Regulation and Guideline 7 February 2019
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UNOFFICIAL TRANSLATION

Finnish Medicines Agency Administrative Regulation and Normative Guideline

REPORTING OF PRODUCT DEFECTS AND SUSPECTED FALSIFICATIONS

Legal basis

Medicines Act (395/1987), section 30o, as amended by Act 1200/2013

The administrative regulation also contains a guideline section, for the issuance of which no separate authorisation under law is required.

Target groups

Holders of marketing authorisations
Pharmaceutical manufacturers
Pharmaceutical wholesalers
National Institute for Health and Welfare
Finnish Food Authority
Finnish Red Cross Blood Service
Pharmacies
Subsidiary pharmacies
Hospital pharmacies
Dispensaries
Military Pharmacy

Period of validity

This Administrative Regulation and Normative Guideline will enter into force on 9 February 2019 and will remain so until further notice.

Regulation repealed

Finnish Medicines Agency Administrative Regulation 4/2009

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ADMINISTRATIVE REGULATION

1 GENERAL

Despite quality assurance measures, errors may be made in the manufacture of medicinal products, thus resulting in the sale of medicinal products which do not meet quality requirements or might be hazardous to users.

A **product defect** means a non-conformity in quality comprising an entire batch, a part thereof or an individual package, occurring in a medicinal product intended for human or animal use or the packaging of said product that is supplied by a medicinal product manufacturer or prepared or supplied by a pharmacy, hospital pharmacy, dispensary or military pharmacy.

Falsified medicinal product means a medicine with, for a reason other than unintentional quality defect, a false representation of:

1) any of its identification data, which include:

   a. labelling and packaging characteristics;

   b. the name of the medicine;

   c. the composition of the medicine, including all the ingredients and other components of the medicine that are not medicinal substances or packaging materials;

   d. the strength of any component of the medicine;

2) the origin, manufacturer, country of manufacture, country of origin or marketing authorisation holder of the medicine; or

3) the product history of the medicine, including materials and documents related to the distribution channels used.

A **suspicion of a falsified medicine** may arise when, for example, the safety features of medicines are examined. The safety features of medicines consist of a unique package identifier and an anti-tampering device. A suspected falsification may also relate to such medicinal products that are not allowed to bear the aforementioned safety features.

This Administrative Regulation concerns actual or suspected cases of product defects and falsified medicines. The regulation also applies to cases where the CEP (Certificate of the European Pharmacopoeia) of the active substance or excipient included in the medicinal product has expired or the place of manufacture of the medicine fails to meet the requirements of good manufacturing practice (GMP) of medicines. Additionally, the regulation applies to any cases of falsification noticed in the legitimate supply chain of medicines.

Marketing authorisation holders and pharmaceutical wholesalers are required to submit to the Finnish Medicines Agency up-to-date information about their employees who are responsible for addressing cases of product defects, complete with contact details. The notification shall be submitted

using the form that is available on the Finnish Medicines Agency website (http://www.fimea.fi).

2 CLASSIFICATION OF PRODUCT DEFECTS

Product defects are classified according to the risk posed to the intended user of a medicine. The classification is used in determining the selection and implementation of proportionate actions.

The classification of product defects calls for expertise and case-by-case risk assessment. The marketing authorisation holder is responsible for assessing the risk and classifying the product defect. Pharmacies, hospital pharmacies, dispensaries and the military pharmacy are responsible for the classification with regard to their own preparations.

Class 1

Product defects which are or may be life-threatening or pose a serious hazard to health.

Examples:

- the package contents do not match the package labelling
- microbiological contamination of a sterile preparation
- chemical or physical contamination with severe consequences

Class 1 product defects must be immediately reported to the Finnish Medicines Agency which, in turn, is responsible for reporting the product defect to other pharmaceutical regulatory authorities internationally at the same time as the necessary measures are initiated in Finland.

Class 2

Product defects which are or may be hazardous to the user or affect the success of medical treatment, but which do not belong to Class 1.

Examples:

- an error in the printed packaging material
- the package leaflet is missing or incorrect
- microbiological, chemical or physical contamination
- the preparation does not conform to quality requirements (e.g. concentration, stability, amount filled)
- leaking package (e.g. cytotoxic preparations, highly active medicines, childproof packaging)

Class 2 product defects must be immediately reported to the Finnish Medicines Agency which, in turn, is responsible for reporting the product defect

to other pharmaceutical regulatory authorities internationally within a prescribed timeframe.

Class 3

Product defects which probably do not pose a significant health hazard to users, but whose occurrence otherwise justifies removal of the product from the market.

Examples:

- defective or inadequate packaging
- a visible, but harmless impurity

Class 3 product defects must be immediately reported to the Finnish Medicines Agency which, if necessary, will report the product defect to other pharmaceutical regulatory authorities internationally.

Other product defects

Product defects which do not pose a health hazard to the user or a risk to the medical treatment.

Examples:

- inconsequential print error
- inconsequential non-conformity in the packaging appearance

Other product defects must be reported to the Finnish Medicines Agency once every six months by no later than 31 January and 31 July.

3 REPORTING PRODUCT DEFECTS TO AUTHORITIES

3.1 Class 1–3 product defects

All Class 1–3 product defects must be reported to the Finnish Medicines Agency after taking the immediate measures necessitated by the case. Product defects must be reported by telephone or e-mail.

Up-to-date contact information and an electronic form for reporting product defects can be found on the Finnish Medicines Agency website (http://www.fimea.fi). Any information given orally must also be submitted in writing.

The following information about the product defect must be given:

- the name, strength, pharmaceutical form and package size of the medicinal product
- the class of the product defect
- the date when the product defect was detected

- the observed defect and its extent
- known damages caused
- an assessment of medicinal safety risks
- the batch number
- any other information necessary to identify the product
- the batch size (the amount manufactured in Finland or imported to Finland) and the quantity in stock
- information on any export of the preparation to other countries
- actions taken and planned
- the marketing authorisation holder, manufacturer of the medicinal product and medicinal product wholesaler responsible for distribution in Finland
- contact details of the person handling the matter

A single missing piece of information may not delay filing the report.

The actions to address the product defect must be initiated even if the authority cannot be immediately reached.

3.2 Other product defects

Product defects that do not belong to classes 1-3 must be reported in an aggregated form once every six months, no later than 31 January and 31 July. The reports shall be submitted by e-mail to the Finnish Medicines Agency (registry@fimea.fi).

The report shall be categorised by medicinal product. The report must contain the following information:

- the name, strength, pharmaceutical form and package size of the medicinal product
- the date when the product defect was detected
- the observed defect and its extent
- the corrective and preventive actions taken and the date on which they were taken.

3.3 Reporting to other authorities

If the product defect involves a medicinal product with a marketing authorisation issued under the centralised procedure, the marketing authorisation holder must contact not only the Finnish Medicines Agency, but also the European Medicines Agency (EMA; contact information can be found on their website at http://www.ema.europa.eu). If a product defect is detected in a medicinal product batch exported to another country, the defect must be immediately reported to the Finnish Medicines Agency as well as the

pharmaceutical regulatory authorities and distributors of the destination country.

4 REPORTING OF SUSPECTED FALSIFICATIONS TO AUTHORITIES

If there is a reason to suspect that the package of a medicine has been tampered with or if the safety features of the medicine indicate that the medicine may not be genuine, this must be immediately reported to the Finnish Medicines Agency. The duty to report also concerns suspected falsifications of medicinal products that are not allowed to bear safety features.

The reporting must be made by telephone or e-mail. Up-to-date contact information for filing the report can be found on the Finnish Medicines Agency website (https://www.fimea.fi). Any information given orally must also be submitted in writing.

When a suspected or actual falsification is reported, the following information must be provided:

- the name, strength, pharmaceutical form and package size of the medicinal product
- the date when the suspected or actual falsification was noticed
- the serial number of the packaging if the product concerned bears safety features
- the batch number and expiry date marked on the package
- any other information necessary to identify the product
- the number of packages on the market
- information about the place(s) where the packages where purchased
- information about the supply chain of the packages
- any other information concerning the case and the packaging related to the suspected or actual falsification
- actions taken and planned
- the marketing authorisation holder, manufacturer of the medicinal product and medicinal product wholesaler responsible for distribution in Finland
- contact details of the person handling the matter

A single missing piece of information may not delay filing the report. The actions to address the suspected or actual falsification must be initiated even if the authority cannot be immediately reached.

5 RESPONSIBILITIES

The marketing authorisation holder shall bear primary responsibility for addressing a product defect or suspected or actual falsification. Pharmacies, hospital pharmacies, dispensaries and the military pharmacy shall bear primary responsibility for addressing product defects and cases of suspected or actual falsification concerning medicines prepared by them.

All entities operating in the pharmaceuticals sector shall be responsible for taking the appropriate measures to address any defects detected in products they manufacture, import, distribute or release for consumption and any cases of suspected or actual falsification.

The Finnish Medicines Agency oversees that the actions taken to address a product defect or a case of a suspected or actual falsification are adequate and appropriate. If the parties or persons responsible fail to take or underestimate the actions required of them, the Finnish Medicines Agency may also order that the distribution, sale or other release for consumption of the medicinal product be stopped and the medicinal product be withdrawn from the market under section 101 of the Medicines Act.

6 PREPARATIONS

All entities operating in the pharmaceuticals sector shall ensure for their part that any product defects detected and cases of suspected or actual falsification are dealt with effectively and appropriately. Adequate preparations to address any such cases must be in place irrespective of the time. The actions to be taken and communications shall be planned, and guidelines shall be provided for them. These guidelines shall be reassessed and updated on a regular basis. The personnel shall be trained to act in accordance with these guidelines.

7 HANDLING OF A PRODUCT DEFECT AND SUSPECTED FALSIFICATION

Any health hazards to the medicinal product user caused by a product defect or falsified medicine shall be prevented or minimised. The actions taken shall also take into consideration other consequential effects, such as the impact on food safety. The distribution and sale of defective medicinal products shall be stopped and, if necessary, they shall be removed from consumption altogether, and information shall be provided as the situation requires.

If a product defect that is or may be life-threatening or extremely hazardous to the health of the user is suspected, it may be necessary to initiate measures based on the currently available information and a risk assessment even before the suspected product defect is verified.

The actions taken related to the handling of a product defect or suspected falsification shall be documented in the order of occurrence in such a way that all the events, actions and persons involved can, if necessary, be traced.

The cause of the product defect shall be determined. The incidence of similar defects in other batches shall be investigated and the necessary actions shall be taken. Corrective actions shall be taken to prevent similar defects from occurring.

The retention period for documentation related to the handling of product defects and suspected falsifications should be at least five years, unless a longer retention period is elsewhere prescribed.

8 RECALLS

Medicinal products with a class 1–3 product defect shall, as a rule, be withdrawn from sale and distribution.

When the recall of a medicinal product is considered, it shall be determined whether this will disrupt the availability of the medicinal product and what kind of effects on the patients' medicinal treatment such withdrawal will have.

If all batches of the medicinal product concerned are withdrawn from sale and distribution, the marketing authorisation holder should immediately take measures to make another batch of the medicinal product that is fully compliant with the quality requirements available for sale.

Pharmacies should ensure that all managers of subsidiary pharmacies and medicine chests working under them are kept informed of product defects and falsified medicines. If a pharmacy supplies medicinal products to social services and health care units, they shall also be informed of product defects and falsified medicines.

At social services and health care units, the recall shall also be carried out in wards and other units.

Defective medicinal products shall be withdrawn from veterinary hospitals, veterinary stations and individual veterinarians.

When a recall is carried out or other measures related to the situation are taken, every effort shall be made to ensure that all storages are taken into consideration. Recalled products shall be separated from the rest of the stock using adequate quarantine procedures.

9 COMMUNICATIONS

In the event of product defects or falsifications, adequate and timely communications shall be ensured.

The marketing authorisation holder shall be primarily responsible for providing wholesalers and retailers and, on a case-by-case basis, other operators

in the health care sector with information about a product defect and the actions taken to address it.

In addition to a potential notification by the phone, notification shall also be made in writing. The notification shall be submitted to the Finnish Medicines Agency in advance.

The notification shall clearly state that the matter involves a product defect that requires immediate action. The notification shall indicate the following:

- The term “product defect” and the product defect class must appear in the header
- The name, strength, pharmaceutical form and package size of the medicinal product
- The batch numbers the notification pertains to
- Any other information necessary to identify the product
- The defect detected
- The necessary actions
- Any additional information deemed necessary (e.g. information pertaining to the availability of the medicinal product)
- Contact details of the person handling the matter

The notification may not be used for the purposes of other communications.

PROVISIONS COMMON TO THE ADMINISTRATIVE REGULATION AND NORMATIVE GUIDELINE

10 GUIDANCE AND ADVICE

On request, the Finnish Medicines Agency will provide guidance and advice on the application of this regulation and the handling of product defects.

11 PERIOD OF VALIDITY

This Administrative Regulation and Normative Guideline will enter into force on 9 February 2019 and will remain so until further notice.

Director General	Eija Pelkonen
Senior Pharmaceutical Inspector	Sami Paaskoski

DISTRIBUTION

Marketing authorisation holders

Pharmaceutical manufacturers

Pharmaceutical wholesalers

National Institute for Health and Welfare

Finnish Food Authority

Finnish Red Cross Blood Service

Pharmacies

Subsidiary pharmacies

Hospital pharmacies

Dispensaries

Military Pharmacy

FOR INFORMATION

Pharma Industry Finland

Finnish Association of Pharmaceutical Distributors

Finnish Generic Pharmaceutical Association

Finnish Parallel Drug Importers Foundation

Finnish Importers of Veterinary Medicines

The Association of Finnish Pharmacies

The Finnish Pharmacists' Association

The Finnish Pharmacists' Society

The Finnish Veterinary Association

The Association of Finnish Local and Regional Authorities

University of Helsinki, Faculty of Pharmacy

University of Helsinki, Faculty of Veterinary Medicine

University of Eastern Finland, Faculty of Health Sciences

Åbo Akademi University, Faculty of Science and Technology

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