of medicinal products to persons in third countries authorised or entitled to supply medicinal products to the public.

(2) In addition, the wholesale dealer shall, in respect of each product he is distributing in Malta, furnish to the Authority an authenticated copy of the marketing authorization together with a letter of access issued by the marketing authorization holder granting the wholesale dealer the use of such marketing authorisation:

Provided that a wholesale dealer may only engage in the wholesale distribution of medicinal products in Malta in respect of which no such authenticated copy of a valid marketing authorization and letter of access has been forwarded to the Authority, if he is in possession of a parallel import licence issued in terms of the law.

(3) Every wholesale dealer shall, within the limits of his responsibilities, ensure that an appropriate and continuous supply of medicinal products is furnished to pharmacies and persons authorized to supply medicinal products in order to satisfy the needs of patients.

(4) It shall be the duty of wholesale distributors of active substances, including active substances that are intended for export, to comply with the current European Union good distribution practice for active substances.

Duty of
responsible person.

10. It shall be the duty of the responsible person to:

- (a) ensure that the licence conditions are adhered to;
- (b) ensure that the conditions for storage of medicinal products are in accordance with the requirements of the marketing authorisation and labelling;
- (c) monitor all areas used for storage and distribution;
- (d) maintain records as required by these regulations;
- (e) ensure that a quality system is maintained by the licensee in accordance with good distribution practice.

Homeopathic
medicinal
products.

11. The provisions of these regulations shall also apply to homeopathic medicinal products.

Falsified medicinal
products.

12. Without prejudice to any of these regulations, the Licensing Authority shall take the necessary measures in order to prevent medicinal products that are introduced into the European Union, but are not intended to be placed on the market of the European Union, from entering into circulation if there are sufficient grounds to suspect that those products are falsified. These measures shall include the application of these regulations to

warehouses situated in free trade zones and customs bonded warehouses used to store medicinal products.

13. Any breaches of:

Offences and penalties.

- (a) regulations 3(1) and 4 shall be an offence and shall be liable to penalties under article 99(1)(a) of the Act;
 - (b) regulation 5 shall be an offence and shall be liable to penalties as prescribed under article 99(1)(b) of the Act;
 - (c) regulations 8, 9 and 10 shall be an offence and shall be liable to penalties as prescribed under article 99(1)(d) of the Act.
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