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Unofficial translation

Finnish Medicines Agency Administrative Regulation

Veterinary pharmacovigilance

Legal basis

Section 30(7) of the Medicines Act (395/1987) as amended by Act 773/2009

Target groups

Pharmaceutical manufacturers
Pharmaceutical wholesalers
Persons responsible for release of medicinal products to market
Finnish Food Safety Authority Evira

Entry into force

2 July 2012

Regulation(s) repealed

Finnish Medicines Agency administrative regulation 2/2010

This regulation implements

Directive 2001/82/EC of the European Parliament and of the Council (32001L0082, OJ L 311 28.11.2001, p.1) as amended by Directive 2004/28/EC of the European Parliament and of the Council (32004L0028, OJ L 136, 30.4.2004, p. 58)

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1. GENERAL

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

- Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products, as amended by Directive 2004/28/EC of the European Parliament and of the Council

2. SCOPE OF APPLICATION

This administrative regulation applies to pharmacovigilance of veterinary medicinal products.

Provisions on pharmacovigilance of veterinary medicinal products granted marketing authorisation in the centralised procedure under Regulation (EC) No 726/2004 are laid down in the said Regulation and in Commission Regulation (EC) No 1234/2008 and Commission Regulation (EC) No 540/95.

3. DEFINITIONS

For the purposes of this administrative regulation:

Adverse reaction means a reaction to a veterinary medicinal product
which is harmful and unintended and which occurs at doses normally used in animals for the prophylaxis, diagnosis or treatment of disease or to re-store, correct or modify a physiological function.

Human adverse reaction means a reaction which is noxious and unintended and which occurs in a human being following exposure to a veterinary medicine. Human adverse reactions are always considered serious.

Serious adverse reaction means an adverse reaction which results in death, is life-threatening, results in permanent or significant disability or in-capacity, is a congenital anomaly/birth defect, or which results in permanent or prolonged signs in the animals treated.

Unexpected adverse reaction means an adverse reaction, the nature, se-verity or outcome of which is not consistent with the summary of the product characteristics of the veterinary medicinal product.

4. STATUS RELATIVE TO OTHER REGULATIONS AND GUIDELINES

More specific guidelines on veterinary pharmacovigilance are issued in the Volume 9B of The Rules Governing Medicinal Products in the European Union – Guidelines on Pharmacovigilance for Medicinal Products for Veterinary Use (http://ec.europa.eu/health/files/eudralex/vol-9/vol_9b_2011-10.pdf).

A separate administrative regulation has been issued to govern the report-ing of adverse reactions arising in clinical trials of veterinary medicinal products

5. DUTIES OF THE MARKETING AUTHORISATION HOLDER

5.1 Person responsible for veterinary pharmacovigilance

Under section 30(6) of the Medicines Act, holders of marketing authorisations, parallel import marketing authorisations and registrations of traditional herbal medicinal products (hereinafter “marketing authorisation holders”) must at all times have available a person responsible for veterinary pharmacovigilance whose domicile must be in a European Economic Area state.

The person responsible for veterinary pharmacovigilance has the following duties:

- the establishment and maintenance of a system which ensures that information about all suspected adverse reactions which are re-ported to the personnel of the company, including its representatives, is collected and collated in order to be accessible at least at one point within the Community;

- the preparation for Fimea of the reports mentioned below in section 5.4 in accordance with the pharmacovigilance guidelines mentioned in section 4;

- ensuring that any request from Fimea for the provision of additional information necessary for the evaluation of the benefits and risks afforded by a veterinary medicinal product is answered fully and promptly, including the provision of information about the volume of sales or prescriptions of the veterinary medicinal product concerned;

- the provision to Fimea of any other information relevant to the evaluation of the benefits and risks afforded by a veterinary medicinal product, in particular appropriate information on post-marketing surveillance studies.

5.2 Reporting of adverse reactions

Under section 30(5) of the Medicines Act, marketing authorisation holders shall maintain detailed records of all suspected adverse reactions occurring within the Community or in a third country. Provisions on the data to be entered in the adverse effects register are laid down in section 30(1) of the Medicines Act.

Save in exceptional circumstances, all suspected adverse reactions occur-ring within the Community or in a third country shall be communicated electronically. For instructions on electronic reporting, see http://eudravigilance.ema.europa.eu/veterinary/index.html.

5.3 Expedited reporting of adverse reactions

5.3.1 Suspected serious adverse reactions and human adverse reactions occurring in Finland

The marketing authorisation holder shall record all suspected serious ad-verse reactions and human adverse reactions relating to the use
of veterinary medicinal products occurring in Finland that are brought to his attention, and report them to Fimea promptly and no later than 15 days fol-lowing receipt of the information.

5.3.2 Suspected serious unexpected adverse reactions, human adverse reactions and suspected transmission via a veterinary medicinal product of an infectious agent occurring in third countries

The marketing authorisation holder shall ensure that all suspected serious unexpected adverse reactions, human adverse reactions and any suspected transmission via a veterinary medicinal product of any infectious agent occurring on the territory of a third country are reported in accordance with the guidelines mentioned above in section 4 promptly and no later than 15 days following the receipt of the information so that they are available to Fimea and to the European Medicines Agency.

5.3.3 Serious adverse reactions and human adverse reactions occurring in the Community in respect pf products for which marketing authorisation has been granted in mutual recognition procedure or decentralised procedure

In respect of veterinary medicinal products for which marketing authorisation has been granted in accordance with Directive 87/22/EEC or to which the procedures laid down in Articles 31, 32, 36, 37 and 38 of Directive 2001/82/EC may have been applied, the marketing authorisation holder shall additionally ensure that all suspected serious adverse reactions and human adverse reactions occurring in the Community are reported in accordance with the guidelines mentioned above in section 4 in such
a way so as to be accessible to the reference Member State.

5.4 Periodic safety update reports

Unless other requirements have been laid down as a condition for the granting of the marketing authorisation or subsequently as indicated in the guidelines mentioned above in section 4, reports of all adverse reactions shall be submitted to Fimea in the form of a periodic safety update report,

immediately upon request or at least every six months after authorisation until the placing on the market. Periodic safety update reports shall also be submitted immediately upon request or at least every six months during the first two years following the initial placing on the market and once a year for the following two years. Thereafter, the reports shall be submitted at three-yearly intervals, or immediately upon request, unless otherwise ordered in connection with renewal.

The periodic safety update reports shall include a scientific evaluation of the risks and benefits of the veterinary medicinal product.

Requests for amendment of the aforementioned time periods may be made already in connection with the marketing authorisation application on the grounds provided in the guidelines mentioned above in section 4.

Following the granting of a marketing authorisation, the holder of such authorisation may request the amendment of the said periods in accordance with the procedure laid down by Commission Regulation (EC) No 1234/2008.

6. OTHER PROVISIONS

The marketing authorisation holder may not communicate to the general public information relating to pharmacovigilance concerning a veterinary medicinal product granted marketing authorisation without giving prior or simultaneous notification to Fimea. The marketing authorisation holder shall ensure that such information is presented objectively and is not misleading.

The marketing authorisation holder shall use internationally agreed medical terminology in the reporting of suspected adverse reactions.

7. GUIDANCE AND INFORMATION

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

8. ENTRY INTO FORCE

This administrative regulation enters into force on 2 July 2012.

Director General	Erkki Palva	Veterinary Officer	Jonna Kumpulainen

DISTRIBUTION

Finnish Food Safety Authority Evira
Pharmaceutical manufacturers
Pharmaceutical wholesalers
Persons responsible for release of medicinal products to market

FOR INFORMATION

Pharmaceutical goods wholesalers
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University of Helsinki, Faculty of Pharmacy

University of Helsinki, Faculty of Veterinary Medicine
University of Helsinki, Faculty of Medicine
University of Eastern Finland Pharmacy
University of Eastern Finland, Faculty of Health Sciences
Social Insurance Institution of Finland Kela
Central Organisation of Health and Food Trade in Finland
Pharma Industry Finland / Veterinary medicines committee
Ministry of Agriculture and Forestry
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