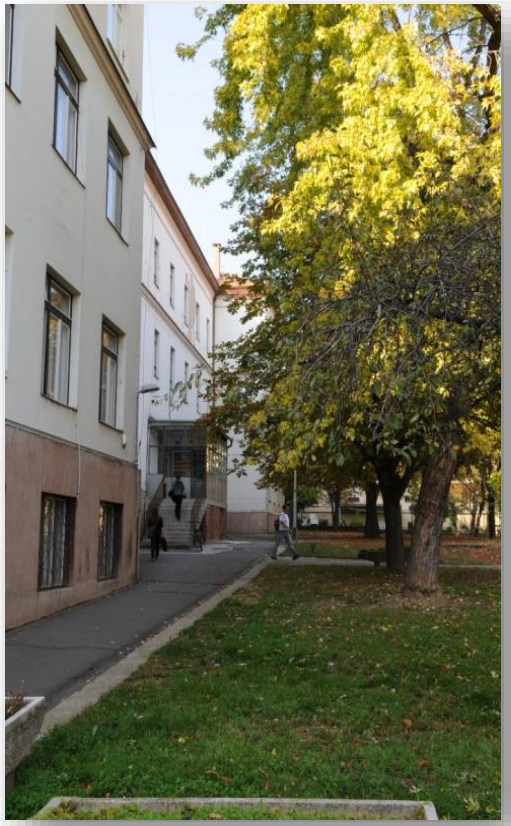
# Characteristics of the pharmaceutical education, its structure, disciplines

**Pharmaceutical Propaedeutics**

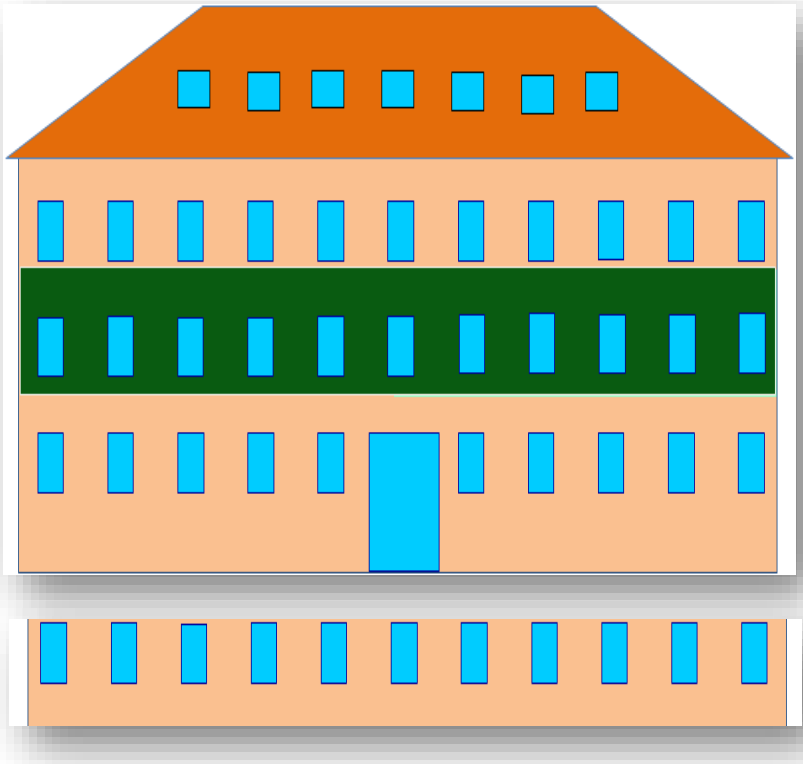
Institute of Pharmaceutical Technology and Biopharmacy

# School of Pharmacy



H-7624 Pécs, Rókus str.2.

# School of Pharmacy



Inst. of Pharmaceutical Biotechnology

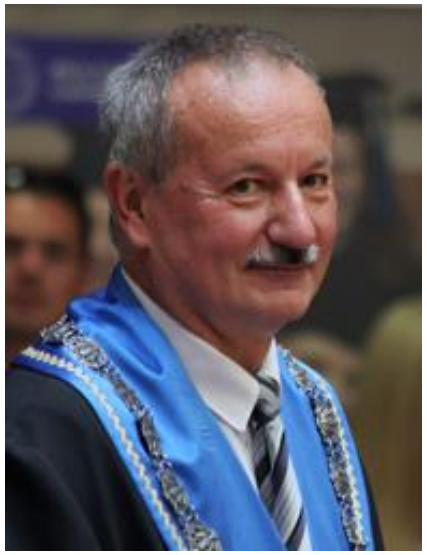
Inst. of Pharmacognosy/Dept. of Pharmaceutics

**Inst. of Pharmaceutical Technology and Biopharmacy**

Inst. of Pharmaceutical Chemistry

Inst. of Pharmaceutical Biology/
**Inst. of Pharmaceutical Technology and Biopharmacy – new lab.**

# Who is who ?



- Dr. Attila Miseta - Rector of the University

- Dr. Lajos Botz- Head of Faculty of Pharmacy

# Pharmaceutical Propaedeutics

**Course director:**

Dr. Szilárd PÁL PhD

Senior Lecturer
Head of Institute of Pharmaceutical Technology and Biopharmacy

# Important notes

## Course literature

http://gytk.pte.hu

(click to English version)

- theoretical knowledge
  - Lecture notes

# Important notes

## Conditions for acceptance of the semester

- Students must fulfil requirements determined by the Code of Studies and Examinations
- Attendance of the lectures according to the Code of Studies and Examinations
  - 2-3 absences are allowed
  - **In case of 4 or more absences the course is rejected!**

# Important notes

- During the semester students have to write **three tests** and they have to reach 60% after average calculation. After two **assessments if students reach average 60% taking into account both tests**, writing the third test is **not compulsory**. **Summarized average of all three tests has to be above 60%!** In case of confirmed absence from the test, re-take chance is possible for the student. Missing the re-take results 0% test.

# Dates of tests

- 1. Week no. 5 (September 30)
- 2. Week no. 10 (November 4)
- 3. Week no. 14 (December 2)

# Pharmaceutical propedeutics

What do you think, what this term ‘propedeutics’ means?

What kind of information is expected during this course?

introduction to the science/discipline

(history, substances, drug design, manufacture, care)

## What is pharmaceutics?

Originally, the **pharmaceutics** is the field which deals with the medications, their design, preparation, dispensing and healthcare.

This is the science and the art of preparation and dispensing of  medicines.

## Who can work at a pharmacy?

A *pharmacist* is necessary for the operation of a pharmacy.
The members of the pharmacies, who assist to the pharmacists, are the *pharmacy assistants.*

# Education - UPPS

**DIPLOMA**

pharmacist

doctor of pharmacy - **Pharm. D.** (pharmacist doctor)

**EDUCATION**

- Form of education: full-time
- Training time: 10 semesters (5 years)
- Language: Hungarian, English, German
- Average number of hours per week: 25-30 hours

# Obligatory courses/Criterion requir.

The obligatory courses/criterion requirements are needed for the signature of the absolutorium of the student. The students do not get credits or payment for this type of requirements.

## Criterion requirements:

- ***LATIN LANGUAGE AND PHARMACEUTICAL TERMINOLOGY***
- ***FIRST AID***
- ***Professional Practices***
  - ***SUMMER PRACTICE 1.,2. (in summer, 4 weeks 2 times)***
  - ***6 month long practice (2+4 months)***
    - ***1 month in hospital pharmacy***
    - ***5 months in community pharmacy***
- ***HEALTH SCIENCE SPECIFIC LANGUAGE EXAM***
- ***SPORTS***

# Education - UPPS

***FUTURE POSSIBILITIES:***

*Employment opportunities - areas:*

- public and hospital / clinical pharmacies,
- pharmaceutical and medicinal product design and manufacture (industry)
- quality control (industry)
- toxicology (lab)
- new drug approval (authorities)
- research and education (universities)

***Specialized pharmacists:*** (post-gradual)

3 main directions:

Pharmaceutical care

Clinical / hospital

Industry

# Structure of the education

Gradual

Postgradual

Basic subjects

Professional subjects

Residents

PhD

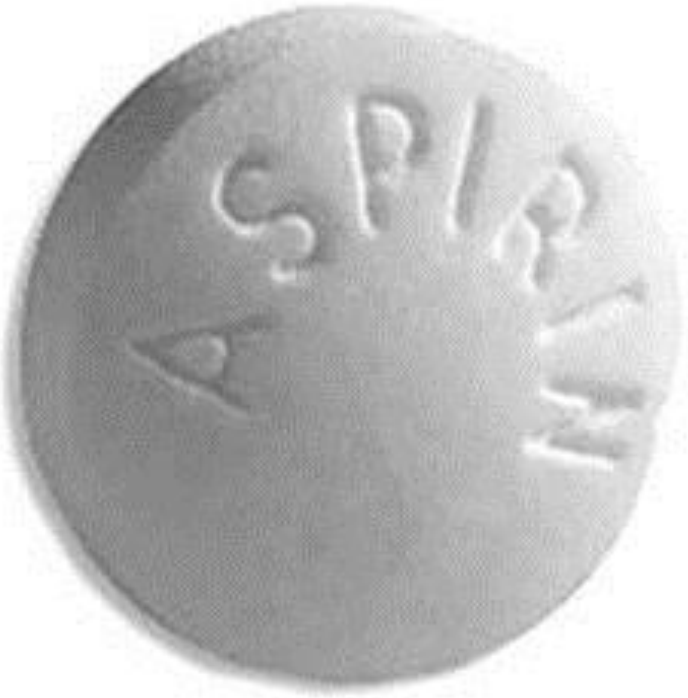
Molecular cell biology
Anatomy (lat.)
Chemistry (in-organic, bio-)
Analysis (conventional, instr.)
Biophysics
Mathematic and statistic
Colloidal chemistry
Phytoterapy
Physiology and pathophysiology
Microbiology
Immunology
Language

- **Pharmacology**
- **Pharmaceutical Technology**
- **Biopharmacy**
- **Pharmaceutical management**
- **Pharmaceutical chemistry**
- **Pharmacognosy**

- Pharmaceutical Technology
- Hospital Pharmacy
- Clinical Pharmacy
- Pharmacognosy and phytotherapy
- Pharmaceutical Care
- Pharmaceutical Inspection
- Pharmaceutical Chemistry
- Clinical laboratory, diagnostics (6)
- Pharmacology
- Quality Assurance
- Toxicology

Undergraduate Research Society

# What is the role of pharmaceutical discipline?



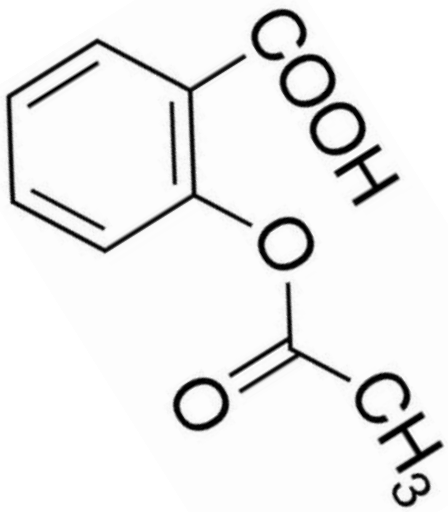

Behind a dosage form such as a tablet there is a plenty of information and science.

The major pharmaceutical subjects:

- **Pharmaceutical chemistry**
- **Pharmacognosy**
- **Pharmaceutical Technology**
- **Biopharmacy**
- **Pharmacology**
- **Pharmaceutical Management and Care**

# Main specific subjects:
## Pharmaceutical chemistry

- **Deals with:**
  - Chemical structure of ingredients
    - Synthetization of APIs
    - Structure - effect correlation
    - Biological effect
  - Qualitative and quantitative analysis
    (according to Ph. Eur)
  - Identification of substances
    - Impurities
    - Content determination (assays)
  - Procedures and methods of examination
    - Such as: chromatography, spectroscopy, HPLC, NMR

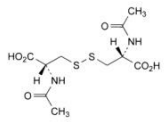


# Main specific subjects:
## Pharmaceutical chemistry

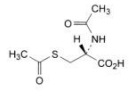
- **Monograph of acetylsalicylic acid**







C. *N,N'*-diacetyl-L-cystine,



D. *N,S*-diacetyl-L-cysteine.

**01/2005:0309**

## ACETYLSALICYLIC ACID

Acidum acetylsalicylicum

$C_9H_8O_4$ $M_r$ 180.2

DEFINITION

Acetylsalicylic acid contains not less than 99.5 per cent and not more than the equivalent of 101.0 per cent of 2-(acetyloxy)benzoic acid, calculated with reference to the dried substance.

CHARACTERS

A white, crystalline powder or colourless crystals, slightly soluble in water, freely soluble in alcohol.

It melts at about 143 °C (instantaneous method).

IDENTIFICATION

*First identification: A, B.*

*Second identification: B, C, D.*

A. Examine by infrared absorption spectrophotometry (*2.2.24*), comparing with the spectrum obtained with *acetylsalicylic acid CRS*.

B. To 0.2 g add 4 ml of *dilute sodium hydroxide solution R* and boil for 3 min. Cool and add 5 ml of *dilute sulphuric acid R*. A crystalline precipitate is formed. Filter, wash the precipitate and dry at 100 °C to 105 °C. The melting point (*2.2.14*) is 156 °C to 161 °C.

C. In a test tube mix 0.1 g with 0.5 g of *calcium hydroxide R*. Heat the mixture and expose to the fumes produced a piece of filter paper impregnated with 0.05 ml of *nitrobenzaldehyde solution R*. A greenish-blue or greenish-yellow colour develops on the paper. Moisten the paper with *dilute hydrochloric acid R*. The colour becomes blue.

D. Dissolve with heating about 20 mg of the precipitate obtained in identification test B in 10 ml of *water R* and cool. The solution gives reaction (a) of salicylates (*2.3.1*).

TESTS

**Appearance of solution**. Dissolve 1.0 g in 9 ml of *alcohol R*. The solution is clear (*2.2.1*) and colourless (*2.2.2, Method II*).

**Related substances**. Examine by liquid chromatography (*2.2.29*). *Prepare the solutions immediately before use.*

*Test solution.* Dissolve 0.10 g of the substance to be examined in *acetonitrile for chromatography R* and dilute to 10.0 ml with the same solvent.

*Reference solution (a).* Dissolve 50.0 mg of *salicylic acid R* in the mobile phase and dilute to 50.0 ml with the mobile phase. Dilute 1.0 ml of this solution to 100.0 ml with the mobile phase.

*Reference solution (b).* Dissolve 10.0 mg of *salicylic acid R* in the mobile phase and dilute to 10.0 ml with the mobile phase. To 1.0 ml of this solution add 0.2 ml of the test solution and dilute to 100.0 ml with the mobile phase.

The chromatographic procedure may be carried out using:

– a stainless steel column 0.25 m long and 4.6 mm in internal diameter packed with *octadecylsilyl silica gel for chromatography R* (5 µm),

– as mobile phase at a flow rate of 1 ml/min a mixture of 2 volumes of *phosphoric acid R*, 400 volumes of *acetonitrile for chromatography R* and 600 volumes of *water R*,

– as detector a spectrophotometer set at 237 nm.

Inject 10 µl of each solution. Continue the chromatography of the test solution for seven times the retention time of acetylsalicylic acid. The test is not valid unless in the chromatogram obtained with reference solution (b), the resolution between the two principal peaks is at least 6.0.

In the chromatogram obtained with the test solution the area of any peak, apart from the principal peak, is not greater than the area of the principal peak in the chromatogram obtained with reference solution (a) (0.1 per cent); the sum of the areas of all the peaks is not greater than 2.5 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.25 per cent). Disregard any peak with an area less than 0.25 times the area of the principal peak in the chromatogram obtained with reference solution (a).

**Heavy metals** (*2.4.8*). Dissolve 1.0 g in 12 ml of *acetone R* and dilute to 20 ml with *water R*. 12 ml of this solution complies with limit test B for heavy metals (20 ppm). Prepare the standard using lead standard solution (1 ppm Pb) obtained by diluting *lead standard solution (100 ppm Pb) R* with a mixture of 6 volumes of *water R* and 9 volumes of *acetone R*.

**Loss on drying** (*2.2.32*). Not more than 0.5 per cent, determined on 1.000 g by drying *in vacuo*.

**Sulphated ash** (*2.4.14*). Not more than 0.1 per cent, determined on 1.0 g.

ASSAY

In a flask with a ground-glass stopper, dissolve 1.000 g in 10 ml of *alcohol R*. Add 50.0 ml of *0.5 M sodium hydroxide*. Close the flask and allow to stand for 1 h. Using 0.2 ml of *phenolphthalein solution R* as indicator, titrate with *0.5 M hydrochloric acid*. Carry out a blank titration.

1 ml of *0.5 M sodium hydroxide* is equivalent to 45.04 mg of $C_9H_8O_4$.

STORAGE

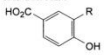
Store in an airtight container.







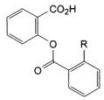
IMPURITIES



A. R = H: 4-hydroxybenzoic acid,

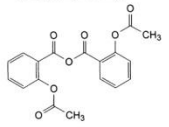
B. R = $CO_2H$: 4-hydroxybenzene-1,3-dicarboxylic acid (4-hydroxyisophthalic acid),

C. salicylic acid,



D. R = O-CO-$CH_3$: 2-[[2-(acetyloxy)benzoyl]oxy]benzoic acid (acetylsalicylsalicylic acid),

E. R = OH: 2-[(2-hydroxybenzoyl)oxy]benzoic acid (salicylsalicylic acid),

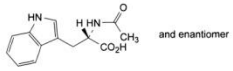


F. 2-(acetyloxy)benzoic anhydride (acetylsalicylic anhydride).

**01/2005:1383**

## *N*-ACETYLTRYPTOPHAN

*N*-Acetyltryptophanum



$C_{13}H_{14}N_2O_3$ $M_r$ 246.3

DEFINITION

*N*-Acetyltryptophan contains not less than 99.0 per cent and not more than the equivalent of 101.0 per cent of (*RS*)-2-acetylamino-3-(1*H*-indol-3-yl)propanoic acid, calculated with reference to the dried substance.

PRODUCTION

Tryptophan used for the production of *N*-acetyltryptophan complies with the test for 1,1'-ethylidenebistryptophan and other related substances in the monograph on *Tryptophan (1272)*.

CHARACTERS

A white or almost white, crystalline powder, or colourless crystals, slightly soluble in water, very soluble in alcohol. It dissolves in dilute solutions of alkali hydroxides.

It melts at about 205 °C.

IDENTIFICATION

*First identification: A, B.*

*Second identification: A, C, D, E.*

A. It complies with the test for optical rotation (see Tests).

B. Examine by infrared absorption spectrophotometry (*2.2.24*), comparing with the spectrum obtained with *N-acetyltryptophan CRS*.

C. Examine by thin-layer chromatography (*2.2.27*), using a *TLC silica gel $F_{254}$ plate R*.

*Test solution.* Dissolve 50 mg of the substance to be examined in 0.2 ml of *concentrated ammonia R* and dilute to 10 ml with *water R*.

*Reference solution (a).* Dissolve 50 mg of *N-acetyltryptophan CRS* in 0.2 ml of *concentrated ammonia R* and dilute to 10 ml with *water R*.

*Reference solution (b).* Dissolve 10 mg of *tryptophan R* in the test solution and dilute to 2 ml with the same solution.

Apply to the plate 2 µl of each solution. Develop over a path of 10 cm using a mixture of 25 volumes of *glacial acetic acid R*, 25 volumes of *water R* and 50 volumes of *butanol R*. Dry the plate in an oven at 100-105 °C for 15 min and examine in ultraviolet light at 254 nm. The principal spot in the chromatogram obtained with the test solution is similar in position and size to the principal spot in the chromatogram obtained with reference solution (a). The test is not valid unless the chromatogram obtained with reference solution (b) shows two clearly separated spots.

D. Dissolve about 2 mg in 2 ml of *water R*. Add 2 ml of *dimethylaminobenzaldehyde solution R6*. Heat on a water-bath. A blue or greenish-blue colour develops.

E. It gives the reaction of acetyl (*2.3.1*). Proceed as described for substances hydrolysable only with difficulty.

TESTS

**Appearance of solution**. Dissolve 1.0 g in a 40 g/l solution of *sodium hydroxide R* and dilute to 100 ml with the same alkaline solution. The solution is clear (*2.2.1*) and not more intensely coloured than reference solution $Y_7$ or $GY_7$ (*2.2.2, Method II*).

**Optical rotation** (*2.2.7*). Dissolve 2.50 g in a 40 g/l solution of *sodium hydroxide R* and dilute to 25.0 ml with the same alkaline solution. The angle of optical rotation is −0.1° to +0.1°.

**Related substances**. Examine by liquid chromatography (*2.2.29*).

*Buffer solution pH 2.3.* Dissolve 3.90 g of *sodium dihydrogen phosphate R* in 1000 ml of *water R*. Add about 700 ml of a 2.9 g/l solution of *phosphoric acid R* and adjust the pH to 2.3 with the same acidic solution.

*Prepare the solutions immediately before use.*

*Test solution.* Dissolve 0.10 g of the substance to be examined in a mixture of 50 volumes of *acetonitrile R* and 50 volumes of *water R* and dilute to 20.0 ml with the same mixture of solvents.

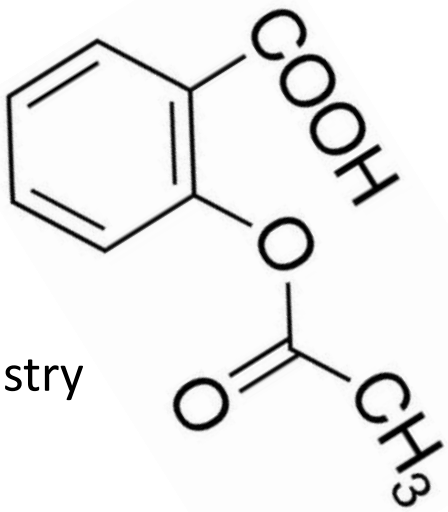
*Reference solution (a).* Dilute 1.0 ml of the test solution to 100.0 ml with a mixture of 10 volumes of *acetonitrile R* and 90 volumes of *water R*.

*Reference solution (b).* Dissolve 1.0 mg of *1,1'ethylidenebis(tryptophan) CRS* in a mixture of 10 volumes of *acetonitrile R* and 90 volumes of *water R* and dilute to 100.0 ml with the same mixture of solvents.

*Reference solution (c).* To 4.0 ml of reference solution (a), add 20.0 ml of reference solution (b) and dilute to 100.0 ml with a mixture of 10 volumes of *acetonitrile R* and 90 volumes of *water R*.

# Main specific subjects:
## Pharmaceutical chemistry

- **Requirements of Pharmaceutical chemistry:**
  - **Analytical chemistry**
    - Deals with quantitative and qualitative analysis of compounds (mostly not organic compounds)
    - Its requirement general and inorganic chemistry
  - **Biochemistry**
    - Its deals with chemical processes of cell and cell particles such as mitochondria
  - **General and organic chemistry**
    - Deals with experiments, properties and possible reactions of organic substances



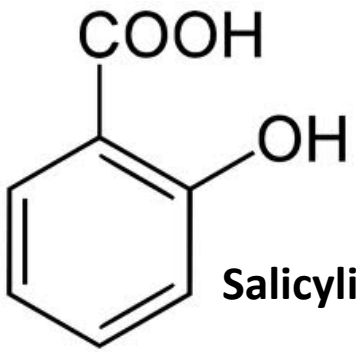
# Main specific subjects:
## Pharmacognosy

- **Deals with:**
  - Drugs, and herbs for treatment or prevention
  - Recognition of herbal parts
  - ***Drugs with strong effect***, ***tea herbs*** and ***extract*** (volatile oils, fatty oils)
  - Substances and its structures being related to herbs
  - Its requirement: **Pharmacobotany** which deals with whole herbs having therapeutic effect

# Main specific subjects:
## Pharmacognosy

**(Salix alba)**
**White willow**

**(Salicis cortex)**
**Willow cortex**




**Salicylic acid**

# Main specific subjects:
## Pharmaceutical technology

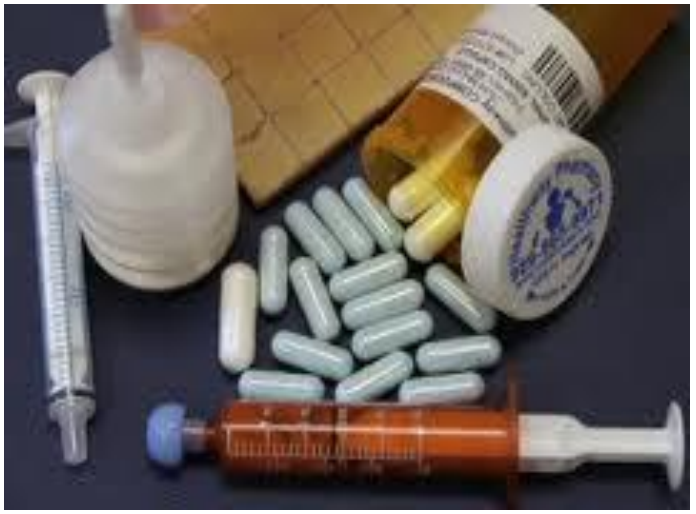
- **Deals with:**
  - Preparation of medicines
  - Industrial manufacture
  - Formulation of medicines, preparations
  - Dosage forms (based on Ph. Eur.)
  - Examination of dosage forms
  - Operations and procedures of manufacturing medicines
  - Drug delivery design

# Main specific subjects:
## Pharmaceutical technology

- **Requirements:**
  - Pharmaceutical terminology (principals of Latin language)
  - Biopharmacy (parallel attandence)
  - Colloidical chemistry
    - Deals with homogeneous, heterogeneous and colloidal disperse system
    - Stability, structure, types physical-chemical properties of colloidal systems
  - Physical chemistry
    - Deals with methods, instruments for examination of physical chemical parameters
    - Evaluation of measurement result)

# Main specific subjects:
## Pharmaceutical technology

- ***Dosage forms: (classification is according to consistency)***
  - **Liquid**: e.g. Solutions, lotions, infusions, injections, enemas, drops etc.
    - Solutions
      - Colloidal solutions
      - True solutions
    - Emulsion
      - O/W
      - W/O
    - Suspension
  - **Semisolid**
    - Ointments, gels, pastes, creams
    - Foams
    - patches
  - **Solid**
    - Tablets, capsules
    - Powder, granules
  - **Gas**
    - Aerosols



# Main specific subjects:
## Pharmaceutical technology

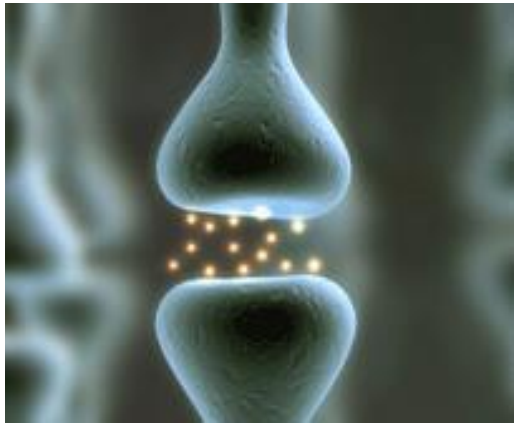
- Rotary tablet press machine

# Main specific subjects:
## **Biopharmacy**

Deals with:

- Behavior of the medicine in the human body
- How the human body affects the medicine after administration

# Main specific subjects:
## Pharmacology



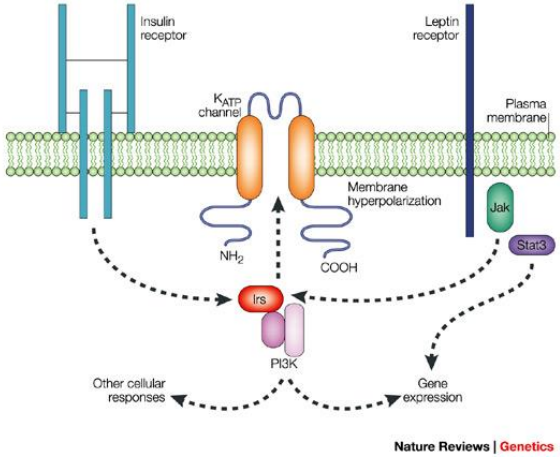
- Deals with:
  - Effect and effect mechanisms of particular medicines separated to pharmacological groups
  - **Pharmacokinetics** :

    is a branch of pharmacology dedicated to the determination of ***the fate of substances administered externally to a living organism***. The substances include pharmaceutical agents, hormones, nutrients, and toxins.
  - **Pharmacodynamics**:

    is the study of the biochemical and physiological effects of drugs on the body or on microorganisms or parasites within or on the body and the ***mechanisms of drug action*** and the relationship between drug concentration and effect.

# Main specific subjects:
## **Pharmacology**

- ***Requirements***
  - Pathophysiology
  - Biochemistry
  - Human physiology
    - Deals with human physiological functions of human body, including functions  and operations of organs and operation.



# Main specific subjects:
## Pharmaceutical management and care

- **Deals with:**
  - History of pharmaceuticals
  - Overview of health care structure
  - Knowledge of regulation of pharmacy
  - Definition and classification of drugs
  - Authorization process of medicines
  - Drug management
  - Regulations in hospital
- **Requirement**:
  - Pharmaceutical biology

**„Pharmaceutics – if you take it seriously, requires life-long learning!”**

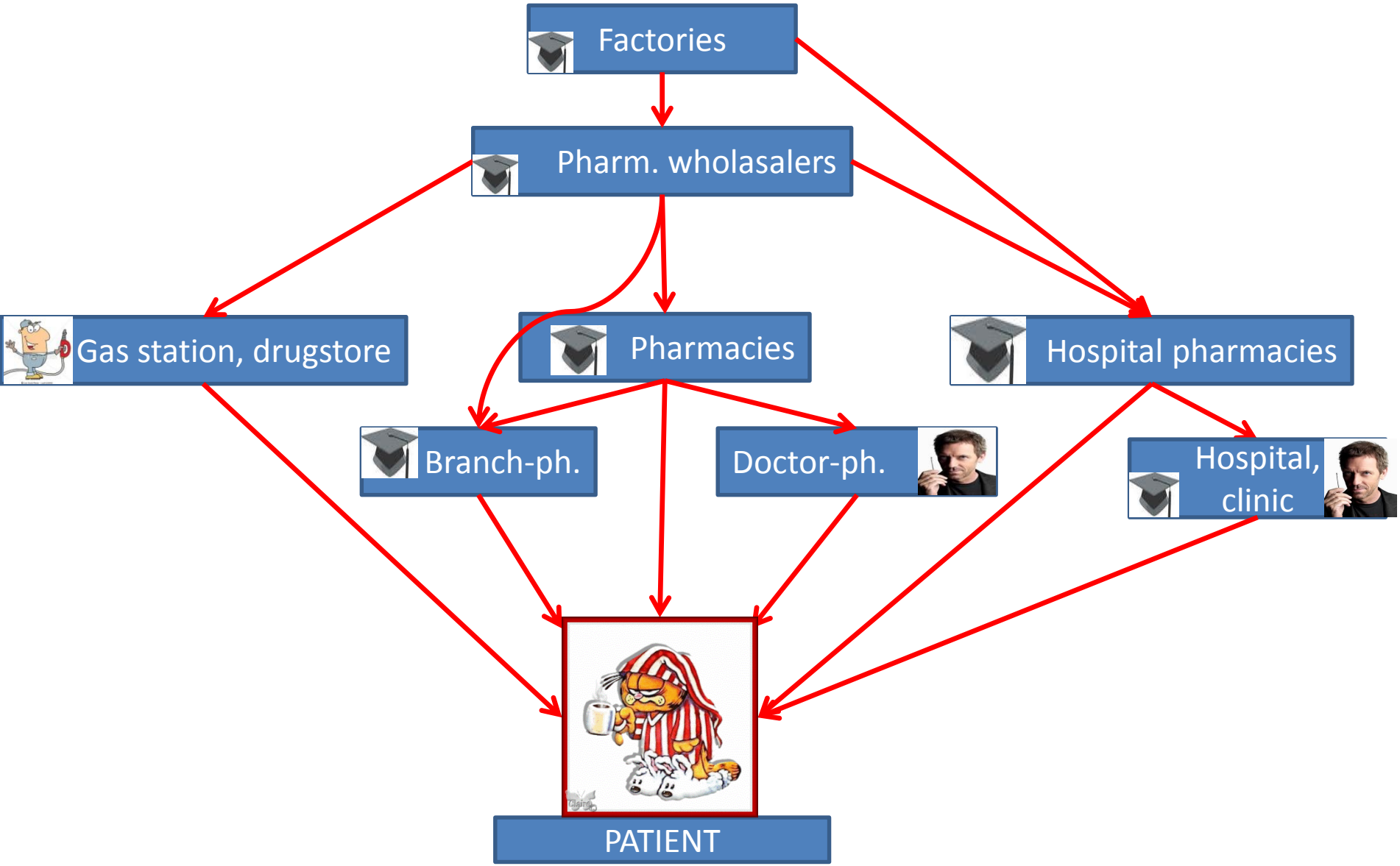
**Thank you for your attention!**

# **Pharmaceutical competencies**
career opportunities

dr. Péter Diós

Institute of Pharmaceutical Technology and Biopharmacy
9/26/2019

# Health care system in Hungary



# Pharmaceutical competencies

**Competency =**

**qualification and right**

**What kind of activities can be done by a pharmacist?**
**What are the rights of the pharmacists?**

- research and development,
- registration/authorization of the IMPs (investigated medical product) in the register book. (authorization process)
  - register.
  - pre-market approval
- compounding preparations, storage, dispensing in pharmacy

# Pharmaceutical competencies

**Competency =**

**qualification and right**

- manufacture of drugs in pharmaceutical industry
  - operation of manufacture process
  - organization of the quality control
  - storage, qualification (analytical labor)
- analytical examinations
- check and supervise the clinical trials
- giving proper advice and information about medication to the patients or to the doctors

# ‘Special’ fields of pharmaceutical profession

**In what position can a pharmacist work?**

- **manager pharmacist**
- employed pharmacist

- hospital/clinical pharmacist (institution pharmacist)
- consultant pharmacists (nursing home)
- ambulatory care pharmacist (chronic patient therapy – office visit)
- nuclear pharmacist
- ***veterinary pharmacist***
- military pharmacist
- pharmacy informatics

Or as a ***researcher***

# Duties of pharmacist

Pharmacist has to be aware of the fact that having:

- professional tasks
- social responsibility.

  - legal regulations
  - professional regulations
  - ethical references

# Duties of pharmacist

- self education
- organized education

**Regularly further self education,**

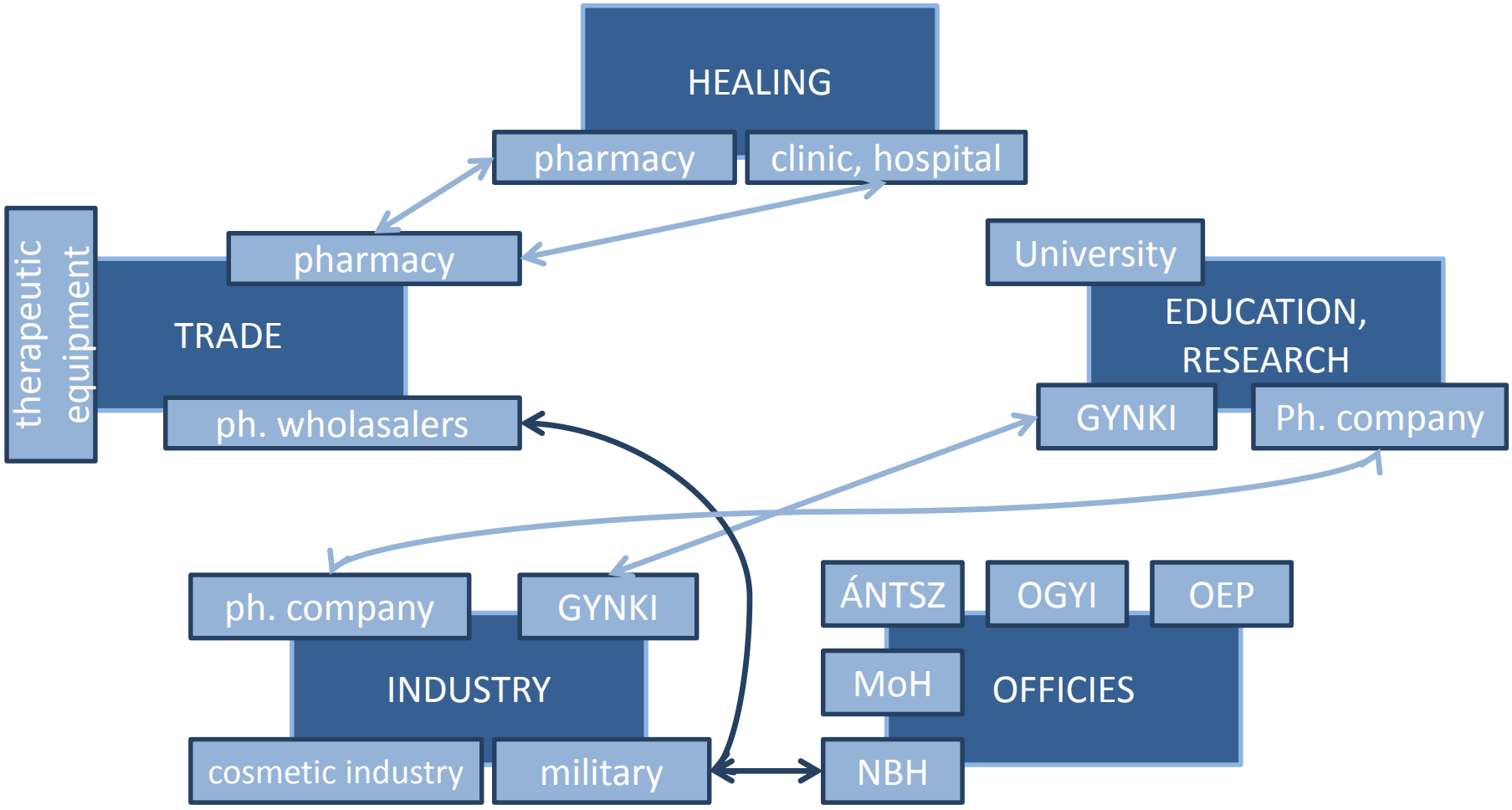
- To enrich professional knowledge
- To know the current state of science
- To do the tasks professionally and in high quality level.

- leadership:
- taking care the staff about further education to be provided and be legal .

# Duties of pharmacist

- **Organized postgradulal education:**
  - In every 5 years, pharmacist has to have 250 credits from further studies
    - Further studies, after which test is written
  - Types of credits:
    - Obligatory
    - Elective
    - Practice

# Career opportunities




GYNKI = Institute of herbs and herbal medicine
OEP = National health insurance fund
OGYI = National institute of pharmacy

ÁNTSZ = National Public Health and Medical Officer Service
MoH = Ministry of health
NBH = National Security Office (agency)

# What have to do a pharmacist at a pharmaceutical company?

**Manufacture** - bases (basic materials)
- end product
- biological medicines (e.g. vaccines, antibodies)
- wrapping

**Examination**
- analytical
- microbiological

**Quality assurance**
- documentation (everything)
- organization of the quality control, qualifying everything (blister, product, persons, devices..)
- official document (register, pre-market approval)
- withdrawal of the register if any quality problem appears

**Registration**

- documentation, connection with examining institutes, performing clinical trials, development

# GYEMSZI – OGYI

**(National Institute for Quality- and Organizational Development in Healthcare and Medicine - National Institute of Pharmacy)**

- Authorization of medicine
- Registration
- Control of ‘Summary of product characteristics’ and ‘package leaflets’
  (excellent pharmacological knowledge)
- Inspection of the preparation process, marketing, wholesalers
- Edition of the Pharmacopoeia – analytic, stability information about the contaminants
- Edition of the FoNo (collection of the traditional prescriptions)

# Organizations connected to pharmaceuticals

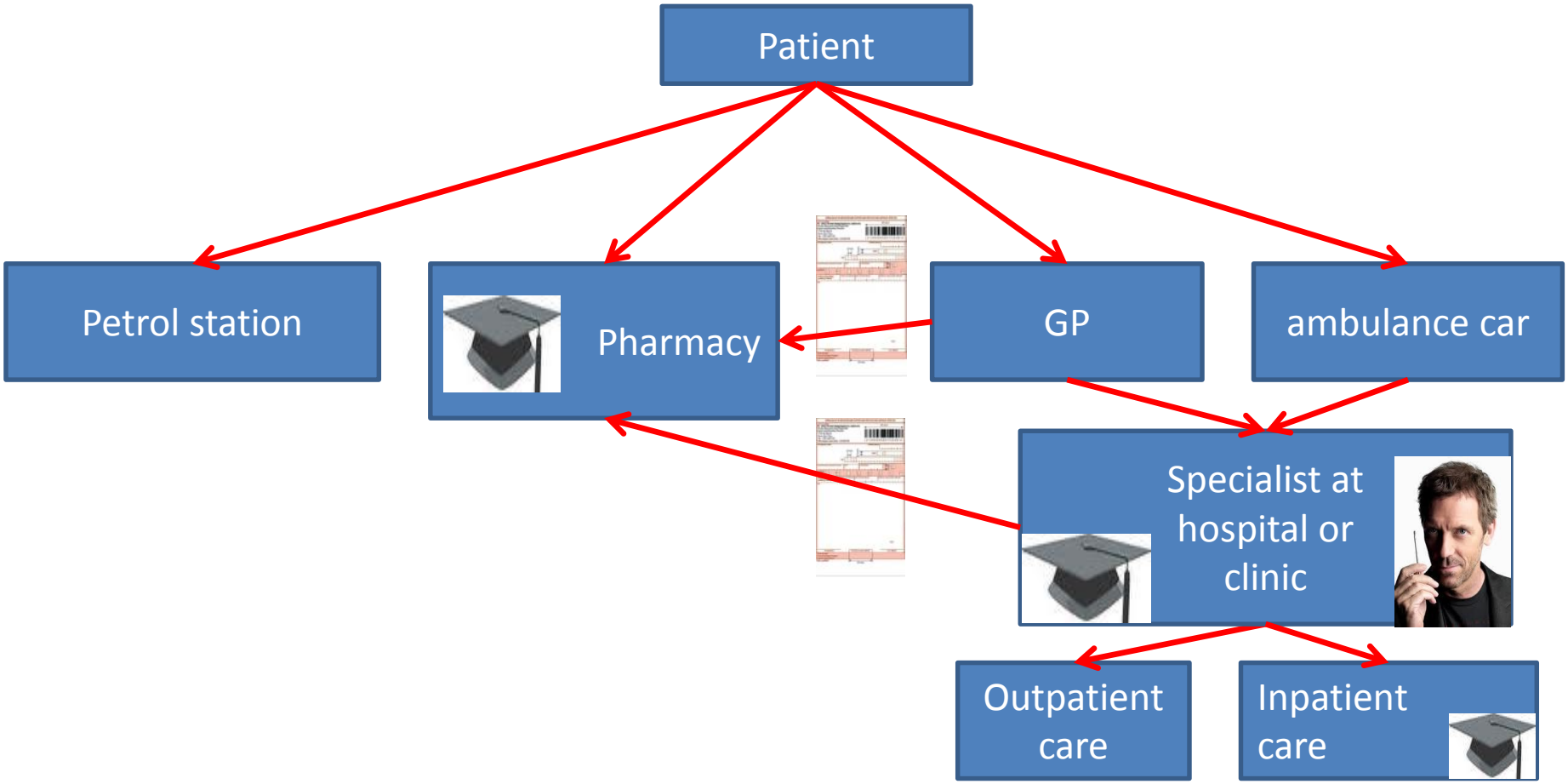
***Professional:***

- Hungarian Society of Pharmaceutical Sciences (MGYT)
- Chamber of the Hungarian Pharmacists (MGYK
- International organizations (FIP, WHO, EMA, FDA)

***Public:***

- ‘politics’, delegates
- Red Cross, Maltese charity …

# Patient care system



**Thank you for your attention !!!**