

# Activities with pharmaceuticals

## HANDLING

- research,
- preparation,
- manufacture,
- distribution,
- storage and keeping,
- supply and transportation,
- offering for the purpose of sale,
- dispensing,
- sale,
- use of pharmaceuticals in the provision of healthcare services or veterinary care, or the disposal of pharmaceuticals.

# Goal

Right MP

Right Patient

Right Dose

Right Route

Right Time

R response, documentation, education..

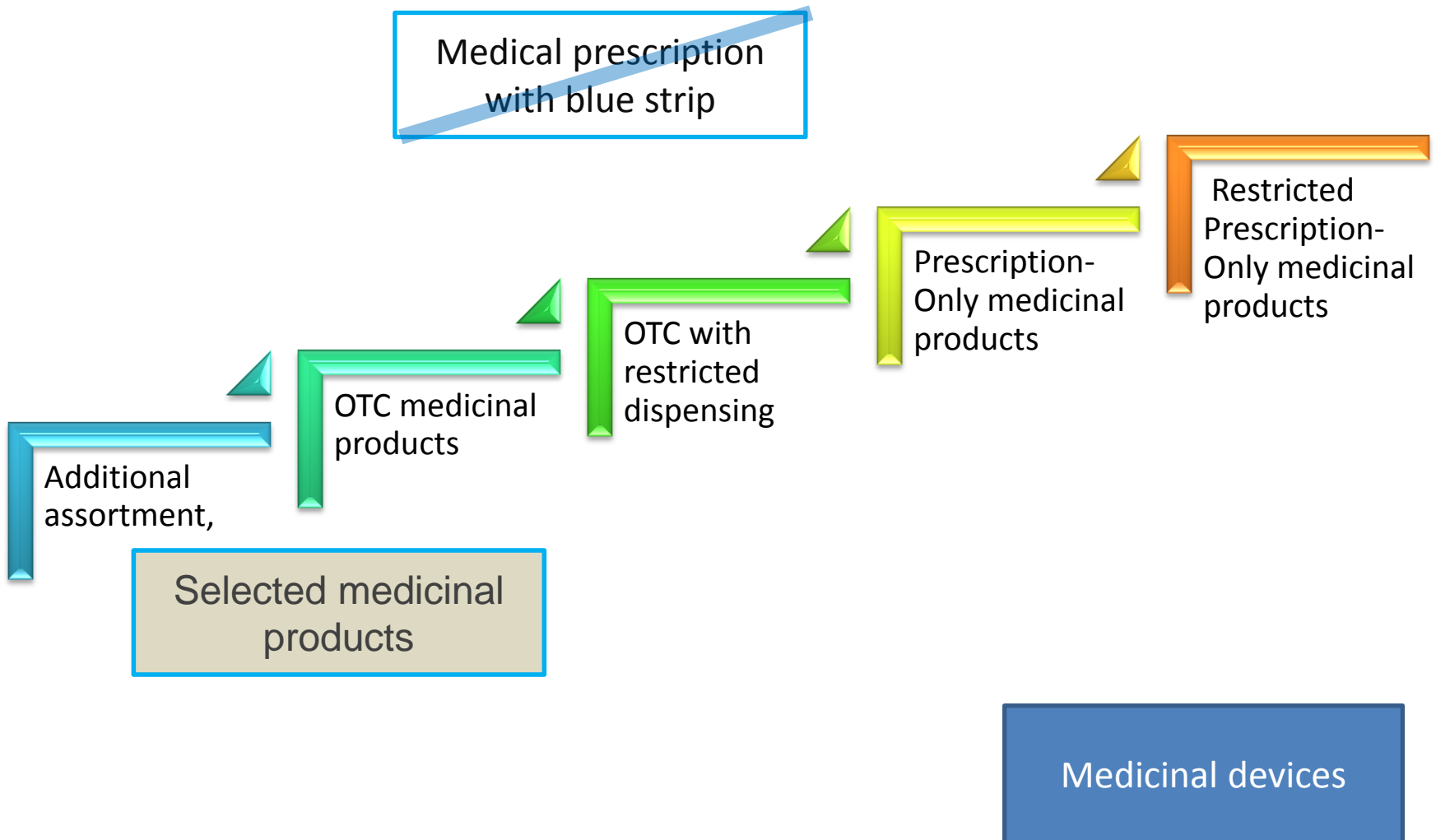
# Dispensing of medicinal products

- DIRECTIVE 2001/83/EC
- REGULATION (EC) No 726/2004

# Dispensing of medicinal products

- Act 378/2007 Coll. on Pharmaceuticals

# Assortment in CZE



# The most important questions – in practical way

Each category :

- Where
- Who
- Whom
- How

# Where?

- Pharmacies
- Public health protection authorities
- Nuclear medicine workplace
- Blood centres
- Immunology or microbiology workplace of a healthcare service provider or a public health protection facility
- Mail ordering
- Veterinarians

- Dispensaries of medical devices
- ....Physicians ?
- Vendors of selected medicinal products



# Dispensing – who, where, what?

Medicinal products may be dispensed in pharmacies by

- pharmacists;
- pharmaceutical assistants: OTC

## Physicians

- may „dispense“ only if the patient's health statute requires immediate medication use

and

it is not possible due to time or local conditions to ensure supply of needed medicines on the prescription.

# Dispensing – who, where, what?

- Vendors of selected medicinal products

Only selected medicinal products

## nuclear medicine workplace

- **only radiopharmaceuticals prepared at this workplace**

employees of **public health protection authorities** with professional qualification

- **only immunological products intended for vaccination**

doctors, pharmacists or other healthcare professionals of **a blood centre and a blood bank**

- **only blood derivatives and transfusion products;**

- immunology or microbiology workplace
- **only human autogenic vaccines prepared at this workplace.**

# Dispensing – who, where, what?

Medicinal products may be, furthermore, dispensed by:

- veterinarians authorised to engage in professional veterinary activities;

Only medicinal products intended for the treatment of animals.



# Dispensing of medicinal products

- quality of MP is not compromised
- MP before dispensing: handling complies with the conditions established in the MA

# Dispensing of medicinal products

- **Not compromise the integrity** of packaging of MP with marketing authorisation

(with the exception:

preparation of medicinal products

dispensing for a healthcare care facility)

# Dispensing of medicinal products

- Obligation:
  - **keep records** for the period of 5 years;

(identification of the pharmaceutical form, quantity of the active substance contained in a unit of weight, volume or pharmaceutical form, type of packaging, and pack size of the medicinal product)

- Obligation to **provide to the SIDC data** about dispensed medicinal products - Rx medicinal products. OTC with restriction...

# Dispensing of medicinal products

- Obligation to **co-operate**:
  - the replacement of a MP in which a quality defect has been detected;

If a pharmacy dispenses medicinal products to other pharmacies or inpatient healthcare providers:

- specified „in the licence“ of such pharmacy

# Obligation - right

- **Inform** the patient **about alternative options** for the MP and may replace (consent of the patient) -

identical in terms of its efficacy and safety, contains the same active substance with the same route of administration and the same pharmaceutical form.

Note: could be restricted by the prescriber

# Obligation - right

MP may be dispensed also to a **person other than the one for whom** it has been **prescribed**.

# Obligation - right

- **Doubts** arise in respect of **credibility** of the medical **prescription**,
- **doubts** as to whether **the person** to whom are products dispensed, **is able to guarantee proper use** of the MP

MAY NOT BE DISPENSED



# Obligation - right

- **Suspected abuse** of the medicinal product
- The **conditions** for dispensing of medicinal products with **restriction haven't been fulfilled**

MAY NOT BE DISPENSED

- -----
- **Interactions**
- (threat to the life or health of the worker)

# Conscientious objection

refusal to fulfill a legal obligation due to a conflict with conscience

## **Refuse**

But !!! - another worker will perform needed service / another health care facility

**Never** - If there is a possibility of:

- a threat to the patient's life
- serious threat to patient's health - due the refuse

(Act No. 372/2011 Coll., on health services and the terms and conditions for the providing of such services, as amended)

# Additional obligations

- **comply** with the principles of  
**good pharmacy practice**

# OTC

- Pharmacist, pharmaceutical assistant
- Statut OTC - SIDC – marketing authorisation
- **Switching** Rx → OTC; eventually. OTC → Rx

# Tools for dispensing

WWHAM:

- Who?
- What?
- How long?
- Action taken?
- Medication?

# Tools for dispensing

## ASMETHOD

- Age/appearance
- Self or someone else
- Medication
- Extra medicines
- Time persisting
- History
- Other symptoms
- Danger symptoms

# Tools for dispensing

## SIT DOWN SIR

- Site or location of a sign/symptom
- Intensity or severity
- Type or nature
- Duration
- Onset
- With (other symptoms)
- Annoyed or aggravated by....
- Spread or radiation
- Incidence or frequency
- Relieved by ....

# Dispensing OTC - ethics

- Do not offer more expensive products
- Do not offer more products than the corresponding to state of health / patient needs
- Do not prefer .... Supplier...
- Provide information to patient (self –service too!)



# Medicinal products - Rx Only

MP shall be available only Rx:

- present a **jeopardy** either directly or indirectly **even when used correctly** if taken without medical supervision;
- **frequently used incorrectly**, and as a result can present a direct or indirect jeopardy to human health;

# Medicinal products - Rx Only

- contain substances **serious** AR
- intended for **parenteral** administration
- contains a substance classified as **narcotic or psychotropic** or a precursor in amounts not allowing for being dispensed without medical prescription

# Medicinal products - Rx Only

- **lead to addiction** or be misused for illegal purposes
- due to its **novelty**

# Dispensing of Rx only

- **Verification of formal correctness**

**Suspend dispensing - absence:** paper form of Medical prescription:

- **signature of the prescribing physician / doctor**
- identification of providers of health services, and can not be completed and there is no risk of delay,
- Name and surname of the patient and can not be added unless if the risk of delay (in danger of death or serious health disorders appear)
- Patient ID-code and the insurance company and can not add, name and surname of breeder, and may not be complete.

# Dispensing of Rx only

- **Verification of formal correctness**
  - Including: prescribed amount of MP

# Dispensing of Rx only

## Verifying the correctness of the therapeutic content:

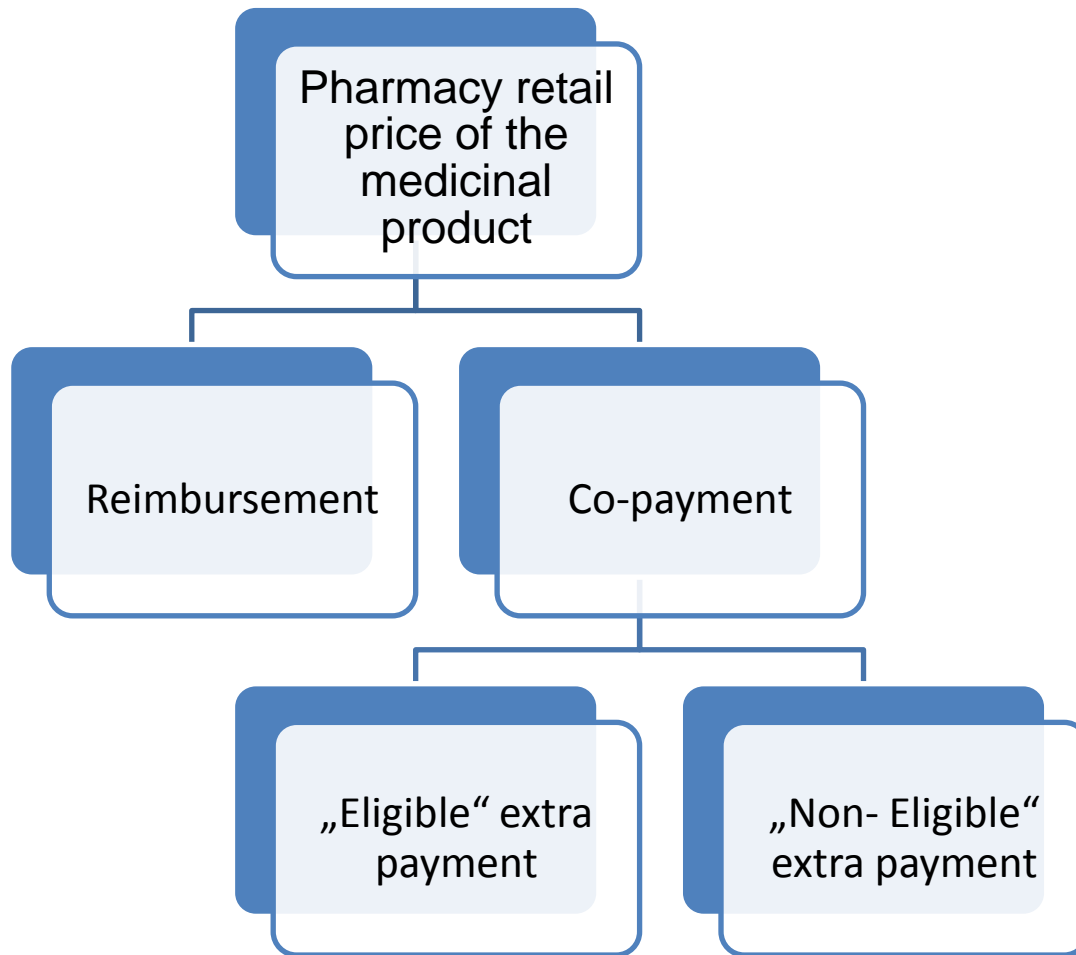
- dosing and dosage form;
- interactions

# Dispensing of Rx only

## Informations

- necessary **for the safe use** of the product
- necessary **for handling** with the product
- inform the patient upon the actual amount of **total reimbursement** covered by the public health insurance for the dispensed packages for each item in the medical prescription;
- .....patient counselling

# Reimbursement vs Co-payment





# Co-payment limit

Annual limit based on „Eligible“ co-payment

# Regulatory fees - patient

- Canceled!!!!
- Dispensing fee - insurance

# Reimbursement from the public health insurance

- List of medicinal products and foods for special medical purposes with reimbursement from the public health insurance
- **Updates – every month**
- SIDC
  - Maximum reimbursement from health insurance
  - Increased maximum reimbursement from health insurance

# Dispensing of medicinal devices

- Verification of formal correctness
- Verifying the correctness of the therapeutic content
- Informations

# OTC with restricted dispensing

In this category if:

- **causing jeopardy to human health which might be prevented by setting:**
  - certain restrictions on such dispensing
  - prior expert consultation with a pharmacist

# OTC with restricted dispensing

Such MP may **only** be dispensed:

- to the person for whom it is intended,

The provider authorised for the dispensing - obliged to maintain records of its dispensing.

# OTC with restricted dispensing

- Details and further restrictions may be established e.g.:
  - determination of the **age limit** of the natural person who requests the dispensing of such medicinal product,
  - specification of the **dose for individual administration**
  - restriction of the amount of the medicinal product to be dispensed to a single patient over a specified **period of time**.

# OTC with restricted dispensing

Pseudoephedrine – MP containing 30 mg / tbl

- the total amount of pseudoephedrine for an individual dispensing shall not exceed 900 mg pseudoephedrine

And

- shall not exceed 900 mg in 7 days concurrently



# Emergency contraception

- From 28.11.2011 – till Spring 2015:  
OTC with restriction
- NOW – OTC!!!

# emergency contraception

- Note : Ellaone – directly OTC....

# Restricted Prescription-Only medicinal products

In this category:

- due to its **pharmaceutical characteristics or novelty** or in the **interest of public health protection**, reserved for disease treatment which may only be conducted in **inpatient** healthcare facilities;
- is used to treat diseases which must be diagnosed in an **inpatient** healthcare facility or in healthcare facilities with adequate diagnostic equipment even if the administration and follow-up need not be carried out in such facilities;
- is intended for **out-patients** care but its use may produce **very serious adverse reactions** or may represent significant risk of abuse requiring special supervision is ensured during treatment.

# Restricted Prescription-Only medicinal products

- Only by specialists
- E-prescription
- **Restrictions** on the **amount** of a medicinal product dispensed to a single patient over a specified period of time can be set.

# Restricted Prescription-Only medicinal products

- „Medical Cannabis“:
  - Limits:
    - Age: 18
    - Diagnosis
    - Prescribed dose: 180 g / month
- MP with Misoprostol, mifepristone intended to:
  - Abortion pill / or induction of the birth under special condition

# Restricted Prescription-Only medicinal products

- Central repository for medicinal products with restriction
- SIDC

# Dispensing for health care facilities

- Not only original package
- Medical Orders

# Dispensing - orders

- Not only for health care facilities
- OTC whose dispensing, according to the marketing authorisation, is not restricted
- Food supplements,..
- Rx MP – only attached with prescription



# Mail-order dispensing

## General principles:

**Announce** to SIDC

Publish information about:

- products on offer,
- prices and costs associated with the mail-order dispensing
- Link to SIDC

# Mail-order dispensing

## Obligations:

- Ensure the origin and quality (packaging and transport)
- OTC whose dispensing is not restricted
- Food supplements,...

# Mail-order dispensing

## Obligations:

- ensure an information service
- collect and handover information on suspected AR and quality defects of MP

# Mail order – public risk:

- Counterfeit / falsified medicinal product