# GOOD PHARMACY PRACTICE

# SITUATION – worldwide overview

- globalization
- Healthcare patient-focused
- The gap: developing and developed countries

(needs to be urgently addressed)

- The demand on limited resources

# 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

# SITUATIONAL ANALYSIS

2) Disease burden factors –

# SITUATIONAL ANALYSIS

3) Health system factors

# SITUATIONAL ANALYSIS

4) Pharmaceutical industry and innovation factors

5) Cooperation factors

# SITUATIONAL ANALYSIS

- 6) Pharmacy profession factors –

# SITUATIONAL ANALYSIS

Healthcare systems

**are realising the imperative role of the pharmacist**

through both experience and research evidence.

# The role of the pharmacist

- The role of the pharmacist:

  “The seven-star pharmacist”

- WHO

# The role of the pharmacist

1) CARE-GIVER

# The role of the pharmacist

## 2) DECISION-MAKER

# The role of the pharmacist

3) COMMUNICATOR –

# The role of the pharmacist

4) LEADER

# The role of the pharmacist

5) MANAGER

# The role of the pharmacist

6) LIFE-LONG-LEARNER

# The role of the pharmacist

7) Teacher

- .

# Seven or eight star pharmacist?

8) **Researcher**:

- „the evidence based“ care

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

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- 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

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The reasons for this gap include:

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- „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

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- all pharmacists
- all pharmaceutical-related services

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- 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 )

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

- 2020 Vision
- …..

- (Note:  WHO - World health organization)

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- *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

Good pharmacy practice =

guidelines developed to set up standards

# GOOD PHARMACY PRACTICE

- These guidelines have been subsequently adapted in a wide number of developed countries

- Focus on differences between countries

  (health care system,…)

- Where national standards exist – reviewed to harmonize with GPP

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- 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

*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

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- 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

- 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,

# 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

# 3.3. Standards for Containers

- Liquid pharmaceuticals – in pharmaceuticals bottles
- Poisonous products – distinguishable bottles

# 3.5. Instruction to the patient

# 3.6. Standards for Records

- Maintained

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

# 3.8. Standards for Self medication

- Protocols to ensure that advice is accurate and appropriate

# 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. 95/204 Coll. ,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 Coll., 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

- Help to assure quality and consistency of pharmacy service:

Provide an opportunity to fully utilize 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:

# 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
- How to perform the process  of „compounding“
- Containers
- Labelling
- Storage
- Expiration date
- Tests
- Date - signature
- Up dates - signature
- Annulment – date - signature