VERŻJONI ELETTRONIKA

L.N. 476 of 2012

MEDICINES ACT
(CAP. 458)

Manufacture and Importation of Medicinal Products for Human Use (Amendment) Regulations, 2012

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

Citation.

1. The title of these regulations is the Manufacture and Importation of Medicinal Products for Human Use Regulations (Amendment) Regulations, 2012 and these regulations shall be read and construed as one with the Manufacture and Importation of Medicinal Products for Human Use Regulations, hereinafter referred to as "the principal regulations".

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Amends regulation 2 of the principal regulations.

2. In regulation 2 of the principal regulations for the definition "active substance (API)" there shall be substituted the following:

" "active substance (API)" means any substance or mixture of substances intended to be used in the manufacture of a medicinal product and that, when used in its production, becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions or to make a medical diagnosis;".

Amends regulation 3 of the principal regulations.

3. Immediately after sub-regulation (5) of regulation 3 of the principal regulations there shall be added the following new sub-regulation:

"(6) The Authority shall enter the information relating to the licence referred to in sub-regulation (1) in the European Union database referred to in Article 111(6) of Directive 2001/83/EC as amended.".

Adds new regulation to the principal regulations.

4. Immediately after regulation 3 of the principal regulations

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there shall be added the following new regulation:

"Registering of activity with the Authority.

3A. (1) Importers and manufacturers 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 imported or manufactured;

(c) particulars regarding the premises and the technical equipment for their activity:

Provided that 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 manufactured or imported shall be notified immediately.

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(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.".

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Amends regulation 7 of the principal regulations.

5. Regulation 7 of the principal regulations shall be amended as follows:

(a) subregulation (1) thereof shall be substituted by the following:

"(1) The holder of the licence, apart from his obligations in article 44 of the Act, shall:

(a) comply with the Community principles and guidelines of good manufacturing practice and any annexes thereof for medicinal products and use only active substances which have been manufactured in accordance with the Community guidelines on good manufacturing practice for active substances and distributed in accordance with good distribution practices for active substances. To this end, the holder of the manufacturing authorisation shall verify compliance by the manufacturer and distributors of active substances with good manufacturing practice and good distribution practices by conducting audits at the manufacturing and distribution sites of the manufacturer and distributors of active substances. The holder of the manufacturing authorisation shall verify such compliance either by himself or, without prejudice to his responsibility as provided for in these regulations and in the Act , through an entity acting on his behalf under a contract;

(b) ensure that the excipients are suitable for use in medicinal products by ascertaining what

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the appropriate good manufacturing practice is. This shall be ascertained on the basis of a formalised risk assessment in accordance with the applicable guidelines referred to in the fifth paragraph of Article 47 of Directive 2001/83/EC, as amended. Such risk assessment shall take into account requirements under other appropriate quality systems as well as the source and intended use of the excipients and previous instances of quality defects. The holder of the manufacturing authorisation shall ensure that the appropriate good manufacturing practice, so ascertained, is applied. The holder of the manufacturing authorisation shall document the measures taken under this paragraph;

(c) inform the competent authority and the marketing authorisation holder immediately if he obtains information that medicinal products which come under the scope of his manufacturing authorisation are, or are suspected of being, falsified irrespective of whether those medicinal products were distributed within the legal supply chain or by illegal means, including illegal sale by means of information society services;

(d) verify that the manufacturers, importers or distributors from whom he obtains active substances are registered with the competent authority of the Member State in which they are established;

(e) verify the authenticity and quality of the active substances and the excipients."; and

(b) immediately after sub-regulation (2) thereof, there shall be added the following new sub-regulations:

"(3) The safety features referred to in regulation 3(o) of the Medicinal Products (Labelling and Packaging) Regulations shall not be removed or covered, either fully or partially, unless the following conditions are fulfilled:

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(a) the manufacturing licence holder verifies, prior to partly or fully removing or covering those safety features, that the medicinal product concerned is authentic and that it has not been tampered with;

(b) the manufacturing licence holder complies with regulation 3(o) of the Medicinal Products (Labelling and Packaging) Regulations, by replacing those safety features with safety features which are equivalent as regards the possibility to verify the authenticity, identification and to provide evidence of tampering of the medicinal product. Such replacement shall be conducted without opening the immediate packaging. Safety features shall be considered equivalent if they:

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(i) comply with the requirements as may be adopted by the European Union Commission pursuant to Article 54a(2) of Directive 2001/83/EC as amended; and

(ii) are equally effective in enabling the verification of authenticity and identification of medicinal products and in providing evidence of tampering with medicinal products;

(c) the replacement of the safety features is conducted in accordance with applicable good manufacturing practice for medicinal products; and

(d) the replacement of the safety features is subject to supervision by the Licensing Authority through inspections or any other means as may be determined by the same Authority.

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(4) Manufacturing licence holders, including those performing the activities referred to in sub-regulation (3), shall be regarded as producers and therefore held liable for damages in the cases and under the conditions set forth in the Consumers Affairs Act.

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(5) It shall be the duty of the importer to ensure that:

(a) in the case of medicinal products and investigational medicinal products imported from third countries, these have been manufactured in accordance with standards which are at least equivalent to the good manufacturing practice standards laid down by the Community;

(b) in the case of medicinal products, such products have been manufactured by manufacturers duly authorised for the purpose; and

(c) in the case of investigational medicinal products, such products have been manufactured by a manufacturer notified to the competent authorities and accepted by them for that purpose.".

Amends regulation 11 of the principal regulations.

6. Immediately after sub-regulation (2) of regulation 11 of the principal regulations, there shall be added the following new sub-regulation:

"(3) The qualified person shall, in the case of medicinal products intended to be placed on the market in the European Union, ensure that the safety features referred to in regulation 3(o) of the Medicinal Products (Labelling and Packaging) Regulations have been affixed on the packaging.".

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Adds new regulation to the principal regulations.

7. Immediately after regulation 12 of the principal regulations, there shall be added the following new regulation:

"Offences and penalties.

13. Any breaches of:

(a) regulations 3 and 3A shall be an offence and shall be liable to penalties under article 99(1)(a) of the Act;

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(b) regulations 7 and 8 shall be an offence and shall be liable to penalties under article 99(1)(b) of the Act;

(c) regulations 11 and 12 shall be an offence and shall be liable to penalties under article 99(1)(c) of the Act.".

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