Regulation 6 February 2019
Ref. no. 007317/00.01.02/2018

1/2019

UNOFFICIAL TRANSLATION

Finnish Medicines Agency Administrative Regulation

GOOD DISTRIBUTION PRACTICE OF MEDICINAL PRODUCTS

Legal basis

Medicines Act (395/1987), section 11, subsection 1 and section 34, subsection 3 as amended by Act 1200/2013, and section 35a, subsection 2 as amended by Act 773/2009.

Target groups

Pharmaceutical wholesalers
Pharmaceutical manufacturers

Period of validity

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

Regulation repealed

Finnish Medicines Agency Administrative Regulation 5/2013

TABLE OF CONTENTS

1 GENERAL

Medicinal products must be distributed in compliance with good distribution practice.

Distributors of medicinal products must maintain a quality system with extensive procedures to ensure the efficacy, safety and quality of the medicinal products at every stage of the supply chain, as well as measures to prevent any medicinal products entering the supply chain from outside the legal manufacture and supply chain. These procedures must include measures to withdraw from sale any non-compliant medicinal products.

The distributor's quality system must provide for proper storage and transport of the medicinal products, and immediate and efficient action in case of product error or falsification. The distributor must ensure the availability and timely delivery of medicinal products and check the delivered orders for accuracy. Any suspicions of falsified medicinal products must be immediately reported to the Finnish Medicines Agency (hereinafter Fimea).

The distributor of medicinal products may procure medicinal products exclusively from legal suppliers, and the distributor must use every means available to verify the origin of a received product to minimise the risk of product falsification.

Medicinal product wholesalers must keep records of imports, procurement, storage and sale of medicinal products as set out in section 36 of the Medicines Act (395/1987) and section 7 of the Medicines Decree (693/1987).

2 SCOPE OF APPLICATION

This regulation pertains to the good distribution practice of medicinal products. It applies to all medicinal product wholesale distributors referred to in section 3 of the Medicines Act and to medicinal product manufacturers acting as distributors of their own products.

This regulation concerns the distribution of medicinal products from the manufacturer through a wholesaler to retail sales or to other licensed dispensers. These include pharmacies, subsidiary pharmacies, hospital pharmacies and dispensaries, as well as veterinarians and doctors or dentists conducting clinical drug trials.

In addition to the above, this Administrative Regulation applies to the supply of medicinal product samples as defined in section 35, subsection 2 of the Medicines Act pursuant to section 35 of the Medicines Act.

3 DEFINITIONS

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

GDP guidelines European Union's Guidelines on Good Distribution Practice of Medicinal Products for Human Use (2013/C 343/1)

Good distribution practice of medicinal products means the part of a quality system that is designed to ensure the unaltered quality of medicinal products through the supply chain from the manufacturer's premises to a pharmacy or other licensed dispenser or retail distributor.

Accountable director means the accountable director in medicinal product wholesale referred to in section 33 of the Medicines Act and the accountable director in medicinal product manufacture referred to in section 9 of the Medicines Act.

Distributor of medicinal products means medicinal product wholesalers and manufacturers

4 RELATIONSHIP TO OTHER REGULATIONS AND GUIDELINES

Fimea's regulations on the delivery of medicines and on online pharmacy services contain provisions regarding retail distribution to pharmacies.

Fimea's regulation on the operations of hospital pharmacies and dispensaries contains provisions on distribution to hospital pharmacies.

Fimea's regulations on clinical drug trials contains provisions regarding clinical drug trials on humans.

Fimea's regulation on product defects must be complied with when dealing with and withdrawing from sales any defective medicinal products.

5 GOOD DISTRIBUTION PRACTICE OF MEDICINAL PRODUCTS

5.1 Medicines subject to a marketing authorisation or registered medicines for human use

All distributors of medicines subject to a marketing authorisation or registered medicines for human use must comply with the GDP guidelines.

5.2 Medicines other than those referred to in section 5.1

The GDP guidelines must be followed in the distribution of medicines, with the following additional instructions:

Each lot delivered must be checked to ensure correct delivery and product quality before approval for re-distribution. In this connection, the manufacturer's certificate of release for distribution must also be checked.

The distributor of the medicinal product must follow their internal guidelines and check the information on the medicinal products, such as names, strengths, product numbers, pharmaceutical forms, package sizes and shelf-life before moving products into storage facilities.

Records must be kept of all medicinal product orders. A document must be attached with each medicinal product delivery lot indicating relevant infor-

mation such as order or delivery date, name of the medicinal product, strength, pharmaceutical form, package size, the number of packages ordered/delivered, and the names and addresses of the supplier and the recipient.

Medicinal products are to be distributed in compliance with the European Union's guidelines on Good Distribution Practice. In connection with medicinal product delivery, the distributor must provide the customer with a quality control certificate from any re-packaging facility as well as the original manufacturer's quality control certificate.

5.3 Ensuring the availability of medicinal products

Section 37 of the Medicine Act requires that medicinal product wholesalers must seek to ensure that the quantity of medicinal products they have for sale corresponds to the need for such products. Medicinal product distributors must inform pharmacies of any temporary availability problems either directly or through their contract distributors in order to keep pharmacies informed of any availability problems and to provide an estimate of the duration of the delivery interruption. The medicinal products distributed must have sufficient shelf-life considering the purpose and dosage of the medicinal product in question. If the shelf-lives of the product lots available are exceptionally short, ordering customers must be duly informed.

6 PERSONNEL

6.1 Accountable director

In the GDP guidelines, the accountable director is referred to as the Responsible Person.

Section 3 of the Medicines Decree requires the licence holder to immediately notify Fimea if the accountable director changes in manufacture, and section 4 if the accountable director changes in wholesale. This notification must include the licensed pharmacist's registration number, issued by the National Supervisory Authority for Welfare and Health, for the new accountable director to be appointed, as well as the person's written acceptance of this position. The medicinal product manufacturer's accountable director must notify Fimea of his/her licensed pharmacist's registration number, if any. If a deputy to the accountable director is appointed, Fimea must be notified as explained above. The distributor must keep records of the accountable director's deputies.

6.2 Other personnel

The distributor must have a designated contact person for all communication between Fimea and the distributor in matters regarding the wholesale and manufacture of medicinal products as well as mandatory reserve supplies. The contact person must be approved by the accountable director, unless the director personally acts as the contact person. The contact person and other persons in key drug safety positions, including the accountable director, must be directly employed by the licence holder.

7 GUIDANCE AND ADVICE

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

8 PERIOD OF VALIDITY

This regulation will enter into force on 9 February 2019 and will remain so until further notice.

Director General	Eija Pelkonen
Senior Inspector	Minna Kurronen

DISTRIBUTION

Pharmaceutical wholesalers

Pharmaceutical manufacturers

FOR INFORMATION

The Ministry of Social Affairs and Health

Ministry of Employment and the Economy

Ministry of Agriculture and Forestry

Finnish Association of Pharmaceutical Distributors

Pharma Industry Finland

Finnish Generic Pharmaceutical Association

The Association of Finnish Pharmacies

The Finnish Pharmacists' Association

The Finnish Pharmacists' Society

University of Helsinki, Faculty of Pharmacy

University of Eastern Finland, Faculty of Health Sciences

Åbo Akademi University, Division for Natural Sciences and Technology, Pharmaceutical Sciences

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