PHARMACY PRACTICE

SITUATION – worldwide overview

- Increasing globalization of healthcare;
- Healthcare patient-focused;
- The gap in healthcare services between developing and developed countries
- The demand on limited resources - growing.

CHARTER OF FUNDAMENTAL RIGHTS OF THE EUROPEAN UNION

- Everyone has the right of access to preventive health care and the right to benefit from medical treatment

- A high level of human health protection shall be ensured

SITUATIONAL ANALYSIS

1) Population factors

- aging of populations
- difference in health distribution

SITUATIONAL ANALYSIS

2) Disease burden factors –

SITUATIONAL ANALYSIS

3) Health system factors –

- cost
- accessibility

SITUATIONAL ANALYSIS

4) Pharmaceutical industry and innovation factors

5) Cooperation factors

SITUATIONAL ANALYSIS

- 6) Pharmacy profession factors

SITUATIONAL ANALYSIS

the imperative role of the pharmacist

The role of the pharmacist

- The role of the pharmacist:

  "The seven-star pharmacist"

- WHO

The role of the pharmacist

1) CARE-GIVER - the pharmacist provides caring services.

The role of the pharmacist

2) DECISION-MAKER

The role of the pharmacist

3) COMMUNICATOR –

- the pharmacist is in an ideal position between physician and patient

- Communication involves verbal, non-verbal, listening and writing skills (soft skills lecture)

The role of the pharmacist

4) LEADER

- Leadership involves:
  - the ability to make decisions, communicate, and manage effectively
  - as well as compassion and empathy.

The role of the pharmacist

5) MANAGER

- manage resources (human) and information;

The role of the pharmacist

6) LIFE-LONG-LEARNER

The role of the pharmacist

7) Teacher

- responsibility to assist with the education and training of future generations of pharmacists.

Seven or eight star pharmacist?

8) **Researcher**:

- sharing and documenting experiences, the pharmacist

- „the evidence based“ care

GOOD PHARMACY PRACTICE

- The health of the public is fundamental to the happiness and welfare of all people.

GOOD PHARMACY PRACTICE

- Medicinal products are an essential and critical part of health-care services in all cultures and societies.

- The potential benefit of medicinal products is often not realized….

GOOD PHARMACY PRACTICE

The reasons for this gap include:

- problems with medicine selection and dosages,
- inappropriate administration of medicines
- medicine–medicine and medicine–food interactions,
- lack of adherence by patients to prescribed treatment,

GOOD PHARMACY PRACTICE

- „All practicing pharmacists are obligated to ensure that the service they provide to every patient is of appropriate quality. GPP is a means of clarifying and meeting that obligation.“

- The aim: to assist in the promotion of the provision of pharmaceutical care
- Complies with universal norms and values,

(in the private and public sector)

GOOD PHARMACY PRACTICE

- all pharmacists
- all pharmaceutical-related services

GOOD PHARMACY PRACTICE

- FIP adopted the guidelines for Good Pharmaceutical Practice in Tokio on September 5th, 1993

- FIP‘s idea: „*Contribute to health improvement and to help patients with health problems to make the best use of their medicines*."

- (Note: FIP - International Pharmaceutical Federation)

GOOD PHARMACY PRACTICE

- The revised version of this document was endorsed by WHO in 1997
- Updates: 2009-2010, 2011

- 2020 Vision
- …..

- (Note: WHO - World health organization)

GOOD PHARMACY PRACTICE

- *GPP 2011:*

„The practice of pharmacy responds to the needs of the people who use the pharmacists' services to provide optimal, evidence-based care.

To support this practice it is essential that there will be an established national framework of quality standards and guidelines."

GOOD PHARMACY PRACTICE

- adapted in a wide number of developed countries
- Focus on differences between countries
- harmonize with GPP

GOOD PHARMACY PRACTICE

- Specific standards of GPP can be developed only within a national pharmacy professional organization framework.

- Who is responsible?

Pharmaceutical organizations

and

Governments

GOOD PHARMACY PRACTICE

- Level 1: Prepare, obtain, store, secure, distribute, administer, dispense and dispose of medical products
- Level 2: Provide effective medication therapy management
- Level 3: Maintain and improve professional performance
- Level 4: Contribute to improve effectiveness of the health-care system and public health

GOOD PHARMACY PRACTICE

- Each level is structured in several parts
- For each part has been set the list of minimum national standards

GOOD PHARMACY PRACTICE

Level 1: Prepare, obtain, store, secure, distribute, administer, dispense and dispose of medical products

- Function A: Prepare extemporaneous medicinal products
- Function B: Obtain, store and secure medicinal products
- Function C: Distribute medicinal products

GOOD PHARMACY PRACTICE

- Function D: Administration of medicines, vaccines and other injectable medications
- Function E: Dispensing of medical products
- Function F: Dispose of medicine preparations and medical products

GOOD PHARMACY PRACTICE

Level 2: Provide effective medication therapy management

- Function A: Assess patient health status and needs
- Function B: Manage patient medication therapy
- Function C: Monitor patient progress and outcomes
- Function D: Provide information about medicines and health-related issues

GOOD PHARMACY PRACTICE

Level 3: Maintain and improve professional performance

- development strategies to improve current and future performance

GOOD PHARMACY PRACTICE

Level 4: Contribute to improve effectiveness of the health-care system and public health

- Function A: Disseminate evaluated information about medicines and various aspects of self-care
- Function B: Engage in preventive care activities and services
- Function C: Comply with national professional obligations, guidelines and legislations
- Function D: Advocate and support national policies that promote improved health outcomes

GOOD PHARMACY PRACTICE

- Implementation example:
- FIP endorsed The paper:

- "GPP in Developing Countries – Guidelines for Implementation"

- September 1998

Recomendation for implementation in developing countries

Main topics:

- ✓ Personnel
- ✓ Training
- ✓ Standards
- ✓ Legislation

1. Personnel

The idea :

- all people should have access to an adequate pharmaceutical service

The goal:

Sufficient numbers of pharmacists

2. Training

The idea: Sufficient numbers of well educated pharmacists

Realization – standard for:

- Education

1st step: to have graduate level pharmacist,

2nd step: provide continuing education for pharmacists (pharmacy technicians)

3. Standards

The goal :

- guarantee the integrity and quality of the product, and minimise the risk of dispensing errors

3.1. Standards for facilities

3.2. Standards for Dispensing

The goal:

- right patient the right medicine

3.3. Standards for Containers

Sample of stepwise implementation:

Step 1: Air-tight, plastic wallet →

Step 2: Air-tight, rigid container →

Step 3: Air-tight container with child resistant closure →

Step 4: Manufacture‘s original pack etc.

3.4. Standards for Labeling

- The required minimum for the label
- Warning
- Standards for written information, standards for pictograms as well!!

3.5. Instruction to the patient

Example of development

Step 1: Verbal →

Step 2: Verbal plus hand-written and affixed to the container →

Step 3: Verbal plus printed and affixed to the container →

Step 4: Step 3 plus additional verbal counselling, supplementary written information

3.6. Standards for Records

- Maintained in a system

3.7. Standards for Health information, patient counselling, pharmaceutical care

3.8. Standards for Self medication

3.9. Standards for Products

- Legal mechanisms to ensure quality, safety, efficacy of medicines

4. Legislation

- The legislation for pharmacy practice must be practical, enforcable
- The legislation controls almost all above
- Needed: independent bodies to control all aspects of medicine registration, distribution,..

4. Legislation

- Set up: National drug policy

To ensure equitable access to safe and effective drug of good quality.

References:

- www.fip.org

Guidlelines for pharmacy practice

Good pharmacy practice in developing countries

Application of Good pharmacy practice

STANDARD OPERATING PROCEDURES and other documentation in pharmacy practice

Good pharmacy practice

- The concept of GPP – adopted in many countries

GPP in CZ

In the CZ:

- **Decree No 84/2008 Coll.,** on good pharmaceutical practice, detailed conditions of handling pharmaceuticals in pharmacies, healthcare facilities and other operators and facilities supplying medicinal products, as amended

(FIP GPP Level 1: Prepare, obtain, store, secure, distribute, administer, dispense and dispose of medical products, Level 2: Provide effective medication therapy management)

GPP in CZ

Education and Qualification:

- Act No…..,on the Conditions for Acquiring and Recognising Professional Qualifications and Specialised Qualifications to Perform the Professions of a Physician, Dentist, and Pharmacist

- Act No. 96/2004 Col…..l., on the Conditions for Acquiring and Recognising Professional Qualifications to Perform Non-medical Health Care Professions and to Perform Activities relating to Health Care Provision and on the Amendment to Some Related Acts (the Act on Non-medical Health Care Professions)

- Rules of Czech chamber of pharmacists

(Level 3: Maintain and improve professional performance, Level 4: Contribute to improve effectiveness of the health-care system and public health)

Standard Operating Procedures in the pharmacy pracitce

Standard Operating Procedures

- SOPs needed in the GPP

- All ativities in the pharmacy - It is possible to describe in the SOP

Standard Operating Procedures

- Help to assure quality and consistency of pharmacy service:

utilise the skills of all team members;

role clarification

What is it?

- Standard Operating Procedure (SOP) is a set of written instructions that document a routine or repetitive activity, followed by an organization .
- SOPs are an integral part of a successful quality control system
- Development and use of SOPs minimizes variation and promotes quality

Limatation

SOPs are of limited value if:

- not written correctly
- are not followed

SOP in CZE pharmacy practice

- SOPs for all repeated activities

- Technological prescription (master formula sheet, SOP for preparing of medicinal products) - Required for repeated preparing of medicinal products

GPP in CZE

Technological prescription for preparing :

- Medicinal product – „name“
- Ingredients
- Preparing directions
- Containers
- Labelling
- Storage
- Expiration date
- Tests
- Date - signature
- Up dates - signature
- Annulment – date - signature

Addictive substances in the pharmacy

International convention on narcotic drugs

- The International Opium Convention, signed at The Hague on January 23, 1912
- Revised International Opium Convention was signed at Geneva on February 19, 1925, entered into force - 1928.
- Convention for Limiting the Manufacture and Regulating the Distribution of Narcotic Drugs was a drug control treaty promulgated in Geneva on 13 July 1931 that entered into force - 1933.

United Nations and Narcotic Drugs

- **Protocol** Amending the Agreements, Conventions and Protocols on Narcotic Drugs concluded at The Hague on 23 January 1912, at Geneva on 11 February 1925 and 19 February 1925, and 13 July 1931, at Bangkok on 27 November 1931 and at Geneva on 26 June 1936 signed on December 11, 1946 at Lake Success, that shifted the drug control functions previously assigned to the League of Nations to the United Nations.

- Protocol of 1948 at Paris

- Protocol of 1953 at New York

SINGLE CONVENTION ON NARCOTIC DRUGS

- SINGLE CONVENTION ON NARCOTIC DRUGS, 1961
  As amended by the 1972 Protocol by United nations

- „*Recognizing* that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes.“

SINGLE CONVENTION ON NARCOTIC DRUGS

- Duty to prevent abusing
- require coordinated and universal action.

SINGLE CONVENTION ON NARCOTIC DRUGS

- Acknowledgment: the competence of the United Nations in the field of narcotics control
- Cooperation - within the framework of that Organization

SINGLE CONVENTION ON NARCOTIC DRUGS

- Schedule I.

- Substances with addictive properties, presenting a serious risk of abuse

- Degree of control: very strict

- Limitation to medical and scientific purposes of all phases of trade (manufacture, wholesale and retail) and of the possession and use

SINGLE CONVENTION ON NARCOTIC DRUGS

- Schedule I.

- Obligation of all participants in the narcotics trade to keep detailed records of their transactions in drugs;

- Requirement of a medical prescription for the supply or dispensation of drugs to individuals;

SINGLE CONVENTION ON NARCOTIC DRUGS

- Schedule II.

- Substances normally used for medical purposes and given the lowest risk of abuse

SINGLE CONVENTION ON NARCOTIC DRUGS

- Schedule II.

- Drugs are regulated only less strictly than Schedule I drugs

SINGLE CONVENTION ON NARCOTIC DRUGS

- Schedule III.

- contains preparations which enjoy a privileged position under the Single Convention

- Preparations of substances listed in Schedule II, under conditions written in the commentary

SINGLE CONVENTION ON NARCOTIC DRUGS

- Schedule IV.
- The most dangerous substances, already listed in Schedule I,
- particularly harmful
- **extremely limited (or none) medical or therapeutic value**

Convention on Psychotropic Substances of 1971

The objectives:

- Again to limit the use of these substances to medical and scientific purposes

- Again some psychotropic substances may have therapeutic value, but they also present a dangerous risk of abuse.

Convention on Psychotropic Substances of 1971

- Schedule I

high risk of abuse,

- particularly, serious threat to public health
- which are of **very little or no therapeutic value**

Convention on Psychotropic Substances of 1971

Schedule I

- Degree of control:
- Very strict;
- use is prohibited except for scientific limited medical purposes

Convention on Psychotropic Substances of 1971

Schedule II

Substances:

- presenting a risk of abuse,
- posing a serious threat to public health
- low or moderate therapeutic value

- Degree of control: strict, special medical prescription form

Convention on Psychotropic Substances of 1971

Schedule III

Substances:

- presenting a risk of abuse,
- posing a serious threat to public health
- which are of moderate or high therapeutic value

Convention on Psychotropic Substances of 1971

Schedule III

- Degree of control:
- available for medical purposes

Convention on Psychotropic Substances of 1971

Schedule IV

Substances presenting:

- a risk of abuse,
- posing a minor threat to public health
- with a high therapeutic value

Convention on Psychotropic Substances of 1971

Schedule IV

- Degree of control:

- These substances are available for medical purposes

Convention against Illicit Traffic Narcotic drugs and Psychotropic substances

- Wien, 1988

Comprehensive measures against:

- drug trafficking,
- Precursors / chemicals.

International cooperation through:

- controlled deliveries and transfer of proceedings.

Convention against Illicit Traffic Narcotic drugs and Psychotropic substances

Drug precursors are chemicals that have primarily a wide variety of legitimate and important industrial uses

but that may be diverted from legal trade to the manufacturing of illicit drugs.

Convention against Illicit Traffic Narcotic drugs and Psychotropic substances

Necessary:

to monitor certain substances,

Convention against Illicit Traffic Narcotic drugs and Psychotropic substances

Licensing

Convention against Illicit Traffic Narcotic drugs and Psychotropic substances

- category 1 covers the most sensitive substances (the 'key' drug precursors)
- category 2 covers less sensitive substances and pre-precursors
- category 3 covers chemicals that can have different types of uses in the manufacturing process (e.g. solvents)

Precursors

- •Regulation (EC) No 273/2004 of the European Parliament and of the Council on drug precursors

CD – records
practical application

NARCOTIC DRUGS

SINGLE CONVENTION
ON NARCOTIC DRUGS

YELLOW LIST

PSYCHOTROPIC SUBSTANCES

SINGLE CONVENTION ON PSYCHOTROPIC SUBSTANCES

GREEN LIST

CD in the pharmacy - special handling

Substances, medicinal products with content of this substances listed in:

- Schedule I in the CONVENTION ON NARCOTIC DRUGS, As amended by the 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961

- Schedule II in the CONVENTION ON PSYCHOTROPIC SUBSTANCES 1971

- „Medical prescription with blue strip“ – in CZE

Addictive substances in the pharmacy

- Records – in written form: Record book for Controlled drugs (addictive medicinal products)

- Every pharmacy is obligated to own this Record book

Record book

- General rules: hardback (bound), specified number of sheets, number of the first and last sheet…

Record book

- Identifying
- Who is authorized to write in the Record book?

Record book

- The date

- Registration Number

Record book

- List of recorded medicinal products, substances

- Medicinal product‘s identification:
- Brand name and supplement (dosage form, strength, package, eventually registration code).
- Substances: name

- Units: g, original package, unit of dosage form

Record book

- One record – one row

- Structure of the record:
  - Input:
  - Date, when the supply was obtained
  - Name and address from whom obtained (e.g. wholesaler, pharmacy)
  - Quantity obtained
  - Output:
  - Name and address of person or firm to which was supplied
  - Prescriber or licence holder - details
  - Quantity and form in which was supplied

Record book

- Inventory check (stock take):

- Last day of every month

Record book

- Storing of the documentation:

- 5 year

Record book

- In clinical trials – recorded as well.

Report on the stock level and movement of inventory addictive substances

- SIDC (SUKL) - by the end of February : all pharmacies

- Report on the stock level and movement of inventory addictive substances – by 10th February: only veterinary

UK – controlled drugs records

- Structure of the record:
  - Input:
  - Date, when the supply was obtained
  - Name and address from whom obtained (e.g. wholesaler, pharmacy)
  - Quantity obtained
  - Output:
  - Name and address of person or firm to which was supplied
  - Prescriber or licence holder - details
  - Quantity and form in which was supplied

UK – controlled drugs records

- As an alternative to a bound book, an electronic CDR.

- special condition for e - records

UK – controlled drugs records

- Registers, requisitions and orders for CDs must be preserved for a minimum of 2 years.

Precursors – records practical application

Precursors

- Regulation (EC) No 273/2004 of the European Parliament and of the Council on drug precursors

CZE:

- Category 1 – written records, stock: in the safe

- Category 2 – e-records enough