Our Ref: 16/2013

CONSULTATION DOCUMENT ON IMPLEMENTATION OF DIRECTIVE 2012/26/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 15 DECEMBER 2010 AMENDING, AS REGARDS PHARMACOVIGILANCE, DIRECTIVE 2001/83/EC ON THE COMMUNITY CODE RELATING TO MEDICINAL PRODUCTS FOR HUMAN USE.

Objectives and Scope

Following the disaster with the "Mediator Case" in France in 2010-2012 whereby the regulator failed to suspend the medicinal product following numerous EU wide referrals. The European Commission stressed the recently amended EU's pharmacovigilance regulations (Directive 2010/84/EC) with respect to situations that could parallel the mediator scenario. Gaps in the EU legislation were identified.

Directive 2012/26/EU addresses these gaps and introduces harmonised EU wide triggered arbitration procedures so that Member states do not act unilaterally when it comes to issues of drug safety. The national regulations implement the provisions of Directive 2012/26/EU of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance, Directive 2001/83/EC on the community code relating to medicinal products for human use.

Main Changes
The Directive is directly applicable to all Member States as from the 28 October 2013.
Major changes compared to Directive 2001/83/EC:

• Providing clear roles and responsibilities for Industry and Regulators and clear obligations against which they perform their roles;
• Rationalising EU decision-making on drug safety issues in order to deliver measures that are equally and fully implemented for all relevant products and across the Community with a view to preventing unnecessary patient exposure to risks;

DIRECTIVE 2012/26/EU:

Comments
Your comments on the proposed Legal Notices are invited.
Comments are to reach the Medicines Authority in writing or via email consultations.medicinesauthority@gov.mt by the **6 August 2013.**
Should any further information be required kindly contact the Medicines Authority using the following contact details:

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Minister of Health

L.N. of 2013

MEDICINES ACT
(CAP. 458)

Pharmacovigilance (Amendment)
Regulations, 2013

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

Title and scope.
L.N. XXX of 2013.
S.L. 458.XX.

1. (1) The title of these regulations is the Pharmacovigilance (Amendment) Regulations, 2013 and they shall be read and construed as one with the Pharmacovigilance Regulations, 2012, hereinafter referred to as "the principal regulations".

(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.

Coming into force.

2. These regulations shall enter into force on the 28 October 2013.

Amends regulation 57 of the principal regulations.

3. Regulation 57 of the principal regulations shall be amended as follows:

(a) sub-regulation (1) shall be substituted by the following:

"(1) A Member State or the Commission, as appropriate, shall, on the basis of concerns resulting from the evaluation of data from pharmacovigilance activities, initiate the procedure provided for in this section by informing the other Member States, the Agency and the Commission where:

(a) it considers suspending or revoking a marketing authorisation;

(b) it considers prohibiting the supply of a medicinal product;

(c) it considers refusing the renewal of a marketing authorisation; or

(d) it is informed by the marketing authorisation holder that, on the basis of safety concerns, the holder has interrupted the placing on the market of a medicinal product or has taken action to have a marketing authorisation withdrawn, or intends to take such action or has not applied for the renewal of a marketing authorisation.

(1a). A Member State or the Commission, as appropriate, shall, on the basis of concerns resulting from the evaluation of data from pharmacovigilance activities, inform the other Member States, the Agency and the Commission where it considers that a new contraindication, a reduction

in the recommended dose or a restriction to the indications of a medicinal product is necessary. The information shall outline the action considered and the reasons therefor.

Any Member State or the Commission, as appropriate, shall, when urgent action is considered necessary, initiate the procedure provided for in this section in any of the cases referred to in this paragraph.

Where the procedure provided for in this section is not initiated, for medicinal products authorised in accordance with the procedures laid down in Chapter 4 of Title III of Directive 2001/83/EC, the case shall be brought to the attention of the coordination group.

Article 31 of Directive 2001/83/EC shall be applicable where the interests of the Union are involved.

(1b) Where the procedure provided for in this section is initiated, the European Medicines Agency shall verify whether the safety concern relates to medicinal products other than the one covered by the information, or whether it is common to all products belonging to the same range or therapeutic class.

Where the medicinal product involved is authorised in more than one Member State, the European Medicines Agency shall without undue delay inform the initiator of the procedure of the outcome of this verification, and the procedures laid down in Articles 107j and 107k of Directive 2001/83/EC shall apply. Otherwise, the safety concern shall be addressed by the Member State concerned. The European Medicines Agency or the Member State, as applicable, shall make the information that the procedure has been initiated available to marketing authorisation holders”.

(b) In sub-regulations (2), (3), (4), and (5) the following the words "sub-regulation (1)" are substituted by the words "sub-regulation (1) and (1a)".

Minister for Health

L.N. 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 of Health, after consultation with the Licensing Authority, has made the following regulations:-

Title and Scope

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".

(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.

Coming into force

2. These regulations shall enter into force on 28 October 2013.

Amends Regulation 18(5)

3. Sub-regulation (5) of regulation 18 of the principal regulations shall be substituted by the following new sub-regulation:

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 market of a Member State, either temporarily or permanently, the marketing authorisation holder shall notify the competent authority of Malta. 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 competent authority of the reasons for such action in accordance with Article 123(2) of Directive 2001/83/EC.

Amends Regulation 23

4. The last paragraph of sub-regulation (4) of Regulation 23 shall be substituted by the following paragaraph:

However, where one of the criteria listed in Regulation 3(a)(1a) is met, the procedure laid down in 60 and 65 of the Pharmacovigilance Regulations apply.

5. There shall be added three other sub-regulations to Regulation 23 of the principal regulations

(7) 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.

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 on its territory 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) of these regulations, 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.

Minister for Health

L.N. of 2013

MEDICINES ACT
(CAP. 458)

Medicinal Products (Packaging and Labelling) Regulations, (Amendment), 2013

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

Title and Scope

1. (1) The title of these regulations is the Medicinal Products (Packaging and Labelling)(Amendment) Regulations, 2013, and these regulations shall be read and construed as one with the Medicinal Products (Packaging and Labelling) Regulations, hereinafter referred to as "the principal regulations".

(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.

Coming into force

2. These regulations shall enter into force on 28 October 2013.

Amends Regulation 10

3. The first paragraph of sub-regulation (1) shall be substituted by the following:

The particulars for labelling listed in Regulations 3, 7 and 9 and shall appear in an official language or official languages of Malta.

4. The first paragraph of sub-regulation (2) shall be substituted by 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 with the help of health professionals. The package leaflet must be clearly legible in an official language or official languages of Malta.

5. Paragraph 3 of shall be substituted by the following:

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 competent authorities 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 must be in an official language or official languages of Malta.

Minister of Health

L.N. XXX 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 of Health after consultation with the Licensing Authority, has made the following regulations:

Title and Scope

1. The title of these regulations is the Wholesale Distribution and Brokering of Medicinal Products and Active Substances (Amendment) Regulations, 2013 and they shall be read and construed as one with the Wholesale Distribution and Brokering of Medicinal Products and Active Substances Regulations, 2012.

Interpretation

2. The scope of these regulations is to transpose article 85a of Directive 2001/83/EC as amended by Directive 2012/26/EU.

Amends regulation 8 of the principal regulations.

3. Sub-regulation 2 paragraph (b) of regulation 8 shall be amended as follows;

Immediately after the wording, "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.", and before the wording "However in such a case the wholesale distributor should exercise all necessary caution and precautions in order to ensure that these medicinal products not intended to be imported, remain in quarantine and do not in any way end up on any Member State market;" the following wording should be inserted:
"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.".

4. Sub-regulation 2 paragraph (c) of regulation 8 shall be amended as follows;

The wording, "Provided that in the case of distribution of medicinal products to third countries this shall not apply;" shall be replaced by the following wording; "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.”.