

DISPENSING OF MEDICINAL PRODUCTS

FIVE RIGHTS

Right Drug

Right Patient

Right Dose

Right Route

Right Time



C1:

Check the name on the order and the patient.
Use 2 identifiers.
Account for color, or solution of
When suitable, use technology (eg, bar code system)

Check the medication label.
Check the order.
CHECK FOR ALLERGIES.

Check the order.
Confirm appropriateness of the dose using a current drug
reference.
If necessary, calculate the dose and compare to other units
of measure to determine if safe.

Right:

Agree on the order and appropriate use of the task
setting.
Confirm that the order can be completed by the medication
by the professional.

Document administration **AFTER** giving the second
medication.
Clarify the time, route, and any other specific information as
necessary (eg, the site of an injection or any laboratory
value or vital sign that, need to be documented) as giving
the drug.

Confirm the rationale for the ordered medication. What's
the patient's story? Why is he/she taking the medication?
Do we target therapy to the RSI (The RSTISE)

Make sure that the drug, lot, or the dose is right.
Be sure to document your monitoring of the patient and
any other nursing interventions for an appropriate

PERSON

MEDICATION

DOSE

TIME

ROUTE

DOCUMENTATION

REASON

RESPONSE

PO
IVI
SC
IMI

When giving medications
THINK

thenursepath.com

The 8 R's of Safe Administration

8R

- Right Time
- Right Patient
- Right Medicines
- Right Dose
- Right Route
- Right Documentation
- Right Effect
- Right Education

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

Dispensing of medicinal products

- ⦿ their provision under the conditions by Act 378/2007 Coll. on Pharmaceuticals)

Where?

- ⦿ **Pharmacies**
- ⦿ Dispensaries of medical devices
- ⦿ Physicians
- ⦿ Veterinarians
- ⦿ Vendors of selected medicinal products
- ⦿ 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

Dispensing – who, where, what?

Medicinal products may be dispensed in pharmacies and facilities by

- ⦿ pharmacists;
- ⦿ pharmaceutical assistants

Dispensing – who, where, what?

Physicians

- ⦿ may dispensed 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 prescription**.

Dispensing – who, where, what?

- 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?

nuclear medicine workplace

- ⦿ **only radiopharmaceuticals prepared at this workplace**

Dispensing – who, where, what?

public health protection authorities

- **only immunological products intended for vaccination**

Dispensing – who, where, what?

blood centre and a blood bank

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

Dispensing – who, where, what?

- **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

- ① quality of medicinal products is not compromised
- ① handling of medicinal products before dispensing: complies with the conditions established in their marketing authorisations;

Dispensing of medicinal products

- **No compromise the integrity** of packaging of a medicinal product subject to marketing authorisation

(with the exception:
preparation of medicinal products
dispensing for a healthcare service
provider)

Dispensing of medicinal products

- Obligation: **keep records** for the period of 5 years;
- Obligation to **provide to the SIDC data** about dispensed medicinal products

Dispensing of medicinal products

- Obligation to **co-operate**:

Dispensing of medicinal products

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

- ⦿ this activity must be specified „in the licence“ of such pharmacy

Dispensing of medicinal products

- ⦿ **Inform** the patient **about alternative options** for the dispensed medicinal product 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.

Medicinal products:

- ⦿ May be dispensed also to a **person other than the one for whom it has been prescribed.**

Medicinal product may not be dispensed:

- ⦿ **Doubts** arise in respect of **credibility** of the medical **prescription**,



Medicinal product may not be dispensed:

- ⦿ **Suspected abuse** of the medicinal product
- ⦿ **restriction haven't been fulfilled**
- ⦿ **Interactions**
- ⦿ (

Conscientious objection

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

Refuse

But - another worker will perform needed service or another health care facility

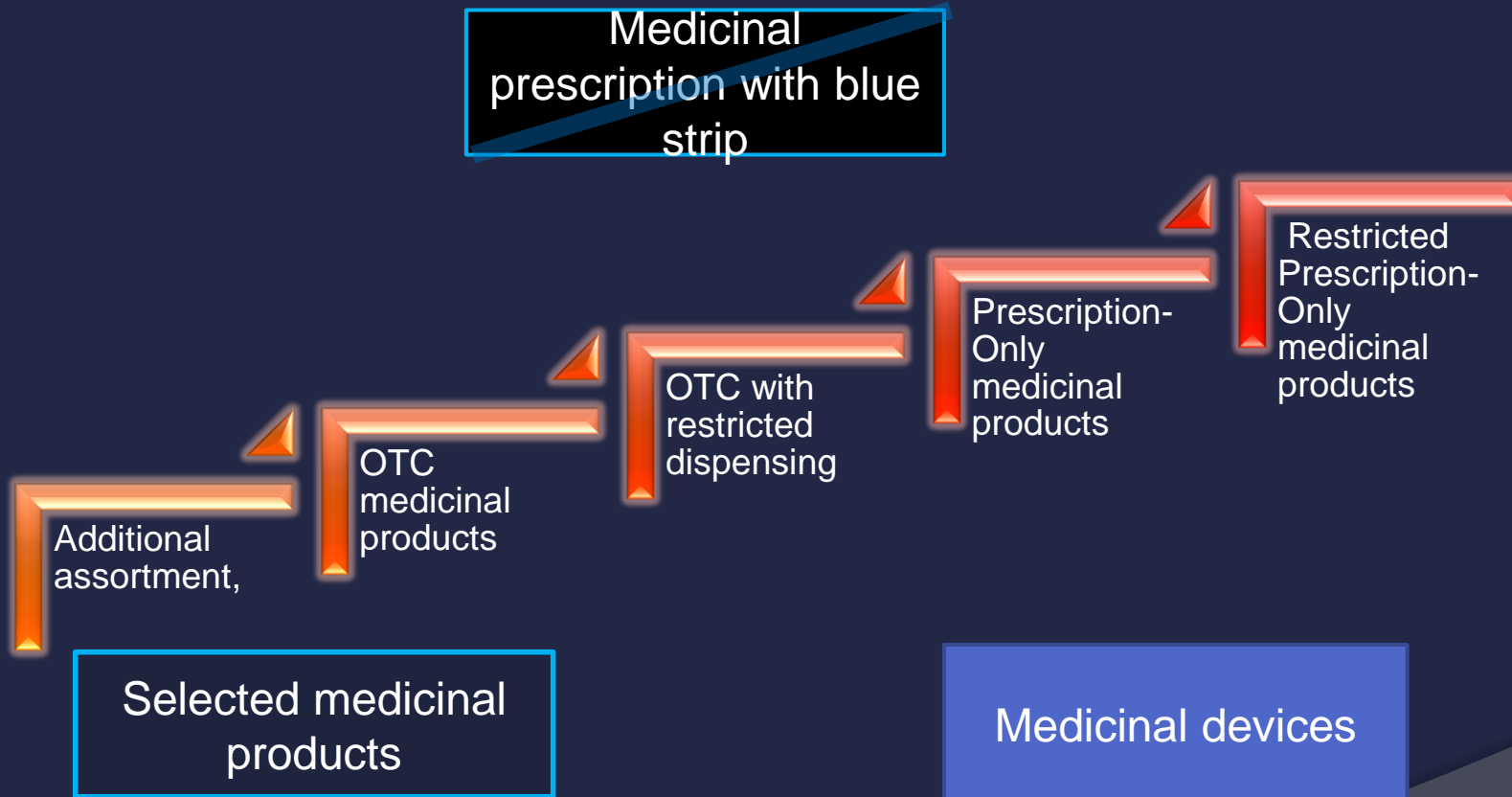
Never - If there is a possibility of:

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

Additional obligations

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

Assortment



OTC

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

Tools for dispensing

WWHAM:

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

Other....

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

...preference...

Dispensing OTC

- ⦿ Do not offer more expensive products
- ⦿ Do not offer more products than the corresponding to state of health / patient needs
- ⦿ Do not prefer manufacturer (supplier, sales representative)
- ⦿ Provide information to patient (self – service too!)

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**

Suspend dispensing - absence:

- ⦿ **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 medicinal products – Regulation . 54/2008 Coll., On prescribing medicines: until the next visit to the physician, up to 3 months.

Dispensing of Rx only

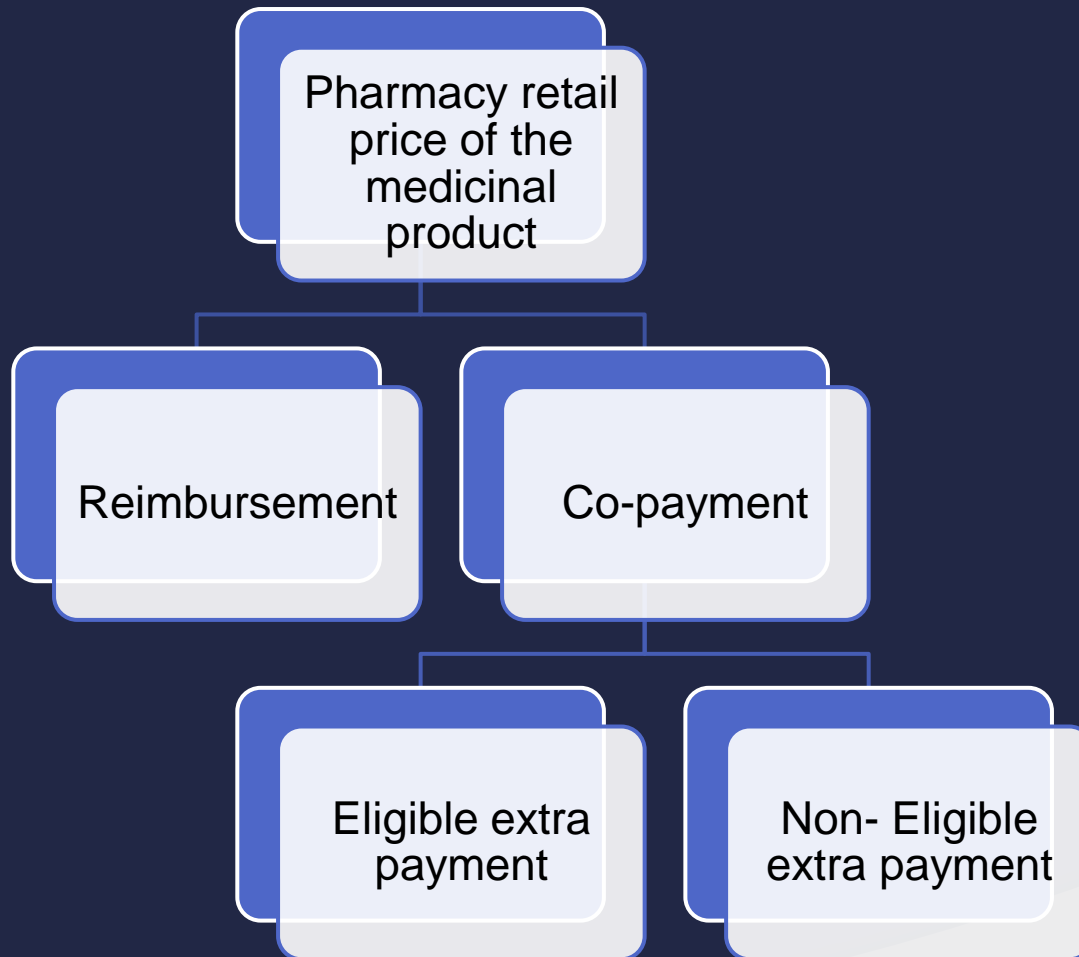
Verifying the correctness of the therapeutic content:

- ⦿ 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 Copayment



Co-payment limit

Annual limit:

- 5000 CZK
- 2500 CZK – under 18; over 65 y.o.

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 medicinal product may only be dispensed:

- ⦿ to the person for whom it is intended,

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

- ⦿ the total amount of pseudoephedrine for an individual dispensing shall not exceed 900 mg pseudoephedrine
- ⦿ Pharmacist keeps a record of dispensing and counselling
- ⦿ **PANADOL PLUS GRIP, por.tbl.flm - 900 mg pseudoephedrine / 7 days**

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
- ⦿ **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“:
 - patient: 18 y.o.,
 - Diagnosis
 - g/month – work sheets

- ⊙ Misoprostol, mifepristone
 - „Abortion pill“ – under set conditions

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:**
- ⦿ ensure an information service provided by a pharmacist or a pharmaceutical assistant within predefined hours of operation
- ⦿ collect and handover of information on suspected adverse reactions and quality defects of medicinal products

Mail order – public risk:

- Counterfeit / falsified medicinal product