

# PHARMACY PRACTICE

Pharmacy retail price

## **Explanation of abbreviations and terms**

- *HAMP* - Human medicinal product with marketing authorisation
- *MD* - Medical device
- *PMP* - Prepared medicinal product
- *GDP* - gross domestic product
- *OECD* - Organisation for Economic Co-operation and Development
- *VAT* - value added tax

## Explanation of abbreviations and terms

- [SÚKL](#)/*SIDC* - Státní ústav pro kontrolu léčiv - State Institut for Drug Control **SIDC**
- [IHIS](#) - Institute of Health Information and Statistics of the Czech Republic
- [CZSO](#) - Czech Statistical Office
- [MZ](#) - Ministerstvo zdravotnictví ČR - Ministry of Health CZE

# How to keep accessibility and availability of healthcare?

By solving this issues:

- Number of health-care facilities /e.g. question of regulation by demographic and geographic criterion/
- Quality of health service /e.g. question of educated and well trained personnel/
- Funding of health care and prices of health services or medicinal products /e.g. question of price regulation, health insurance/

# Regulation - is it the right way?

Deregulation or regulation in the health-care is often discussed topic.

For example in the pharmacy sector:

Deregulation in this sector is usually aimed to:

- increase the accessibility of medicinal products and pharmaceutical services
- increase the quality of services through competition
- drive down prices of these products or services through competition

...However, these could be false expectations or not fully met expectations.

# Regulation - is it the right way?

Even - there is no evidence that liberalisation has reduced prices of medicinal products.

(these are influenced by many other factors.)

# Health expenditures and importance of price regulation in health care

In general - Why are the prices in health care regulated?

- providing availability of health care
- regulation and saving of health expenditure - mainly from public sources
- to have the possibility of guess the future expenditures



# The basic principles of price regulation of Pharmaceuticals

- For the Course Pharmacy Practice is the most important the part of Expenditures on pharmaceuticals.
- Foremost, will be described the general principle and samples from different states and then we will focus on situation in Czech Republic.

# The basic principles of price regulation of Pharmaceuticals

Price control is a **competence of each country** (there is no unify method within EU as well) and reflects:

- the different national healthcare policy priorities
- prescribing behavior
- patterns of utilization of pharmaceuticals
- purchasing power or willingness to pay
- Price control may be applied to all pharmaceutical whether or not they are reimbursed, or to specific groups of pharmaceuticals (e.g. only reimbursed, only for inpatient care or outpatient, ..)

without compromising patient access!!

# The basic principles of price regulation of Pharmaceuticals

Where can be prices of these products influenced?

At the level of:

- the manufacturer price (ex-factory price)
- the wholesaler price
- the pharmacy retail price
- VAT

# Prices of pharmaceuticals

- Furthermore - prices of pharmaceuticals differ in the international scale due to factors:
  - different pack sizes and distribution channels
  - import duties/taxes
  - exchange rate fluctuations
- So it looks like that there is a tremendous difference in prices at each stage of chain from ex-factory price to pharmacy retail price between countries.
- This price spread between lowest and highest is significantly more apparent:
  - in generic medicines than in branded
  - in less expensive medicines than more expensive medicines

# Levels of government influence and regulation

Ex-factory price:

Possibilities:

- national authority determines
- without regulation

# Levels of government influence and regulation

## Wholesale level

Possibilities:

- 1) The wholesale mark up is not regulated by the government, but based on free agreements between manufacturers / wholesalers and pharmacy
- 2) The wholesale mark up is regulated by degressive/regressive or flat mark-up
  - *Actual margins of wholesalers in EU are ranging between 1.5 – 3.5%*

# Levels of government influence and regulation

## Pharmacy retail price level

- Pharmacy retail price = Rough price for the final consumer
- - **ex-factory price + mark up + VAT**

## Types of Mark up - usually based on ex-factory price

- Constant mark up (flat) -
- Higher ex-factory price means - lower allowed mark-up

# Levels of government influence and regulation

- Types of Mark up:
  - Can be set like maximum
  - Fixed



# Pharmacy retail price regulation

Specific group of pharmaceuticals in the field of price setting are **medicinal products prepared in the pharmacy** - in here the situation differs greatly among the world:

- The fee for preparing usually depends on the dosage form of prepared product.
- In some countries, this fee is paid for each preparing, regardless of quantity.
- Elsewhere is changed when multiple quantities are prepared or even is account the exact time spent by preparing.
- And vice versa In some countries is it without official benefit for pharmacy...

# Value added tax in European countries

Value added tax (VAT) is a form of consumption tax added to a product's sales price  
The purpose of VAT is to generate tax revenues to the government

## VAT in EU

- each Member State's national VAT legislation must comply with the provisions of EU VAT law as set out in [Directive 2006/112/EC](#)
- sets out the basic framework for EU VAT, but does allow Member States some degree of flexibility:

**have a minimum standard (basic) rate of VAT of 15%**

**could be applied one or two reduced rates, but cannot be below 5%**

## Value added tax and medicinal products

- vary significantly across EU

*Note:* some old EU Member States have a exempt and shall apply 0% VAT rate on certain supplies – like UK exempting some groups of medicinal products from VAT

Pharmacy retail price in CZE

# Pharmacy retail price regulation in the CZE

Simplified, In the Czech Republic, there is statutory pricing for all reimbursable pharmaceuticals and prices of non-reimbursable pharmaceuticals are not regulated - it means:

## **With price regulation:**

### Reimbursed:

- medicinal products and foods for special medical purposes
- prepared medicinal products
- medicinal devices

## **Without price regulation**

### Not-Reimbursed:

- medicinal products
- medicinal devices
- (Veterinary medicinal products)
- Additional products which are sold in the pharmacy

# Pharmacy retail price regulation in the Czech republic

The maximum pharmacy retail price based on common maximum wholesale and pharmacy mark up and VAT.

The administrative authority of price regulation in Czech Republic is SIDC (State Institute for Drug Control) and [Ministry of Health CZE](#).

# Pharmacy retail price regulation in the Czech republic

## The legislation of price regulation

- - Act No 526/1990 Coll., on Prices, as amended Price Ruling of the Ministry of Health of December 20 2007, laying down the conditions of price regulation for medicinal products and foods for special medicinal purposes
- - Price regulation by the Ministry of health MZ ČR (1/2019 FAR)
- - Price regulation by Ministry of health ČR (1/2019/CAU) – medicinal devices
- - OOP 01 – 16 (Regulation by SIDC) - measures of a general nature concerning the amount and terms of payment of prepared medicinal products and other regulation by SIDC (OOP)

# Pharmacy retail price regulation in the Czech republic

## VAT in Czech pharmacies

### 2nd Reduced VAT – 10 %:

- Medicinal products for human use, Prepared medicinal products, some medicinal products for veterinary use.

### 1st reduced VAT – 15%:

Some groups of medicinal devices, some additional products

### Standard VAT – 21%:

- Medicinal products - for veterinary use (some), some groups of medicinal devices, some additional products

Note: documents added to each supply to pharmacy, contains information about delivered products like: brand name, code of product, batch number, expiration date, ex-factory price, wholesale mark-up, recommended maximum pharmacy retail price and VAT

*Note: till 2004: Medicinal product exempt from VAT*

# Price regulation of Human authorised medicinal product in CZE

## Medicinal products with price regulation in the pharmacy

- based on the ex-factory price:
  - .... - 2006 - *maximum mark up 32%*
  - *1.1. 2006 - 1.8. 2006 - 29%*
  - *From 1.8.2006 - first Degressive mark up*
- 
- 1.1.2019 - now (table below)



# Zone – ex-factory price

Zone	Ex – factory price From (CZK)	Ex-factory price To (CZK)	Mark-up	Additional Part (in CZK)
1	0,00	150,00	37 %	0,00
2	150,01	300,00	33 %	6,00
3	300,01	500,00	24 %	33,00
4	500,01	1 000,00	20 %	53,00
5	1 000,01	2 500,00	17 %	83,00
6	2 500,01	5 000,00	14 %	158,00
7	5 000,01	10 000,00	4 %	658,00
8	10 000,01	9 999 999,00	2 %	858,00

# Price regulation of Human authorised medicinal product in CZE

- This Mark up
  - is common wholesale and pharmacy
  - there are no official agreements on how the mark-ups are split,
- mark-up = maximum (not fixed!) - this can distinguish prices in pharmacy

# Price regulation of Medical devices in CZE

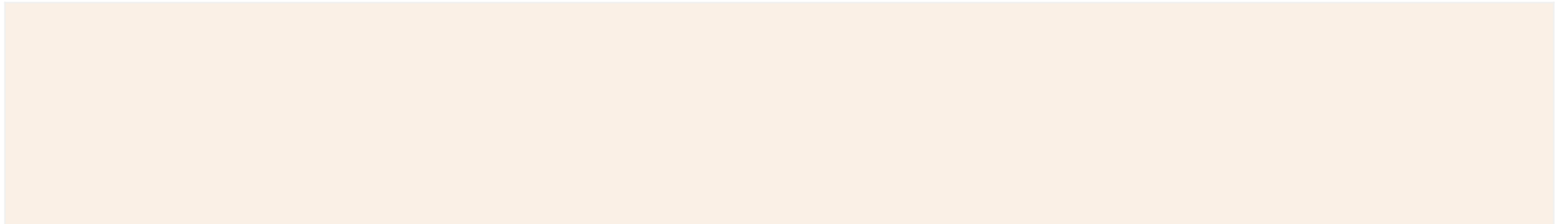
With price regulation:

Maximum mark-up 25 % of the ex-factory price

it is common wholesale and pharmacy mark-up (divided between wholesaler and pharmacy)

there are no official agreements on how the mark-ups are split

VAT: 1st reduced or standard



# Prices of medicinal products prepared in the pharmacy in CZE

**$\Sigma$  (purchase prices of all used substances, materials without VAT +  $\Sigma$  Taxa laborum) + VAT (10%)**

## Prices of medicinal products prepared in the pharmacy in CZE

**Taxa laborum** – fee for preparing – depends on activity provided (dissolving, mixing,...), number of components in the medicinal product, whole prepared amount –

- cover costs for preparing
- given: price regulation by Ministry of health MZ 1/2019/FAR
- possibility of cumulation - but only:
  - one of groups No 1.1 - 1.12.,
  - one from groups 2.1.1 - 2.1.2.,
  - one from groups 2.2.1. - 2.2.3,
  - one from groups 2.3.1. - 2.3.5.
- taxa laborum is chosen according to the real methods (activities) used by preparing

## Reimbursement of medicinal products

- SIDC
- List of reimbursed medicinal products
- Announced 1st day/every month

# Reimbursement of medicinal products prepared in the pharmacy

## **Oop 01 – 16 („Regulation“ by SIDC) - reimbursement of medicinal products prepared in the pharmacy**

**- there are written groups of medicinal products which prepared in the pharmacy and which are NOT reimbursed in accordance to their use or content:**

- a) combination of substances with analgetic and/or antipyretic effect, except of combination with codeine for non-analgesic use (gastroenterology);
- b) antiphlogistics – for local application
- c) decongescents of nose mucose, combinations - decongescens + other substances
- d) medicinal products with herbal origin (tea...)
- e) vitamins, combination of vitamins, combination - vitamins + minerals or other substances for p.o. use
- f) methionin for p.o. use except of hereditary diseases
- g) expectorants and antitusics
- h) treatment of erectile dysfunction
- i) products containing:
  - chinidin
  - hydrargyri amidochloridum.
  - - latanoprost
- j) products containing combination of:
  - coffein and ephedrin
- k) antihemorrhoidalia for local application and rectal use

## Medicinal products without price regulation

- Mark up:
- usually - 20 % - 30 % in the CZE
- reflects marketing strategy of the pharmacy