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Finnish Medicines Agency Guideline

REPORTING OF ADVERSE REACTIONS

Target group

Persons authorised to prescribe or supply drugs

Period of validity

This guideline will enter into force on 1 March 2017 and be valid until further notice.

Regulation repealed

Finnish Medicines Agency Guideline 2/2013

NB: Unofficial translation, legally binding only in Finnish and Swedish
Finnish Medicines Agency

Lääkealan turvallisuus- ja kehittämiskeskus | Säkerhets- och utvecklingscentret för läkemedelsområdet | Finnish Medicines Agency
P.O. Box 55, 00034 FIMEA | Tel. 029 522 3341 | kirjaamo@fimea.fi | www.fimea.fi | Business ID 0921536-6

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1 REPORTING OF ADVERSE REACTIONS

The Finnish Medicines Agency Fimea maintains a national register of adverse reactions to drugs, which contains adverse reactions reported by persons authorised to prescribe or supply drugs, other healthcare professionals, and drug users. The register of adverse reactions to drugs is governed by section 30 e of the Medicines Act (395/1987) as well as by the Act (556/1989) and Decree (774/1989) on National Personal Records Kept under the Health Care System. Under section 53 of the Infectious Diseases Act (1227/2016), reports of adverse reactions to vaccines are recorded in Fimea's register of adverse reactions. Vaccines are medicinal products as specified in the Finnish Medicines Act; any reference to drugs herein therefore also includes vaccines.

An adverse reaction means a harmful and unintended response to a drug.

Persons authorised to prescribe or supply drugs are advised to report any adverse reactions they observe or suspect in association with the use of drugs to Fimea, in the following cases in particular:

- When the use of a drug has or is suspected of having caused a serious adverse reaction. These include reactions which have:
  - resulted in death,
  - been life-threatening,
  - required or prolonged hospitalisation,
  - resulted in permanent or significant disability or incapacity, and
  - caused congenital anomalies/birth defects.
- When the use of a drug has or is suspected of having caused a harmful interaction with another drug.
- When the adverse reaction is unexpected (nature or seriousness is not consistent with the summary of product characteristics of the drug).
- When the adverse reaction has or is suspected to have been caused by a new drug.
- When the person reporting the adverse reaction feels that the reaction occurs more frequently.
- When the adverse reaction is due to a medication error (e.g. the adverse reaction is caused by incorrect route of administration, or administration to a wrong patient).
- When the adverse reaction is due to a drug overdose.
- When the adverse reaction is due to unlicensed use of the drug, including abuse and occupational exposure.

2 CONTENTS OF A REPORT OF AN ADVERSE REACTION

The person reporting an adverse reaction should ensure that he or she is able to submit, if necessary, detailed information and additional details that may be required for an evaluation of the case reported, such as:

- **Description of the adverse reaction**: symptoms, diagnosis, examinations to determine the case and any treatments
- **Suspected drug or medication**: dose, method of administration, date of initiation and discontinuation of medication, therapeutic indication, other concomitant medication
- **Drug user data**: identifiable/traceable person (age, sex, social security number), health condition before initiation of medical treatment, other illnesses and familial predisposition, other risk factors
- **Course of the event**: duration of the adverse reaction, hospital treatment, recovery, effect of the discontinuation or recommencement of the drug or medication on the adverse reaction
- **Identification information of person reporting the adverse reaction**: the identifiable person and whether the person is a healthcare professional
- Product trade name and batch number in **biological products** (including vaccines)

The person reporting the adverse reaction should ensure that adverse reactions, particularly severe and medically significant ones, can be associated with a specific drug user to allow the identification of the same reaction if it has been reported from several different sources.

3 SUBMITTING A REPORT OF AN ADVERSE REACTION

It is recommended that reports of adverse reactions be submitted by using the electronic form on Fimea's website (www.fimea.fi) or the PDF form "Report of a suspected adverse reaction to a drug/vaccine", which can be printed out.

Under section 52 of the Infectious Diseases Act (1227/2016), health care professionals are entitled to report to Fimea all diagnosed or suspected adverse reactions to a vaccine. Reports on adverse reactions to vaccines are submitted in the form provided by Fimea for reporting adverse reactions.

Drug users can also report adverse drug reactions to Fimea's register of adverse reactions (www.fimea.fi). Submitting a report of an adverse reaction is not a substitute for a consultation with the relevant health care provider to determine whether treatment or medication is required. This is why the treating physician or dentist should be informed of any suspected adverse drug reactions.

Fimea submits information in the register of adverse reactions regarding vaccines to the National Institute for Health and Welfare for vaccine safety monitoring purposes. Fimea submits details of all reported adverse reactions to the marketing authorisation holder of the suspected drug, the World Health Organization's (WHO) Register of Adverse Reactions and, where serious adverse reactions are concerned, to the European Medicines Agency (EMA). The primary purpose of the reporting system is to detect previously unidentified rare adverse drug reactions. The benefits and risks of drugs are continuously assessed on the basis of information obtained from the register of reported adverse reactions.

4 ENTRY INTO FORCE

This guideline enters into force on 1 March 2017.

Sinikka Rajaniemi	Tiina Jaakkola
Director General	Senior Medical Officer

DISTRIBUTION

Persons authorised to prescribe or supply drugs

FOR INFORMATION

Ministry of Social Affairs and Health

National Supervisory Authority for Welfare and Health

National Institute for Health and Welfare

Regional State Administrative Agencies

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

Helsinki University, Faculty of Pharmacy

Helsinki University, 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

The Finnish Pharmacists' Association

Finnish Dental Association

Finnish Medical Association

Finnish Nurses Association

Finnish Public Health Nurse Association

Finnish Medical Society Duodecim

Finnish Pharmacists Society

Poison Information Centre.

Finnish Mutual Insurance Company For Pharmaceutical Injury Indemnities