

PHARMACEUTICAL INDUSTRY AND WHOLESALING ORDERING AND STORAGE OF MEDICINAL PRODUCTS

Medicinal products in most European countries reach the patients by this classic distribution chain:

Manufacturer (producer) > Wholesaler (distributor) > Pharmacy > Patient

PHARMACEUTICAL INDUSTRY

The function of the industry (manufacturers) is mass producing of pharmaceutical products:

- *medicinal products (for human or veterinary use)*
- *pharmaceutical substances*
- *medical devices*
- *laboratory and diagnostic kits, equipment, ...*

Good Manufacturing Practice (GMP)

The basic requirements of medicinal product quality are included in the European Pharmacopoeia.

Pharmaceutical industry – contact with wholesalers:

- *business contact*
- *specialized information on medicinal products*

Pharmaceutical industry – contact with pharmacies:

- *specialized information on medicinal products, administrative information*
- *pharmaceutical/medical advertising*

PHARMACEUTICAL DISTRIBUTION

Pharmaceutical distribution includes prewholesaling and wholesaling:

- Prewholesaling - manufacturer`s activity
- Wholesaling - wholesaler`s activity

There are 2 possible ways of distribution:

- Direct distribution
- Indirect distribution

Types of wholesalers – classification according to the distributed range of products

- Full-line wholesalers
- Short-line wholesalers
- Specialized wholesalers

Wholesaler`s obligations

The basic obligations of the holders of a wholesale dealing authorisation are defined by the directive of the European Community 2001/83/EC.

The wholesalers should be:

- obtain their supplies of medicines only from a distributor or from a manufacturer
- supply medicines only to a distributor or who are authorised to supply medicines to the public
- keep records, for inspection purposes, giving for any transaction with medicines received or dispatched
- comply with the principles and guidelines of Good Distribution Practice

Good Distribution Practice (GDP)

- is a quality warranty system, which includes requirements for purchase, receiving, storage and export of medicinal products
- regulates the division and movement of pharmaceutical products

PHARMACEUTICAL DISTRIBUTION IN THE CZECH REPUBLIC

Legislation

- Act on Pharmaceuticals No. 378/2007 Coll.
- Health Ministry Decree on Manufacture and Distribution of Pharmaceutical No. 229/2008 Coll.

Authorisation for wholesaling is issued by:

- in case of human medicinal products: *State Institute for Drug Control (SÚKL)*
- in case of veterinary medicinal products: *Institute for State Control of Veterinary Biologicals and Medicines (ÚSKVBL)*

Distributed may be:

- authorised medicinal products
- non-authorised medicinal products – only in specific cases

Nationwide pharmaceutical full-line wholesalers:

- *Alliance Healthcare, Via Pharma, Phoenix, Pharmos*
- AVEL – Association of Full-line Wholesalers – national organization of the Czech full-line distributors

LOGISTICS IN PHARMACY

Ordering – possible forms:

- *via internet – the most frequent form*
- by phone
- in written form

- ordering is possible several times in a day

- wholesalers deliver products to pharmacies also several times

- number of wholesalers – pharmacy can choose

Receipt of the delivery

- confirmation of receipt – stamp and signature of the pharmacy on the copy of delivery list

- control of the delivery - according to the delivery list

- *amounts of each medicines, expiration, integrity of packages, price*

Medicinal product storage in the pharmacy

- basic sources and rules (Decree on Good Pharmacy Practice, Pharmacopoeia, marketing authorisation)

- storage conditions

- system of storage – application forms / alphabetically / expiration

- separate storage

- separately from human medicines: veterinary medicines, medical devices, other products
- separately, marked: after date of expiration, defective packages, unusable medicines

Control activities

- storage conditions
- expiration
- batches with quality defects
- documentation