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**UNOFFICIAL TRANSLATION
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Product defects

Authorisation provisions

Medicines Act (395/1987) section 30 a, as amended by 773/2009

The regulation also includes a guideline section, whose issuance does not require separately specified authorization in law

Target groups

Marketing authorisation holders
Medicinal product manufacturers
Medicinal product wholesalers
National Institute for Health and Welfare
Finnish Food Safety Authority Evira
Finnish Red Cross Blood Service
Pharmacies
Subsidiary pharmacies
Hospital pharmacies
Dispensaries
Military Pharmacy

Validity

The regulation and guideline will enter into force on 1 January 2010 and are valid indefinitely

Norm to be repealed

National Agency for Medicines regulation 3/2004

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Contents

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 involves a non-conformity in quality comprehending 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.

This regulation applies to product defect cases. The regulation is also applied in cases where the CEP (Certificate of the European Pharmacopoeia) of an active ingredient or excipient contained in a medicinal product has expired or the product's place of manufacture does not meet the requirements set for the good manufacturing practices (GMP) of medicinal products. Furthermore, the regulation is applied in cases involving counterfeit products found in legal distribution chain.

Marketing authorisation holders and pharmaceutical wholesalers must provide the Finnish Medicines Agency with up-to-date information on personnel appointed to oversee the handling of product defects and their contact information. Notifications are made using the appropriate form, which can be found 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. Classification is used in determining the selection and implementation of the correct, proportional actions.

Product defect classification requires expertise and case-specific risk assessment. The marketing authorisation holder is responsible for assessing the risk and classifying the defect. Pharmacies, hospital pharmacies, dispensaries and military pharmacy are responsible for the classification of 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 label
- microbiological contamination of a sterile preparation

- chemical or physical contamination with serious consequences

Class 1 product defects must be reported immediately to the Finnish Medicines Agency, which is, in turn, responsible for reporting the product defect to other, international medicine control authorities 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 reported to the Finnish Medicines Agency, which is, in turn, responsible for reporting the product defect to other, international medicine control authorities 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 reported immediately to the Finnish Medicines Agency, which, if necessary, will report the product defect to other, international medicine control authorities.

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 to authorities

3.1 Class 1-3 product defects

All Class 1-3 product defects must be reported to the Finnish Medicines Agency immediately after taking the necessary initial measures. Product defects must be reported by telephone or email. 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). All information given orally must also be submitted in writing.

The following information on the product defect must be given:

- name, strength, dosage form and package size of the medicinal product
- the product defect class
- the date on which 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 required to identify the product
- the batch size (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 holder of the marketing authorisation, manufacturer of the medicinal product and medicinal product wholesaler responsible for distribution in Finland
- the contact information for the person handling the case

A single missing piece of information should not delay making a report.

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

3.2 Other product defects

Product defects, which do not belong to classes 1-3, must be compiled and reported together once every six months, no later than 31 January and 31 July. Reports should be made by email to the Finnish Medicines Agency (registry@fimea.fi).

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

- name, strength, dosage form and package size of the medicinal product
- the date on which 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 centralised marketing authorisation, the marketing authorisation holder must contact the Finnish Medicines Agency as well as the European Medicines Agency (EMA; contact information can be found on their website http://www.ema.europa.eu).

If a product defect is detected in a medicinal product batch exported to another country, the defect must be reported immediately to the Finnish Medicines Agency as well as the medicine control authority and distributors of the destination country.

Guideline

4. Responsibilities

The marketing authorisation holder shall bear primary responsibility for addressing a product defect. Pharmacies, hospital pharmacies, dispensaries and military pharmacy shall bear primary responsibility for addressing product defects 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 dispense.

The Finnish Medicines Agency ensures that the actions taken to address a product defect are adequate and appropriate. If the parties or persons responsible for the product defect neglect or compromise the actions being taken, the Finnish Medicines Agency may prohibit the distribution, sale and dispensing of a defective or allegedly defective medicinal product batch, as stipulated in section 101 of the Medicines Act.

5. Preparations

All entities operating in the pharmaceuticals sector shall ensure that any product defects detected are dealt with effectively and appropriately. Adequate preparations to address any cases should be made regardless of the time. There should be adequate preparedness to address any cases regardless of the time. Actions to be taken and communications shall be planned and guidelines set. These guidelines shall be reassessed and updated on a regular basis. Personnel shall be trained in accordance with these guidelines.

6. Handling of product defect cases

Any health hazards to the medicinal product user caused by a product defect shall be prevented or minimised. Actions taken shall also take into consideration other effects, such as the impact on food safety. The distribution and sale of defective medicinal products shall be stopped and,

if necessary, removed from consumption altogether and information shall be provided in accordance with the situation.

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

Measures related to the handling of a product defect shall be documented in the order of occurrence in such a way that all events, measures and persons involved can, if necessary, be traced.

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

The archiving period for documentation related to the handling of product defects shall be at least five years, unless a longer archiving period is otherwise enacted.

7. Recalls

Medicinal products with a class 1-3 product defect shall be fundamentally removed from sale and distribution.

When considering the recall of a medicinal product, it shall be determined whether this will affect availability of the medicinal product and what impact it will have on patient medicinal therapies.

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

Pharmacies shall ensure that all managers of subsidiary pharmacies and medicine chests working under them are kept informed of the product defect. If a pharmacy supplies medicinal products to social and health care institutions, the product defects shall also be reported to them.

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

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

When carrying out a recall or taking other measures related to the situation, 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 measures.

8. Communications

In the event of a product defect adequate and timely communications shall be ensured.

The marketing authorisation holder shall be primarily responsible for providing information on the product defect and actions being taken to address it to wholesalers and retailers as well as, on a case-specific basis, other health care actors.

In addition to a possible telephone report, 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 mention the following items:

- The term "product defect" and product defect class must appear in the header
- Name, strength, form and package size of the medicinal product
- Batch numbers to which the notification applies
- Any other information required to identify the product
- Detected defect
- Necessary actions
- Additional information that may be considered necessary (e.g. information pertaining to the availability of the medicinal product)
- The contact information for the person handling the case

No other information should be included to the notification being submitted.

Common statutes applicable to the regulation and guideline

9. Guidance and counselling

Upon request, the Finnish Medicines Agency shall provide guidance and counselling in the application of this regulation and guideline and the handling of product defects.

10. Entry into force

This regulation and guideline shall enter into force on 1 January 2010.

Director General Sinikka Rajaniemi

Senior Pharmaceutical Officer Sami Paaskoski

Distribution

Marketing authorisation holders
Medicinal product manufacturers
Medicinal product wholesalers
National Institute for Health and Welfare
Finnish Food Safety Authority Evira
Finnish Red Cross Blood Service
Pharmacies
Subsidiary pharmacies
Hospital pharmacies
Dispensaries
Military pharmacy

For information

Pharma Industry Finland
Apteekkitavaratukkukauppiaat ry
Finnish Generic Pharmaceutical Association
Suomen Lääkerinnakkaistuojat ry
Importers of veterinary medicines
Association of Finnish Pharmacies
Finnish Pharmacists' Association
Finnish Pharmacists' Society
Finnish Veterinary Association
Association of Local and Regional Authorities
University of Helsinki, Faculty of Pharmacy
University of Helsinki, Faculty of Veterinary Medicine
University of Kuopio, Faculty of Pharmacy
Åbo Akademi University, Department of Biosciences, Pharmaceutical Sciences