

L.N. 351 of 2013

**MEDICINES ACT
(CAP. 458)**

**Medicinal Products (Labelling and Packaging)
(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:-

1. (1) The title of these regulations is the Medicinal Products (Labelling and Packaging) (Amendment) Regulations, 2013, 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
commencement.

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 2012/26/EU, as regards pharmacovigilance.

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

2. Regulation 10 of the principal regulations shall be amended as follows:

Amends
regulation 10 of
the principal
regulations.

(a) in sub-regulation (1) thereof, for the words from "The particulars" to "languages of Malta:" there shall be substituted the following:

"The particulars for labelling listed in regulations 3, 7 and 9 shall appear in an official language or official languages of Malta:";

(b) in sub-regulation (2) thereof, for the words from "The package leaflet" to the words "languages of Malta" there shall be substituted the following:

"The package leaflet must be written and designed in such a way as to be clear and understandable, enabling users to act appropriately, when necessary even with the help of health professionals. The package leaflet must be clearly legible in an official language or official languages of Malta:"; and

(c) for sub-regulation (3) thereof there shall be substituted the following:

"(3) Where 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. The Licensing Authority may also grant a full or partial exemption to the obligation that the labelling and the package leaflet must be in an official language or official languages of Malta.".

