VERŻJONI ELETTRONIKA

L.N. 350 of 2013

MEDICINES ACT
(CAP. 458)

Wholesale Distribution and Brokering of Medicinal Products and Active Substances (Amendment) Regulations, 2013

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

Citation and scope.

1. (1) The title of these regulations is the Wholesale Distribution and Brokering of Medicinal Products and Active Substances (Amendment) Regulations, 2013 and these regulations shall be read and construed as one with the Wholesale Distribution and Brokering of Medicinal Products and Active Substances Regulations, hereinafter referred to as "the principal regulations". S.L.458.37

(2) The scope of these regulations is to transpose 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.

(3) These regulations shall be deemed to have come into force on the 28th October, 2013.

Amends regulation 8 of the principal regulations.

2. Sub-regulation (2) of regulation 8 of the principal regulations shall be amended as follows:

(a) for the proviso to paragraph (b) thereof, there shall be substituted the following:

"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,

VERŻJONI ELETTRONIKA

remain in quarantine and do not in any way end up on any Member State market;"; and

(b) for the proviso to paragraph (c) thereof, there shall be substituted the following:

"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;".

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