

L.N. 372 of 2012

**MEDICINES ACT
(CAP. 458)**

**Medicinal Products (Labelling and Packaging)
(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, after consultation with the Licensing Authority, has made the following regulations:-

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

Citation, scope
and coming into
force.

S.L. 458.33

(2) The scope of these regulations is to transpose amendments to Directive 2001/83/EC on the Community code relating to medicinal products for human use, brought about by Directive 2010/84/EU, as regards pharmacovigilance and Directive 2011/62/EU, as regards the prevention of the entry into the legal supply chain of falsified medicinal products.

(3) Regulations 3 and 4 shall come into force on the 2nd January, 2013.

2. In paragraph (n) of regulation 3 of the principal regulations, for the words "instructions for use." there shall be substituted the words "instructions for use;", and immediately thereafter there shall be added the following new paragraphs:

Amends
regulation 3 of
the principal
regulations.

"(o) for medicinal products other than radiopharmaceuticals referred to in paragraph (p), safety features enabling wholesale distributors and persons authorised or entitled to supply medicinal products to the public to:

(i) verify the authenticity of the medicinal product, and

(ii) identify individual packs,

as well as a device allowing verification of whether the outer packaging has been tampered with;

(p) medicinal products subject to prescription shall bear

the safety features referred to in paragraph (o), unless they have been listed in accordance with the procedure pursuant to Article 54a of Directive 2001/83/EC as amended.

Medicinal products not subject to prescription shall not bear the safety features referred to in paragraph (o), unless, by way of exception, they have been listed in accordance with the procedure pursuant to Article 54a of Directive 2001/83/EC as amended, after having been assessed to be at risk of falsification;

(q) the Licensing Authority may, for the purposes of reimbursement or pharmacovigilance, extend the scope of application of the unique identifier referred to in paragraph (o) to any medicinal product subject to prescription or subject to reimbursement;

(r) the Licensing Authority may, for the purposes of reimbursement, pharmacovigilance and pharmacoepidemiology, use the information contained in the repositories system as may be established by the Commission referred to in Article 54a of Directive 2001/83/EC as amended;

(s) the Licensing Authority may, for the purposes of patient safety, extend the scope of application of the anti-tampering device referred to in paragraph (o) to any medicinal product."

Adds new regulation to the principal regulations.

3. Immediately after regulation 5 of the principal regulations, there shall be added the following new regulation:

"Licensing Authority may require use of certain labelling forms.

5A. Notwithstanding the proviso to regulation 8(2), the Licensing Authority may require the use of certain forms of labelling of the medicinal product making it possible to ascertain:

(a) the price of the medicinal product;

(b) the reimbursement conditions of social security organizations;

(c) the legal status for supply to the patient, in accordance with Title VI of Directive 2001/83/EC as amended; and

(d) authenticity and identification in accordance with regulation 3(q), (r) and (s).".

4. Sub-regulation (1) of regulation 7 of the principal regulations shall be amended as follows:

Amends regulation 7 of the principal regulations.

(a) paragraph (e) thereof shall be substituted by the following new paragraph:

"(e) a description of the adverse reactions which may occur under normal use of the medicinal product and, if necessary, the action to be taken in such a case;"

(b) in paragraph (h) thereof, for the words "the package leaflet was last revised.", there shall be substituted the words "the package leaflet was last revised;"; and

(c) immediately after paragraph (h) thereof, there shall be added the following new paragraphs:

"(i) for medicinal products included in the list referred to in Article 23 of Regulation (EC) No 726/2004, the following additional statement shall be included "This medicinal product is subject to additional monitoring". This statement shall be preceded by the black symbol referred to in Article 23 of Regulation (EC) No 726/2004 and followed by an appropriate standardized explanatory sentence.

For all medicinal products, a standardized text shall be included, expressly asking patients to communicate any suspected adverse reaction to his/her doctor, pharmacist, healthcare professional or directly to the national spontaneous reporting system referred to in regulations 24 and 25 of the Pharmacovigilance Regulations, 2012, and specifying the different ways of reporting available (electronic reporting, postal address and/or others) in compliance with regulation 25 of the Pharmacovigilance Regulations, 2012."

5. Sub-regulation (3) of regulation 10 of the principal regulations shall be substituted by the following new sub-regulation:

Amends regulation 10 of the principal regulations.

"(3) When the medicinal product is not intended to be delivered directly to the patient, or where there are severe problems in respect of the availability of the medicinal product,

the Licensing Authority may, subject to measures they consider necessary to safeguard human health, grant an exemption to the obligation that certain particulars should appear on the labelling and in the package leaflet. They may also grant a full or partial exemption to the obligation that the labelling and the package leaflet have to be in the official language or languages of Malta."

