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UNOFFICIAL TRANSLATION

Finnish Medicines Agency Administrative Regulation

PHARMACOVIGILANCE

Legal basis

Section 30 c subsection 3, section 30 d subsection 3, section 30 e subsection 6 of the Medicines Act (396/1987) as they are in Act 330/2013 and the transitional provision of Act 330/2013

Target groups

Holders of a marketing authorisation, marketing authorisation for parallel import or registration for medicinal product

Entry into force

This administrative regulation will enter into force on 1 June 2013 and shall be valid until further notice

Regulation repealed

Administrative Regulation of the Finnish Medicines Agency 5/2010

This regulation implements

Directive 2001/83/EC of the European Parliament and of the Council (32001L0062, Official Journal L 311, 28/11/2001, p. 67) as amended by Directive 2004/24/EC of the European Parliament and of the Council (32004L0024, Official Journal L 136, 30/4/2004, p. 85), Directive 2004/27/EC of the European Parliament and of the Council (32004L0027 Official Journal L 136, 30/4/2004, p. 34) and Directive 2010/84/EC of the European Parliament and of the Council (32010L0084 Official Journal L 348, 31/12/2010, p. 74)

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1 GENERAL

By this administrative regulation, the Finnish Medicines Agency (Fimea) implements the requirements regarding pharmacovigilance in compliance with the following European Union regulation:

- Directive 2001/83/EC of the European Parliament and of the Council on the Community Code relating to medicinal products for human use as amended by Directive 2004/24/EC of the European Parliament and of the Council, by Directive 2004/27/EC of the European Parliament and of the Council and by Directive 2010/84/EC of the European Parliament and of the Council

2 SCOPE OF APPLICATION OF THE ADMINISTRATIVE REGULATION

This administrative regulation applies to medicinal products for human use.

Pharmacovigilance for medicinal products that have been granted marketing authorisation by the centralised procedure according to EC Regulation (EEC) No 2004/726[1] is stipulated on in these regulations and by Commission Regulation (EC) No 1234/2008[2] and Regulation (EC) No 1235/2010[3] as well as by Commission Regulation No 540/95.

3 DEFINITIONS

For the purposes of this regulation, the following terms have the following meanings:

Adverse reaction means a harmful and unintended response to a medicinal product.

Serious adverse reaction means an adverse reaction which results in death, is life-threatening, requires in-patient hospitalisation or prolongation of existing hospitalisation, or results in permanent or significant disability or incapacity, or in a congenital anomaly/birth defect.

[1] Regulation No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency

[2] Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products

[3] Regulation (EC) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance of medicinal products for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, and Regulation (EC) No 1394/2007 on advanced therapy medicinal products

Unexpected adverse reaction means an adverse reaction, the nature, severity or outcome of which is inconsistent with the summary of product characteristics of the drug.

4 STATUS RELATIVE TO OTHER REGULATIONS AND GUIDELINES

More detailed guidelines on drug safety monitoring are given in the good pharmacovigilance practices (GVP) published on the website of the European Medicines Agency. The guideline on GVP is divided into modules, each of which covers one major process in pharmacovigilance. Once implemented, the modules will replace the relevant sections of the Commission guidelines: Rules governing medicinal products in the European Union, Volume 9 − Pharmacovigilance.

The reporting of adverse reactions occurring in clinical trials is governed by other regulations.

5 RESPONSIBILITIES OF THE MARKETING AUTHORISATION HOLDER, MARKETING AUTHORISATION HOLDER FOR PARALLEL IMPORT AND REGISTRATION HOLDER

5.1 Person responsible for pharmacovigilance

The person responsible for pharmacovigilance shall be responsible for ensuring that pharmacovigilance with regard to a drug marketed in Finland is locally sufficient for monitoring and ensuring the safety of the drug in accordance with the pharmacovigilance guidelines referred to in section 4. Communication with Fimea and the national implementation of measures required by medicines authorities in relation to pharmacovigilance must not be prevented or delayed due to inadequate familiarity with pharmacovigilance and local conditions, including language proficiency.

5.2 Maintaining of a register of adverse reactions

In maintaining a register of adverse reactions, account shall be taken of the requirements of the pharmacovigilance guidelines referred to in section 4 and conditions for timely monitoring and reporting of drug safety information according to the guidelines.

5.3 Reporting of adverse reactions

The marketing authorisation holder, marketing authorisation holder for parallel import and registration holder shall be required to report electronically any suspected serious adverse reactions that have occurred in Finland and that have come to its attention to Fimea promptly and no later than 15 days following the receipt of the information according to the pharmacovigilance guidelines referred to in section 4.

5.4 Periodic safety update reports

Periodic safety update reports shall be submitted according to the list of Union reference dates and frequency of submission of periodic safety update reports published by the European Medicines Agency. The marketing authorisation holder, marketing authorisation holder for parallel import and registration holder shall submit an application to vary the terms of their marketing authorisation accordingly as required.

The European Medicines Agency also publishes changes to the submission dates and frequency of submission of periodic safety update reports. The changes become legally binding six months after publication. The marketing authorisation holder, marketing authorisation holder for parallel import and registration holder shall submit an application to vary their marketing authorisation accordingly.

With regard to marketing authorisations and registrations for which no Union reference date and frequency of submission of periodic safety update reports have been confirmed, periodic safety update reports shall be submitted according to a submission date agreed with the authorities.

Periodic safety update reports shall also be submitted promptly on request by the authorities.

Periodic safety update reports shall contain a scientific evaluation of the risk-benefit balance of the medicinal product, which shall be based on all available data, including data from clinical trials in unauthorised indications and populations.

Periodic safety update reports shall be compiled in accordance with the pharmacovigilance guidelines referred to in section 4.

5.5 Risk management system

With regard to the risk management system, the pharmacovigilance guidelines referred to in section 4 shall be observed.

6 GUIDANCE AND INFORMATION

Fimea will provide on request guidance and advice on the application of this administrative regulation.

7 ENTRY INTO FORCE

This administrative regulation enters into force on 1 June 2013.

Sinikka Rajaniemi
Director General

Suvi Loikkanen
Senior Pharmaceutical Officer

DISTRIBUTION

Holders of a marketing authorisation, marketing authorisation for parallel import or registration for medicinal product

FOR INFORMATION

Ministry of Social Affairs and Health

Pharmaceutical goods wholesalers

Central Organisation of Health and Food Trade in Finland

Pharma Industry Finland

Finnish Generic Pharmaceutical Association

Pharmaceutical Information Centre

Finnish Parallel Drug Importers Foundation

University of Helsinki Pharmacy

University of Eastern Finland Pharmacy

Social Insurance Institution

Consumer Ombudsman

University of Helsinki, Faculty of Pharmacy

University of Helsinki, Faculty of Medicine

University of Eastern Finland, Faculty of Health Sciences

University of Oulu, Faculty of Medicine

University of Tampere, Faculty of Medicine

University of Turku, Faculty of Medicine

Åbo Akademi, Department of Biochemistry and Pharmacy

Association of Finnish Pharmacies

Finnish Pharmacists Association

Finnish Dental Association

Finnish Medical Association

Finnish Nurses Association

Finnish Medical Society Duodecim

Finnish Pharmacists Society

Poison Information Centre

Finnish Pharmaceutical Insurance Pool

Pharmaceutical manufacturers

Pharmaceutical wholesalers