

PHARMACY PRACTICE

Dispensing of medicinal products

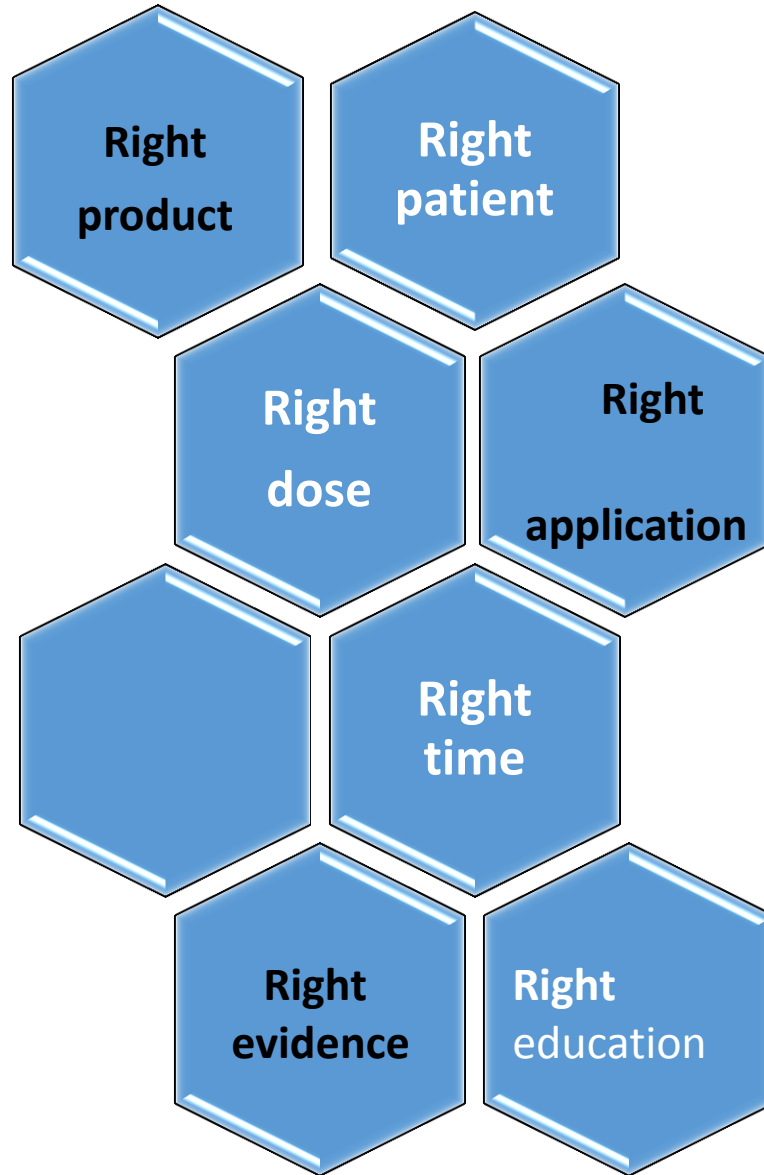
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Activities with pharmaceuticals

- 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.

HANDLING

....REASON....



...response

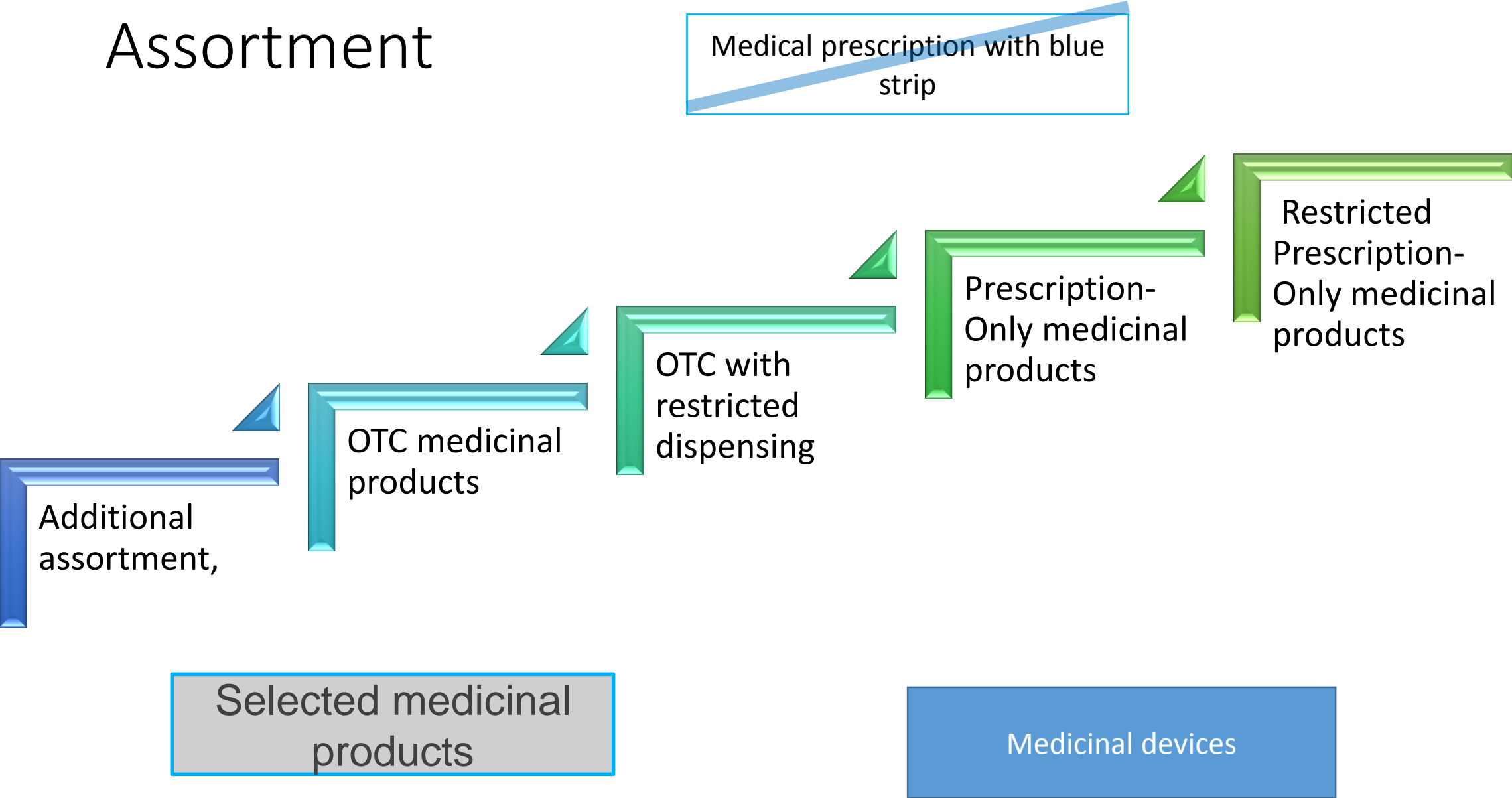
Medicinal products

- DIRECTIVE 2001/83/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 November 2001 on the Community code relating to medicinal products for human use
- REGULATION (EC) No 726/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency

Dispensing of medicinal products

- Act 378/2007 Coll. on Pharmaceuticals
- Decree 84/2008 Coll. on good pharmacy practice, detailed conditions for handling pharmaceuticals in pharmacies, healthcare establishments and by other operators and on establishments dispensing medicinal products

Assortment



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

Where?

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

Who?

- pharmacists;
- pharmaceutical assistants:

Who?

- Vendors of selected medicinal products

Only selected medicinal products

Dispensing of medicinal products

Selected medicinal products :

only by competent vendors of selected medicinal products

- Obtain selected medicinal products only from a manufacturer or from a distributor
- Store them for the purposes of sale under the conditions established in SPC
- Provide information about correct use and storage of the medicinal product (PIL)

Dispensing – who, where, what?

doctors, pharmacists or other healthcare professionals of a **nuclear medicine workplace**

- **only radiopharmaceuticals prepared at this workplace**

Dispensing – who, where, what?

employees of **public health protection authorities** with professional qualification to engage in the healthcare profession

- **only immunological products intended for vaccination**

Dispensing – who, where, what?

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

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

Dispensing – who, where, what?

- doctors, pharmacists or other healthcare professionals of an **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 - not compromised
- handling of medicinal products before dispensing - conditions established in the marketing authorisation;

Dispensing of medicinal products

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

Dispensing of medicinal products

- Obligation to **co-operate**:

If a pharmacy - to other pharmacies or inpatient healthcare providers:

- specified „in the licence“

Obligation - right

- **Inform** the patient **about alternative options**

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 medicinal product

MAY NOT BE DISPENSED

Obligation - right

- **Suspected abuse**
- The **conditions / 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

Additional obligations

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

OTC

- Pharmacist, pharmaceutical assistant
- Self-service
- marketing authorisation
- **Switching**

Tools for dispensing

WWHAM:

SIT DOWN SIR

ASMETHOD

Dispensing OTC - ethics

Medicinal products - Rx Only

Medicinal products shall be available only on medical prescription:

- 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** adverse reactions
- 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 Rx**

Dispensing of Rx only

Verifying the correctness of the therapeutic content:

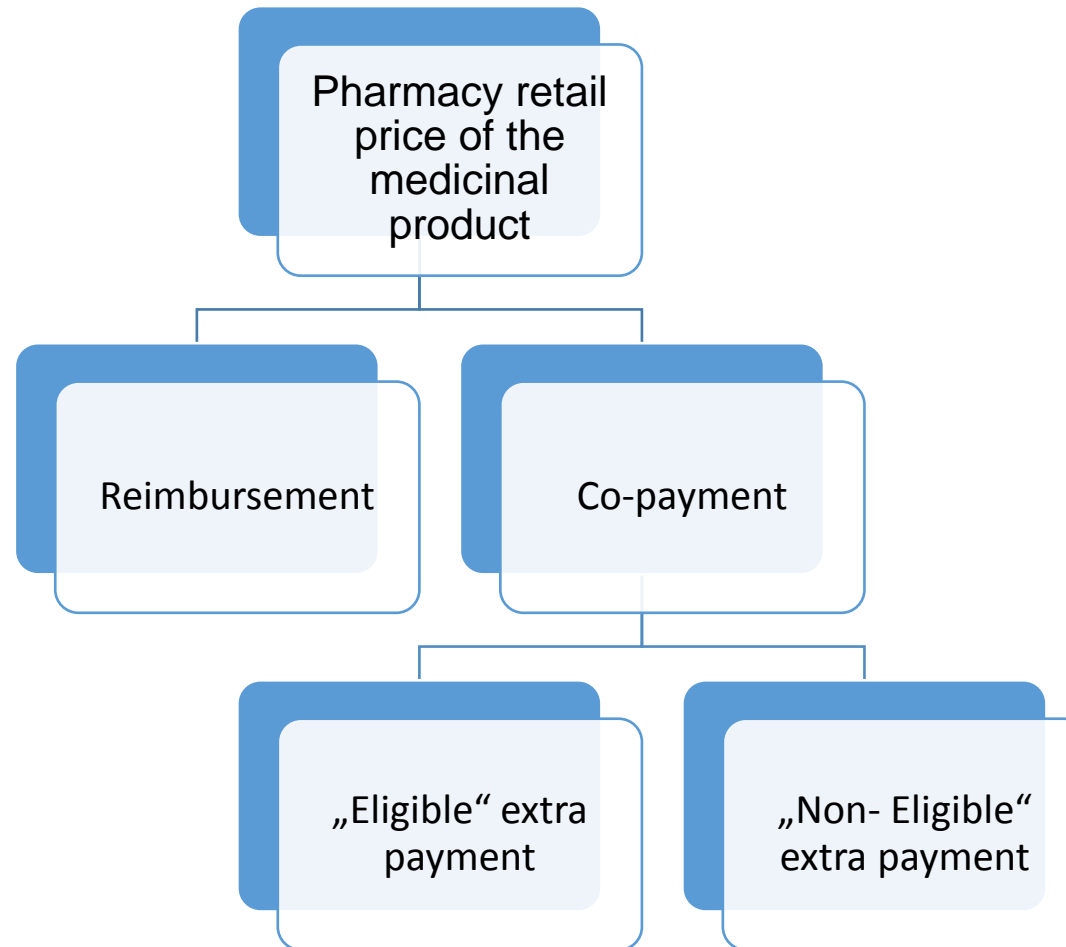
- dosing and dosage form;
- interactions

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; CZE*
-patient counselling

Reimbursement vs Co-payment CZE



Co-payment limit

Annual limit based on „Eligible“ co-payment

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
- Information

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 medicinal product 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.:
 - **age limit**
 - **dose for individual administration**
 - **period of time.**

OTC with restricted dispensing CZE

Pseudoephedrine

- 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!!!

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 CZE
- **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“:
 - *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 medicinal products – only 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:

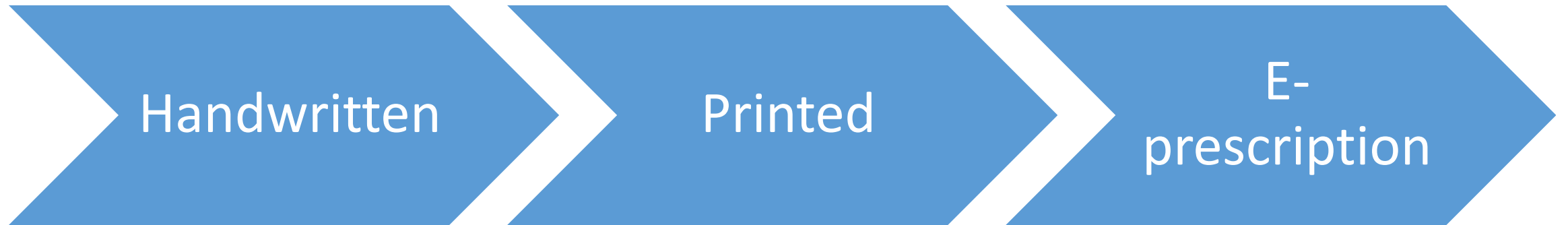
- information service
- collect information on suspected AR and QD of MP

Mail order – public risk:

- Counterfeit / falsified medicinal product.....

Dispensing,
Medical prescription

Evolution of the prescription



++ E-Rx

E-prescribing

Repository of E-prescription“:

Information available for:

- Prescribers
- Pharmacists

- Public ?

Paper form of medical prescription CZE:

- CD
- Exceptions from e-prescription:
 - „Emergency“, failure of Central repository,..
 - Prescription for MP, if the patient would like to take the MP in other EU country
- Veterinary prescription

E-prescription only:

- Rx drugs with restriction

Insurance in CZE

- Compulsory health care insurance system
- Consists of not-for-profit health insurance companies
- Health insurance company - freedom of choice,

Insurers

- 111 Všeobecná zdravotní pojišťovna ČR (VZP ČR)
- 60 % of the population
- Other health insurance companies, which are referred to as “employee insurance companies”:
 - 201 Vojenská zdravotní pojišťovna České republiky (VoZP ČR)
 - 205 Česká průmyslová zdravotní pojišťovna (ČPZP)
 - 207 Oborová zdravotní pojišťovna zaměstnanců bank, pojišťoven a stavebnictví (OZP)
 - 209 Zaměstnanecká pojišťovna Škoda (ZPŠ)
 - 211 Zdravotní pojišťovna ministerstva vnitra ČR (ZPMV ČR)
 - 213 Revírní bratrská pokladna, zdravotní pojišťovna (RBP)

Patient information

- Name
- ID
- Address

- Telephone number - only with agreement of the patient

- Year of birth - only if it isn't in the ID

- Weight of preschool children - if it is unusual

Medical Prescription

Medical prescription:

- 2 different medicinal products,
- limit - 3 months therapy;
- More than 3 months – prescription for repeating dispensing
- 1 medicinal product – narcotic drugs or psychotropic given lists

Medical order:

- No limit for medicinal products
- 5 different medicinal products – narcotic drugs...

Medical Prescription

- Brand name, dosage form, strength, package
- INN of the substance, dosage form, strength, package

Name of the substance written in the Pharmacopoeia, synonym or abbreviation in the Pharmacopoeia - prepared medicinal products

- Which benefits are associated with prescription via INN name of the active substance (not by brand name)

Diagnosis - ICD

- International Classification of Diseases (ICD) by the United Nations and World Health Organization
- "standard diagnostic tool for epidemiology, health management and clinical purposes"

Noninfective enteritis and colitis (K50-K52)

Incl.: noninfective inflammatory bowel disease

Excl.: irritable bowel syndrome ([K58.-](#))
megacolon ([K59.3](#))

K50 Crohn disease [regional enteritis]

Incl.: granulomatous enteritis

Excl.: ulcerative colitis ([K51.-](#))

K50.0 Crohn disease of small intestine

Crohn disease [regional enteritis] of:

- duodenum
- ileum
- jejunum

Ileitis:

- regional
- terminal

Excl.: with Crohn disease of large intestine ([K50.8](#))

K50.1 Crohn disease of large intestine

Colitis:

- granulomatous
- regional

Crohn disease [regional enteritis] of:

- colon
- large bowel
- rectum

Excl.: with Crohn disease of small intestine ([K50.8](#))

Prescribers

- Physicians – human, veterinary - providing preventive health care
- Physicians not providing preventive health care (i.e. university employees, pensioners etc.) if:
 - Mini-license with the insurance company where they are insured
 - Possibility of prescribing Medicinal products for themselves and family members if they are insured with the same insurance company
 - Member of the Czech Medical Chamber or the Czech Dental Chamber (liable for their professional competence)
 - In the insurance must be announced the ID number of family members, to which will apply prescribing the right
 - Note in the prescription "for family member" or "Ad usum proprium"

Medical Prescription

„Expiration“ of Rx in CZE:

- 14 days
- 5 days
- 1 day after prescribing

Dispensing

Communication with specific groups...