

L.N. 349 of 2013

**MEDICINES ACT
(CAP. 458)**

**Medicines (Marketing Authorisation) (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 Medicines (Marketing Authorisation) (Amendment) Regulations, 2013, and these regulations shall be read and construed as one with the Medicines (Marketing Authorisation) Regulations, hereinafter referred to as "the principal regulations".

Citation, scope
and
commencement.

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(2) The scope of these regulations is to transpose the 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. For sub-regulation (5) of regulation 18 of the principal regulations there shall be substituted the following new sub-regulation:

Amends
regulation 18 of
the principal
regulations.

"(5) After a marketing authorisation has been granted, the holder of the authorisation shall inform the Authority of the date of actual marketing of the medicinal product for human use in Malta, taking into account the various presentations authorised.

If the product ceases to be placed on the Maltese market, either temporarily or permanently, the marketing authorisation holder shall notify the Medicines Authority. Such notification shall, other than in exceptional circumstances, be made no less than two months before the interruption in the placing on the market of the product. The marketing authorisation holder shall inform the Medicines Authority of the reasons for such action in accordance with regulation 23(7)".

Amends
regulation 23 of
the principal
regulations.

3. Regulation 23 of the principal regulations shall be amended as follows:

(a) in the last paragraph of sub-regulation (4) thereof, for the words from "However, where urgent action" to the words "shall apply." there shall be substituted the following:

"However, where one of the criteria listed in regulation 57(1)(a)(i) of the Pharmacovigilance Regulations is met, the procedure laid down in regulation 57 thereof applies."; and

(b) immediately after sub-regulation (6) thereof, there shall be added the following new sub-regulations:

"(7) (a) Where the referral to the Committee concerns a range of medicinal products or a therapeutic class, the Agency may limit the procedure to certain specific parts of the authorisation. In that event, regulation 24 shall apply to those medicinal products only if they were covered by the authorisation procedures referred to in regulations 22 and 23.

(b) Where the scope of the procedure initiated under regulations 22 and 23 concerns a range of medicinal products or a therapeutic class, medicinal products authorised in accordance with Regulation (EC) No 726/2004 which belong to that range or class shall also be included in the procedure.

(8) Without prejudice to sub-regulation (4), the Licensing Authority may, where urgent action is necessary to protect public health at any stage of the procedure, suspend the marketing authorisation and prohibit the use of the medicinal product concerned in Malta until a definitive decision is adopted. It shall inform the Commission, the Agency and the other Member States, no later than the following working day, of the reasons for its action.

(9) Where the scope of the procedure initiated in accordance with sub-regulation (7) includes medicinal products authorised in accordance with Regulation (EC) No 726/2004, the Commission may, where urgent action is necessary to protect public health, at any stage of the procedure, suspend the marketing authorisations and prohibit the use of the medicinal products concerned until a definitive decision is adopted. The Commission shall

inform the Agency and the Licensing Authority no later than the following working day of the reasons for its action."

4. Immediately after regulation 30 of the principal regulations there shall be added the following new regulation:

Adds new regulation 31 to the principal regulations.

"Informing the Agency of the actions taken.

31. (1) The Medicines Authority shall take all the appropriate measures to ensure that decisions authorising marketing, refusing or revoking a marketing authorization, cancelling a decision refusing or revoking a marketing authorization, prohibiting supply, or withdrawing a product from the market, together with the reasons on which such decisions are based, are brought to the attention of the Agency forthwith.

(2) The marketing authorisation holder shall be obliged to notify the Medicines Authority forthwith of any action taken by the holder to suspend the marketing of a medicinal product, to withdraw a medicinal product from the market, to request the withdrawal of a marketing authorisation or not to apply for the renewal of a marketing authorisation, together with the reasons for such action. The marketing authorisation holder shall in particular declare if such action is based on any of the grounds set out in article 28(1) of the Medicines Act.

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(3) The marketing authorisation holder shall also make the notification pursuant to sub-regulation (2) in cases where the action is taken in a third country and where such action is based on any of the grounds set out in article 28(1) of the Medicines Act.

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(4) The marketing authorisation holder shall furthermore notify the Agency where the action referred to in sub-regulation (2) is based on any of the grounds referred to in article 28 of the Medicines Act.

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(5) The Medicines Authority shall ensure that appropriate information about action taken pursuant to sub-regulations (1) and (2) which may affect the protection of public health in third countries is forthwith brought to the attention of the World Health Organization, with a copy to the Agency."

