L.N. 61 of 2006

MEDICINES ACT, 2003
(ACT NO. III OF 2003)

Pharmacovigilance Regulations, 2006

IN exercise of the powers conferred by article106 of the Medicines Act, 2003, the Minister of Health, the Elderly and Community Care has made the following regulations:

Title and commencement.

1. The title of these regulations is the Pharmacovigilance Regulations, 2006.

Scope.

2. These regulations shall apply to authorised medicinal products for human use and any pharmacovigilance activity connected therewith. These regulations shall also apply to homeopathic medicinal products, with the exception of those referred to in paragraph (a), (b) and (c) of regulation 10(3) of the Medicines (Marketing Authorisation) Regulations, 2005.

Interpretation.

3. For the purposes of these regulations

"abuse of medicinal products" means persistent or sporadic, intentional excessive use of medicinal products which is accompanied by harmful physical or psychological effects;

"the Act" means the Medicines Act, 2003;

"adverse reaction" refers to a response to a medicinal product which is noxious and unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function;

"the Agency" means the European Medicines Agency established by Regulation (EC) No 726/2004;

"the Authority" means the Licensing Authority set up in terms of article 3 of the Act;

"the Commission" means the Commission in accordance with Council Decision 1999/468/EC of the 28th June, 1999;

"the Community" means the European Union and the European Economic Area;

"Member State" means a State which is a member of the Community;

"serious adverse reaction" refers to an adverse reaction which results in death, or is life threatening, or requires in-patient hospitalisation or the prolongation of existing hospitalisation, or which results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect;

"Periodic Safety Update Report" refers to the periodical reports containing the records referred to in regulation 6 of these regulations;

"post-authorisation safety study" means a pharmacoepidemiological study or a clinical trial carried out in accordance with the terms of the marketing authorisation, conducted with the aim of identifying or quantifying a safety hazard relating to an authorised medicinal product;

"Risk-benefit balance" means an evaluation of the positive therapeutic effects of the medicinal product in relation to any risk relating to the quality, safety or efficacy of the medicinal product as regards patients' health or public health;

"unexpected adverse reaction" refers to an adverse reaction, the nature, severity or outcome of which is not consistent with the summary of product characteristics.

Setting up of pharmacovigilance system.

4. (1) (a) The Authority shall set up a pharmacovigilance system which shall be used to collect information which is useful in the surveillance of medicinal products, with particular reference to adverse reactions in human beings, to evaluate scientifically such information and to take into account any available information on the misuse and the abuse of medicinal products which may have an impact on the evaluation of their benefits and risks.

(b) The suitable information collected within this system shall be communicated by the Authority to the other Member States and the Agency. The information shall be recorded in the database referred to in point (l) of the second subparagraph of Article 57(1) of Regulation (EC) No 726/2004 and shall be permanently accessible to all Member States and without delay to the public.

(c) It shall be the duty of doctors and other healthcare professionals to immediately report to the Authority any suspected serious or unexpected adverse reaction to a medicinal product in Malta.

Duty of the marketing authorization holder.

5. (1) It shall be the duty of the marketing authorisation holder to have permanently and continuously at his disposal an appropriately qualified person responsible for pharmacovigilance.

(2) Such qualified person shall reside in the Community and shall be responsible for the following:

(a) for the establishment and maintenance of a pharmacovigilance system to ensure that any information about suspected adverse reactions which has been reported to the personnel of the company and to medical representatives, is collected and collated to be made available to the Authority;

(b) for the drawing up of the necessary reports in accordance with Volume 9 of the Rules Governing Medicinal Products in the European Union;

(c) to reply fully and promptly to any request made by the Authority for the provision of additional information necessary for the evaluation of the benefits and risks afforded by a medicinal product, including the provision of information about the volume of sales or prescriptions of the medicinal product concerned;

(d) to provide any information to the Authority in relation to the evaluation of the risk-benefit balance of a medicinal product, including appropriate information on post-authorisation safety studies.

Detailed documents.

6. (1) The marketing authorisation holder shall maintain detailed records of all suspected adverse reactions occurring either in the Community or in a third country to any medicinal product marketed by him. Save in exceptional circumstances, these reactions shall be communicated electronically in the form of a report in accordance with Volume 9 of the Rules Governing Medicinal Products in the European Union.

(2) (a) The marketing authorisation holder shall also immediately record and report electronically to the Authority all suspected serious adverse reactions occurring in Malta which are brought to his attention by a healthcare professional and in no case later than 15 calendar days from receiving the information.

(b) The marketing authorisation holder shall also immediately record and report all suspected serious adverse reactions occurring in the territory of other Member States and which are brought to his attention by a healthcare professional to the competent authority of the Member State in whose territory the adverse reaction occurred and in no case later than 15 calendar days following the receipt of the information.

(c) The marketing authorisation holder shall record and report all other suspected serious adverse reactions which meet the notification criteria in accordance with the guidelines published in Volume 9 of The Rules governing Medicinal Products in the European Union, of which he can reasonably be expected to have knowledge, promptly to the competent authority of the Member State in whose territory the incident occurred, and no later than 15 calendar days following the receipt of the information.

(d) The marketing authorisation holder shall ensure that all suspected serious unexpected adverse reactions and any suspected transmission via a medicinal product of any infectious agent occurring in the territory of a third country are reported promptly in accordance with the guidelines referred to in the preceding paragraph, so that the Agency and the competent authorities of the Member States in which the medicinal product is authorized are informed of them and no later than 15 calendar days following the receipt of the information.

(e) For medicinal products which are covered by Directive 87/22/EC or which have qualified for the procedures laid down in Articles 28 and 29 of Directive 2001/83/EC as amended by Directive 2004/27/EC, or which have been the subject of the procedures under Articles 32,33 and 34 of Directive 2001/83/EC as amended by Directive 2004/27/EC, the provisions of paragraphs (b), (c) and (d) above shall not apply and the marketing authorisation holder shall ensure that all suspected serious adverse reactions occurring in the Community are reported in such a way as to be accessible to the reference Member State or to any competent authority acting as reference Member State. If Malta is the reference Member State, the Authority shall assume the responsibility of analysing and monitoring such adverse reactions.

(3) (a) Unless other requirements have been laid down as a condition for the granting of the marketing authorisation, or subsequently as indicated in the guidelines referred to above, reports of all adverse reactions shall be submitted to the competent authorities in the form of a periodic safety update report, immediately upon request or at least every six months after authorisation and until the placing on the market.

(b) Periodic safety update reports shall also be submitted immediately upon request and periodically after the initial placing on the market as follows:

(i) every six months during the first two years;

(ii) annually for the subsequent two years.

Thereafter, the reports shall be submitted at three-yearly intervals, or immediately upon request.

(c) The periodic safety update reports shall include a scientific evaluation of the risk-benefit balance of the medicinal product.

(4) Following the granting of a marketing authorisation, the marketing authorisation holder may request the amendment of the periods referred to above in accordance with the procedure laid down by Commission Regulation (EC) No. 1084/2003.

(5) In accordance with Volume 9 of The Rules Governing Medicinal Products in the European Union, marketing authorisation holders shall use internationally agreed medical terminology for the reporting of adverse reactions.

(6) The marketing authorization holder may not communicate information relating to pharmacovigilance concerns to the general public in relation to its authorised medicinal product without giving prior notification to the Authority:

Provided that the marketing authorization holder may communicate the information in the first paragraph to the general public if the Authority does not oppose the communication within 24 hours of receipt of the marketing authorization holder's notification:

Provided further that in any case, the marketing authorisation holder shall ensure that such information is presented objectively and is not misleading.

Availability through network system.

7. By making use of the network referred to in Article 105 of Directive 2001/83/EC as amended by Directive 2004/27, the Authority shall ensure that reports of suspected serious adverse reactions that have taken place on its territory are immediately made available to the marketing authorisation holder, the Agency and other Member States within 15 days after their notification at the latest.

Suspension, withdrawal, variation.

8. (1) The Authority shall suspend, withdraw or vary a marketing authorisation whenever such action results necessary following an evaluation of pharmacovigilance data. Such decision shall be communicated to the Agency, to the Member States and to the marketing authorisation holder.

(2) Where urgent action to protect public health is necessary, the Authority may suspend the marketing authorisation of a medicinal product, provided that the Agency, the Commission and the Member States are informed no later than the following working day.

Repeals L.N. 22 of 2004.

9. The Pharmacovigilance Regulations, 2004 are hereby being repealed.

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