

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

- *EU* - European Union
- *CZE* - Czech Republic
- *SÚKL* - Státní ústav pro kontrolu léčiv - State Institut for Drug Control **SIDC**
- *CZK* - Czech crown
- *IHIS* - Institute of Health Information and Statistics of the Czech Republic
- *CZSO* - Czech Statistical Office
- *MZ* - Ministerstvo zdravotnictví ČR - Ministry of Health CZE

- *Mark-up* - common “surcharge“ for the distributor and pharmacy, is determined on a percentage rate calculated from the price actually applied by producer in CZK without VAT

- *Ex-factory price* - the price at which the manufacturer shall provide the medicinal product on the market

How to keep accessibility and availability of healthcare?

By solving this issues:

- Number of health-care facilities
- Quality of health service
- Funding of health care and prices of health services or medicinal products



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.

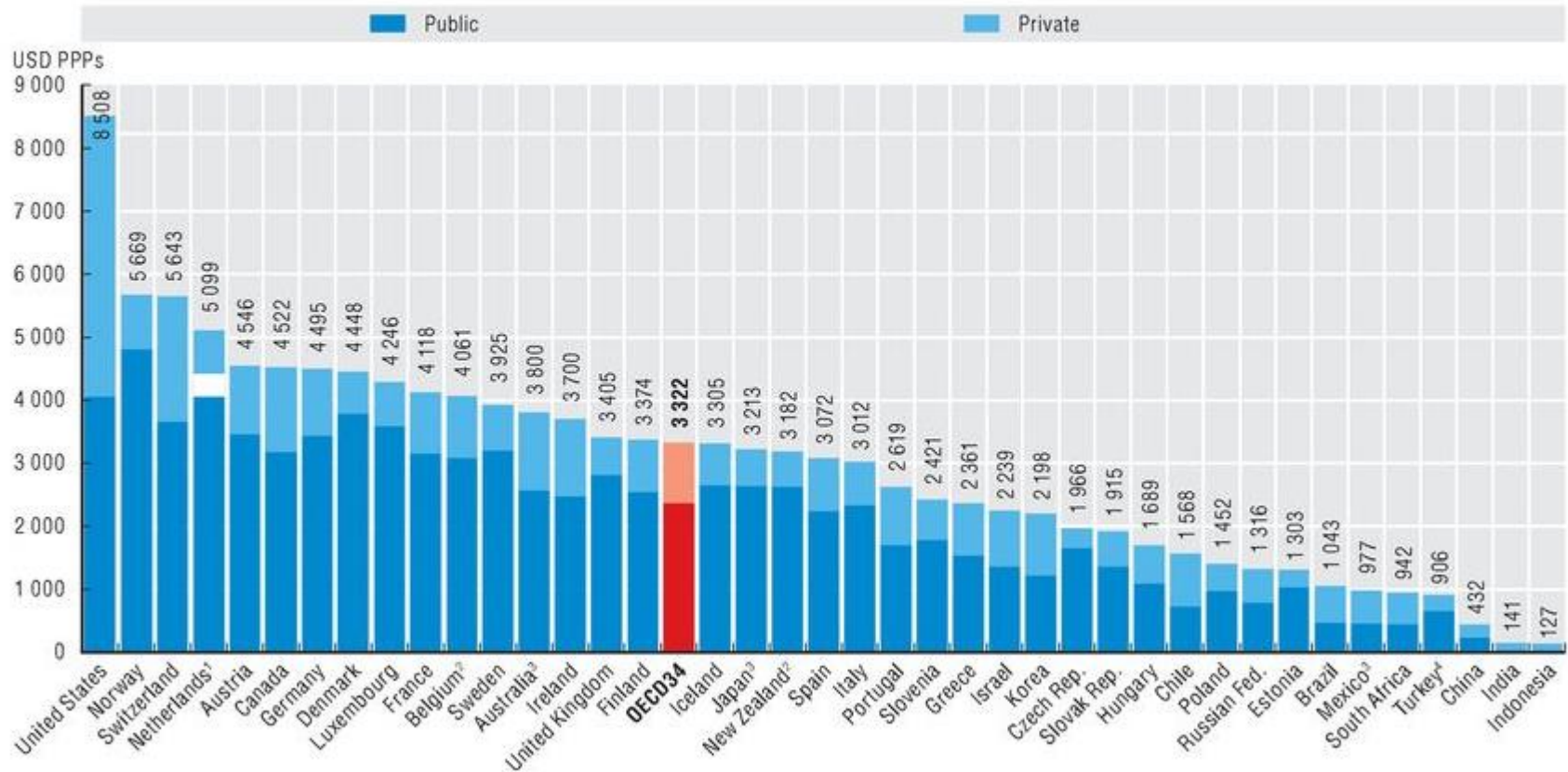


Health expenditures and importance of price regulation in health care

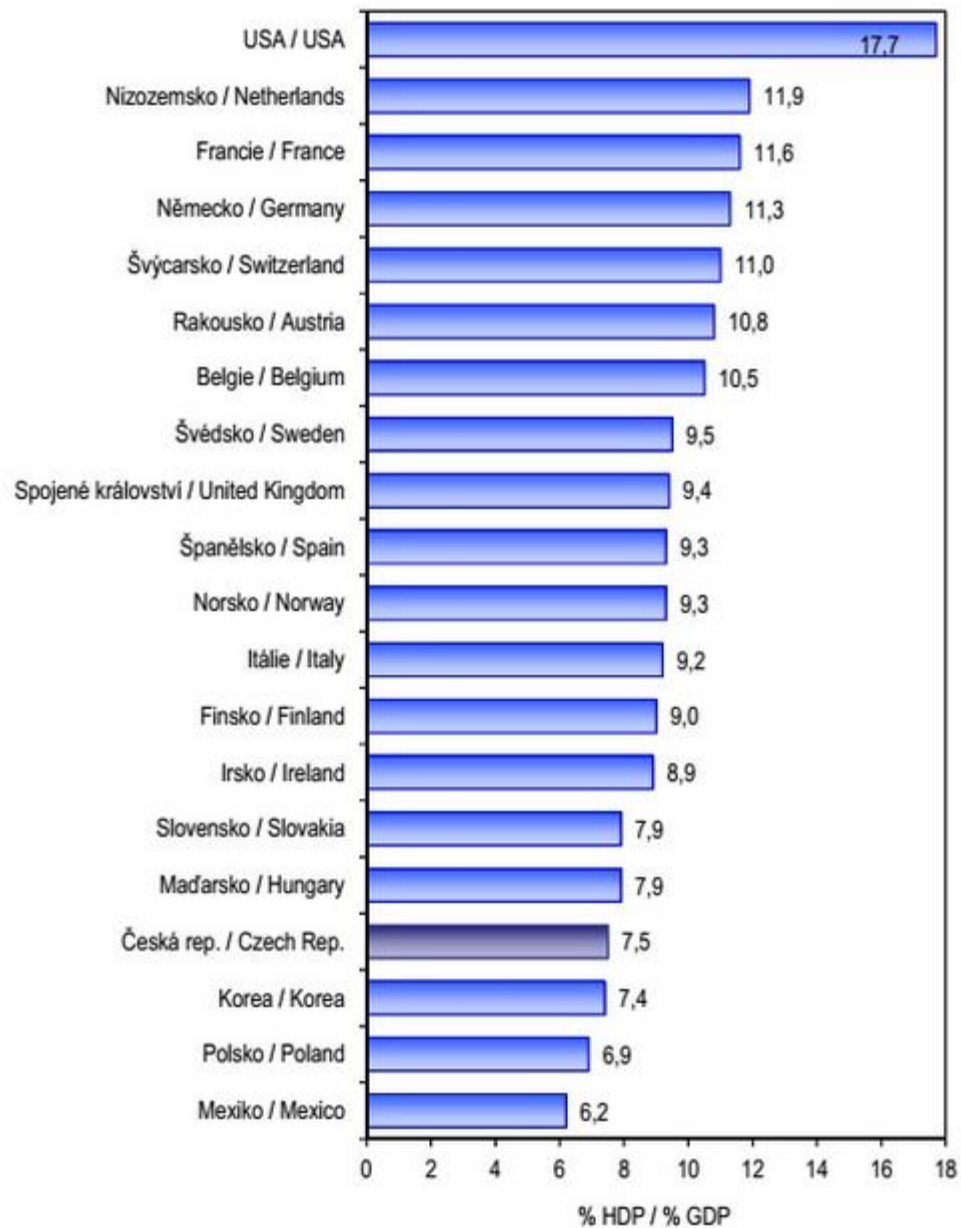
In general - Why are the prices in health care regulated?

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

7.1.1. Health expenditure per capita, 2011 (or nearest year)



migration-health/health-at-a-glance-2013/health-expenditure-per-capita_health_glance-2013-64-en#page4



Source: OECD Health Data June 2013

Figure 7.5.1 Expenditure on health by type of financing, 2009 (or nearest year)

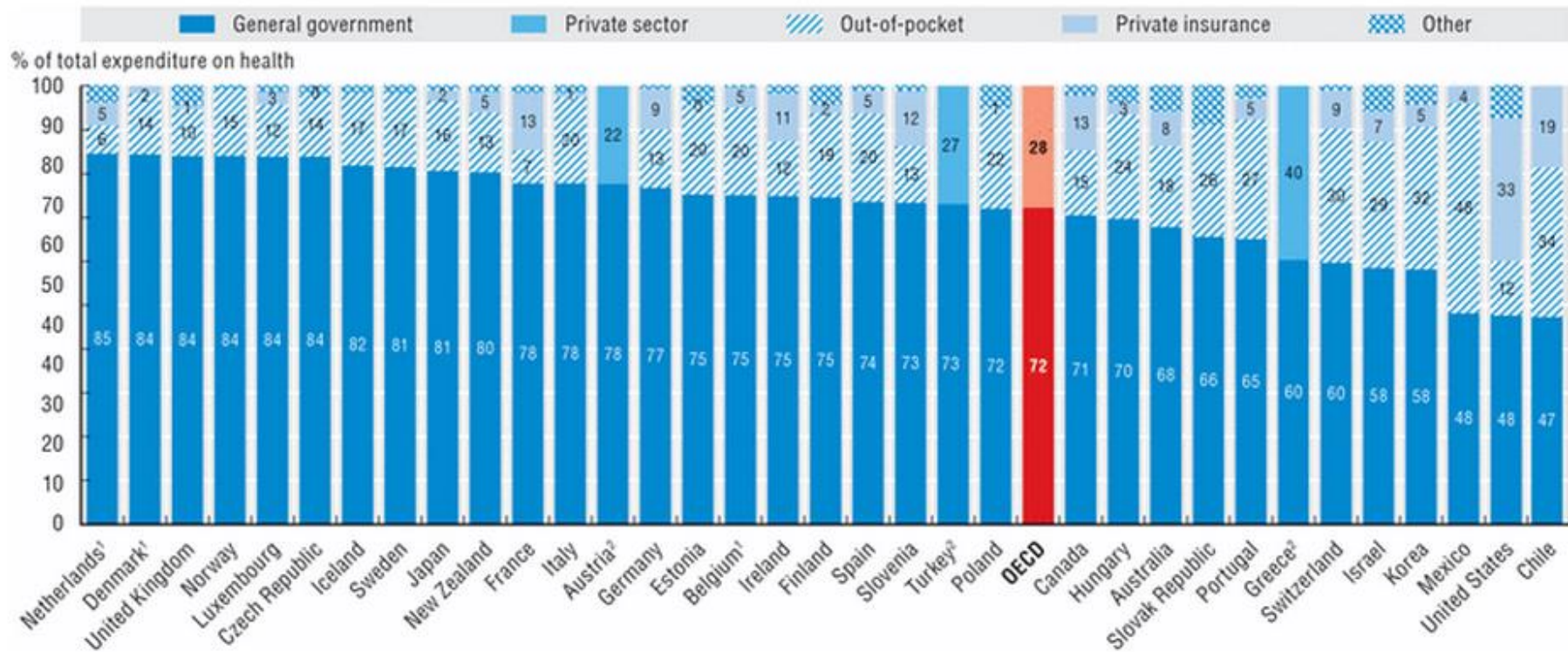
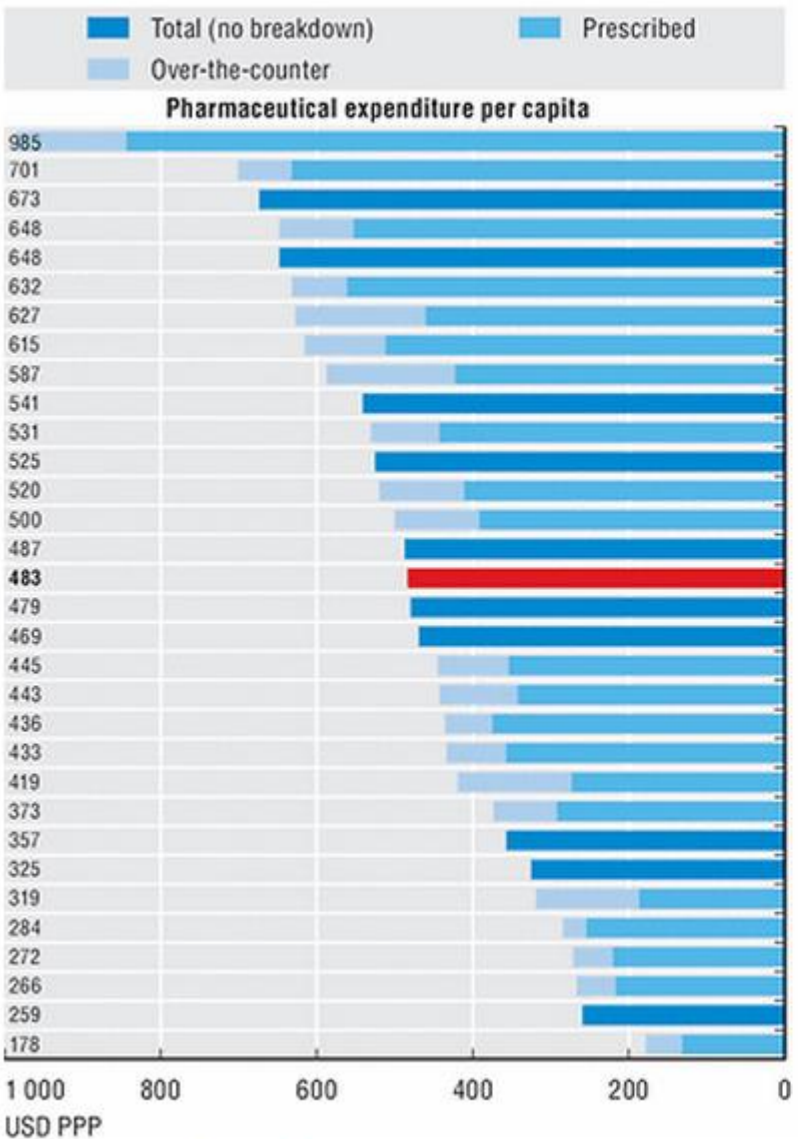
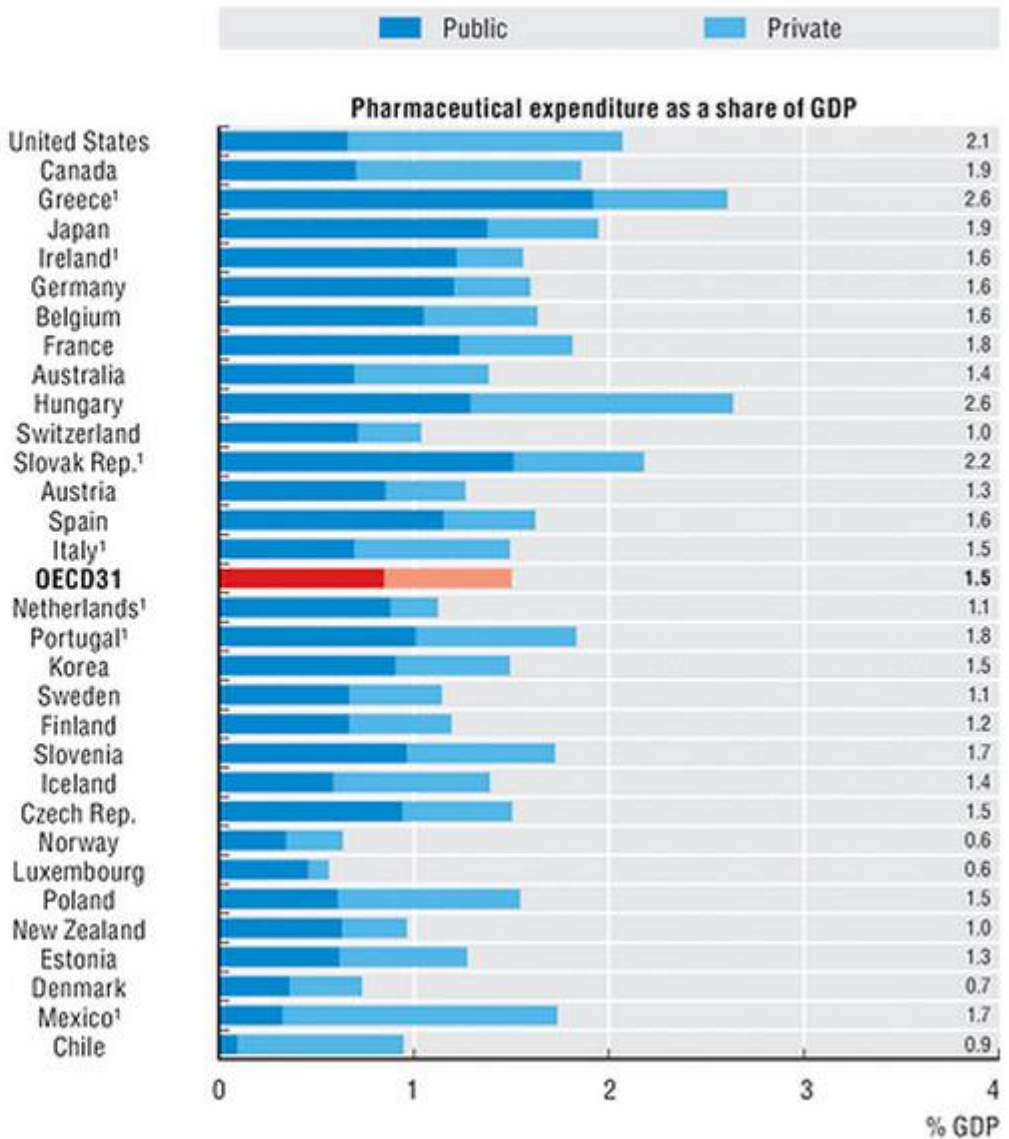


Figure 7.4.1 Expenditure on pharmaceuticals per capita and as a share of GDP, 2011 (or nearest year)



Includes medical non-durables.



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 e.g.:

1) national authority determines

the maximum ex-factory price e.g. via reference pricing (details will be explained in "Social pharmacy")

2) without regulation

Levels of government influence and regulation

Wholesale level

Possibilities e.g.:

- 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 regressive/degressive or flat mark-up
 - Discount?

Levels of government influence and regulation

Example: Pharmacy retail price level based on Mark-up:

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

Possibilities - the mark up:

- statutory – usually if there is reimbursement
- one's (own free) choice - usually if these products are not reimbursed

Types of Mark up

Constant mark up (flat) - e.g. 28 % for all goods
degressive mark up - e.g. Higher ex-factory price means - lower allowed mark-up

Levels of government influence and regulation

- Types of Mark up:
 - Can be set like maximum /≠it is not necessary to apply full mark-up/
 - Fixed
- So based on the principle of the regulation - in the end of supply chain - price of the medicinal product can be consistent in all pharmacies (fixed prices) in one country or vary pharmacy to pharmacy in another country.

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

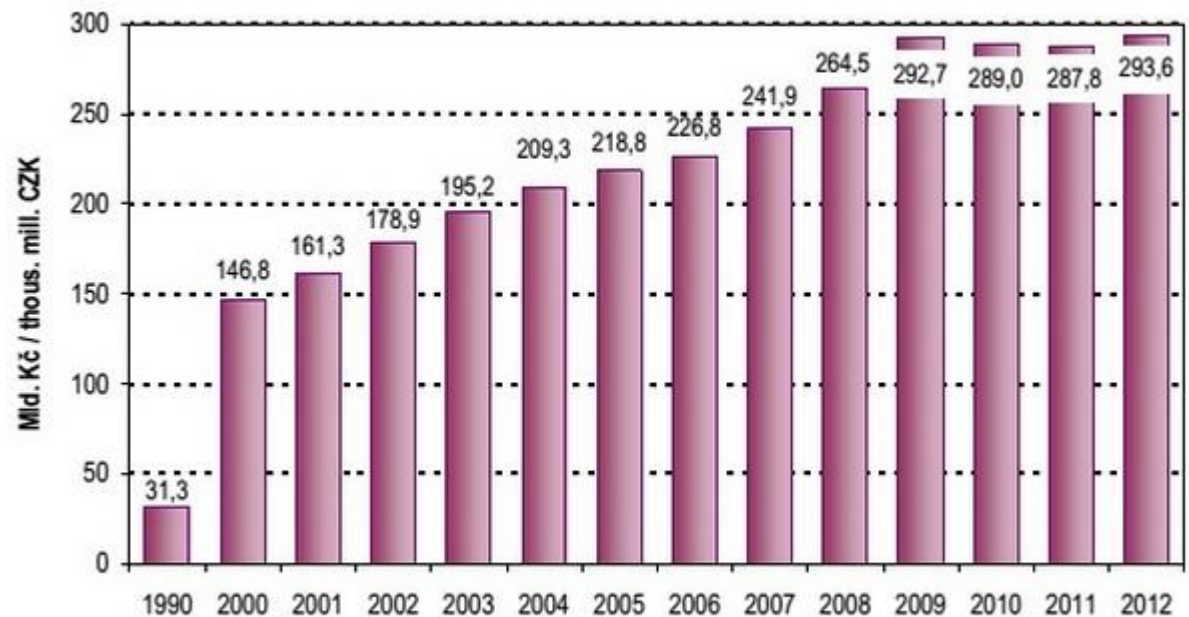
Note: some old EU Member States have a exempt and shall apply 0% VAT rate on certain supplies – like UK exempting some groups of medicinal products from VAT

Pharmacy retail price in CZE ...

Health expenditures in Czech Republic

To describe health expenditures in the years 1990 - 2012, see graph below- every year health expenditures grows (sharp growth in the years after "Velvet revolution,,)

Graph No 5: [Health expenditure in thousand milion CZK](#)



Source: Ministry of Health, CZSO, IHIS CR

Pharmacy retail price regulation in the Czech republic

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

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

- - Acton Prices,
- - Price regulation by the Ministry of health MZ ČR (1/2013 FAR)
- - Price regulation by Ministry of health ČR (3/2012/FAR) – 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



Zone – ex-factory price

Zone	From (CZK)	To (CZK)	Mark-up	Additional part /in CZK/
1	0,00	150,00	37 %	0
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	6%	558,00
8	10 000,01	9 999 999,99	4 %	758,00

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,
but wholesale distributors - mostly 2 % - 5%
 - mark-up = maximum (not fixed!) - this can distinguish prices in pharmacy

How to calculate the price?

- choose the zone according to ex-factory price
- add the mark-up according to the level
- add VAT – human authorised medicinal products – 10%

*Example: the calculation of pharmacy retail price of HAMP:
Ex-factory price = 200 CZK - It means calculation according
to Zone 2*

*Maximum mark-up = 33% of Ex-factory price + 6 CZK
additional part*

VAT = 10%

*Pharmacy retail price without VAT: **200 CZK + 33% (of 200 CZK) + 6 CZK = 272 CZK***

*Pharmacy retail price with VAT: **272 CZK + 10% (of 272 CZK) = 299,20 CZK***

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

Example: calculation of pharmacy retail price of MD

Ex-factory of elastic bandage is 15 CZK.

VAT for this product is set: 21%.

Calculate the maximum of pharmacy retail price:

Pharmacy retail price = $15 \times 1,25 \times 1,21 = 22,68$ CZK

Prices of medicinal products prepared in the pharmacy in CZE

**Σ (purchase prices of all used substances, materials
without VAT + Σ 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 1/2013/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

ACTIVITY



1.3. Compounding of emulsions, suspensions, syrups, infusions and decoctions

Range		Units	Taxa laborum /in Czk/ according to the number of components			
From	To	G	1-2	3	4	More than 4
0	30	G	86,94	92,61	98,28	109,62
31	50	G	90,72	96,39	102,06	113,40
51	100	G	94,50	100,17	105,84	117,18
101	200	G	98,28	103,95	109,62	120,96
201	300	G	113,40	119,07	124,74	136,08
301	500	G	141,75	147,42	153,09	164,43
501	700	G	198,45	204,12	209,79	221,13
701	1000	G	270,27	275,94	281,61	292,95
1001	3000	G	344,93	350,60	356,27	367,61
3001	5000	G	411,08	416,75	422,42	433,76
5001	7000	G	491,40	497,07	502,74	514,08
7001	10000	G	567,95	573,62	579,29	590,63

TOTAL AMOUNT



NUMBERS OF COMPONENTS



Calculation of pharmacy retail price of PMP

Rp.

Mentholi 4,0
Methylis salicylatis 9,0
Vasellini albi ad 100,0
M.f.ung.
D.S.ointment

Price of substances without VAT:

Mentholum ... 1CZK/g;

Methylis salicylatum ... 2CZK/g;

Vaselinum album ... 0,50CZK/g

Containers without VAT: jar 125ml ...5CZK; label ...1CZK

Calculation of pharmacy retail price of PMP

It is a preparation of ointment and the determined number of components is 2 components - active substances.

From group we choose appropriate groups of taxa laborum and we calculate along formula:

Σ (purchase prices of all used substances, materials without VAT + Σ Taxa laborum) + VAT (10%)

Price of substances and containers = $(4,0 \times 1 + 9,0 \times 2 + 87,0 \times 0,5 + 5 + 1)$

Taxa laborum = group 1.7. (91,67 CZK) + group 2.1.1. (3,10 CZK) +

group 2.2.2. (13,95 CZK)

Pharmacy retail price = $((4,0 \times 1 + 9,0 \times 2 + 87,0 \times 0,5 + 5 + 1) + (91,67 + 3,10 + 13,95)) \times 1,10 = 198,20$ CZK

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) antihemorrhoidalialia 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