

PHARMACY PRACTICE

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 under the conditions established by national laws and practices.
- ⦿ A high level of human health protection shall be ensured in the definition and implementation of all the Union's policies and activities.

SITUATION – worldwide overview

- ⦿ Increasing globalization of healthcare;
- ⦿ Healthcare is becoming more and more patient-focused;
- ⦿ The gap in healthcare services between developing and developed countries (needs to be urgently addressed)
- ⦿ The demand on limited resources (both human and financial) - growing.

SITUATIONAL ANALYSIS

1) Population factors

- ⦿ the population of the world will continue to grow
(and its economy, prevalence of poverty ??)
- ⦿ aging of populations
- ⦿ difference in health distribution in urban/rural developments.

SITUATIONAL ANALYSIS

2) Disease burden factors –

- leading causes of disease burden continue to include a mix of communicable and noncommunicable diseases.

Variation exists between high-, low- and middle-income countries.

SITUATIONAL ANALYSIS

3) Health system factors –

- ⦿ cost
- ⦿ accessibility



ability to provide high quality healthcare with best possible outcomes

Note: growing healthcare worker shortages - affecting healthcare delivery around the world.

SITUATIONAL ANALYSIS

4) Pharmaceutical industry and innovation factors

5) Cooperation factors

SITUATIONAL ANALYSIS

- ⑥ 6) Pharmacy profession factors –
it is speculated that the number of trained and competent pharmacists may be either unavailable or inadequately distributed to meet population needs.

This is a result of varying education and training processes of pharmacists and pharmaceutical scientists around the world!

SITUATIONAL ANALYSIS

Healthcare systems

are realising the imperative role of the pharmacist

through both experience and research evidence.

The role of the pharmacist

Pharmacist



What everyone thinks I do



What society thinks I do



What the media thinks I do



What doctors think I do



What I think I do



What I do

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 pharmacist must view the pharmacy practice as integrated in the health care system and has to co-operate with others health care professionals

The role of the pharmacist

2) DECISION-MAKER

- ⦿ the appropriate, efficacious and cost effective use of resources

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

- effectively manage resources (human) and information;

The role of the pharmacist

6) LIFE-LONG-LEARNER

- learning must be supported throughout the pharmacist's career.

The role of the pharmacist

7) Teacher

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

the practitioner - gain new knowledge and to fine-tune existing skills.

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

- ① Medicinal products are an essential and critical part of health-care services in all cultures and societies.
- ① The potential benefit of medicinal products is often not realized — there is a gap between the proven efficacy of medicines demonstrated in clinical trials and their actual effectiveness in practice.

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

- ◎ „It has been estimated that the cost of problems with the use of medicines is equal to or greater than the cost of the medicines themselves.“
- ◎ (Medicinal products are also increasingly expensive)

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

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

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

- ① Function D: Administration of medicines, vaccines and other injectable medications
- ① Function E: Dispensing of medical products
- ① 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,

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

Clean, tidy, hygienic conditions

Adequate space, light

Appropriate condition for storage, dispensing
(including security)

Protection from exposure to excessive light,
heat

Appropriate equipment for dispensing,
preparing, manufacturing...

3.2. Standards for Dispensing

The goal:

- ⦿ right patient the right medicine (see seminar)

(Possible interaction are avoided, shelf time, correct and clear instruction to the patient - instruction for use, warnings, adverse - side effects...)

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.

3.3. Standards for Containers

- ① Liquid pharmaceuticals – in pharmaceuticals bottles
- ① Poisonous products – distinguishable bottles

3.3. Containers



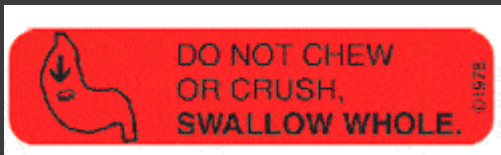
3.4. Standards for Labeling

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

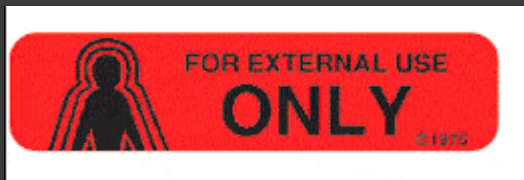
4	 <p>TAKE WITH FOOD OR MILK</p> <p>©1987</p>	Take with food or milk.	
5	 <p>DO NOT TAKE THIS DRUG IF YOU BECOME PREGNANT</p> <p>©1976</p>	Do not use if you are pregnant, think you are pregnant, or breast feeding.	
6	 <p>MAY CAUSE DROWSINESS. ALCOHOL MAY INTENSIFY THIS EFFECT. USE CARE WHEN OPERATING A CAR OR DANGEROUS MACHINERY.</p> <p>©1979</p>	May cause drowsiness. Be careful when driving a car or using machinery.	
7	 <p>DO NOT DRINK ALCOHOLIC BEVERAGES WHEN TAKING THIS MEDICATION</p> <p>©1986</p>	Do not drink alcohol.	
8	 <p>YOU SHOULD AVOID PROLONGED OR EXCESSIVE EXPOSURE TO DIRECT AND/OR ARTIFICIAL SUNLIGHT WHILE TAKING THIS MEDICATION.</p> <p>©1986</p>	Limit your time in the sun.	
9	 <p>OBTAIN MEDICAL ADVICE BEFORE TAKING NONPRESCRIPTION DRUGS. SOME MAY AFFECT THE ACTION OF THIS MEDICATION.</p> <p>©1986</p>	Talk to your doctor before using any over-the-counter drugs.	

Labeling - pictograms

◉ Samples of misinterpretation:



"Chew pill and crush before swallowing."
"Chew it up so it will dissolve, don't swallow whole or you might choke."

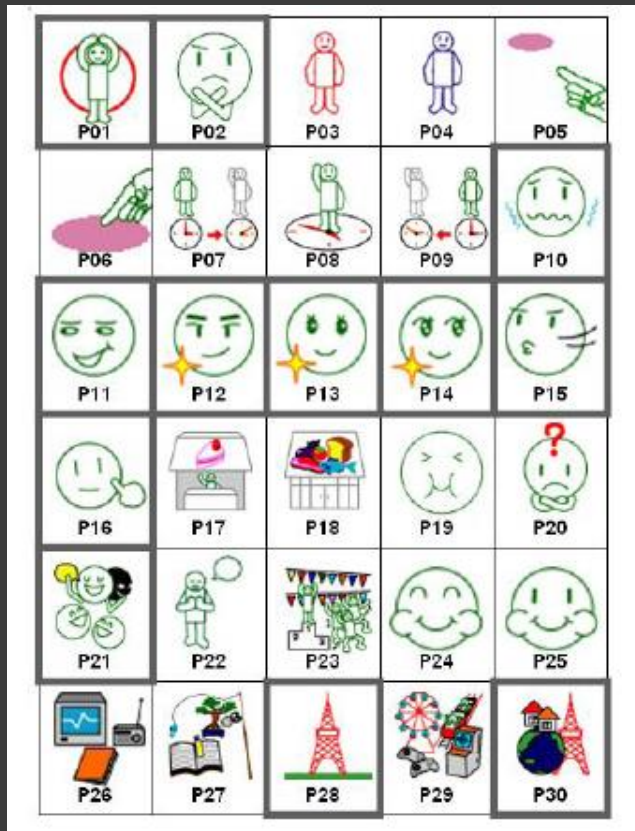


"Use extreme caution in how you take it."
"Medicine will make you feel dizzy."
"Take only if you need it."



"Don't take medicine if you've been in the sunlight too long."
"Don't leave medicine in the sun."

Cultural differences in pictogram:



P28

U.S.: Eiffel tower

Japanese: Japan tower



P10

U.S: Scared

Japanese: Cold

3.5. Instruction to the patient

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

3.5. Instruction to the patient



Pharmacy name and address

Number used by the drugstore to identify this drug for your refills

Person who gets this drug

Instructions about how often and when to take this drug

Name of drug and strength of drug

Number of refills before certain date

Doctor's name

Drugstore phone number

Prescription fill date

Local Pharmacy
123 MAIN STREET
ANYTOWN, USA 11111 (800) 555-5555

DR C. JONES

NO 0060023-08291 DATE 06/23/09

JANE SMITH
456 MAIN STREET ANYTOWN, US 11111

TAKE ONE CAPSULE BY MOUTH THREE TIMES DAILY FOR 10 DAYS UNTIL ALL TAKEN

AMOXICILLIN 500MG CAPSULES

QTY MFG
NO REFILLS - DR. AUTHORIZATION REQUIRED
USE BEFORE 06/23/12
SLF/SLF

Don't use this drug past this date

<http://www.womenshealth.gov>

3.6. Standards for Records

- ⦿ Records of all dispensed medicinal products – patient, name and strength of medicine, dosage, quantity of supplied, date of dispensing....
- ⦿ Maintained in a system (manual or computerised) – easy retrieval patient information

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

Provide **health promotion literature** →

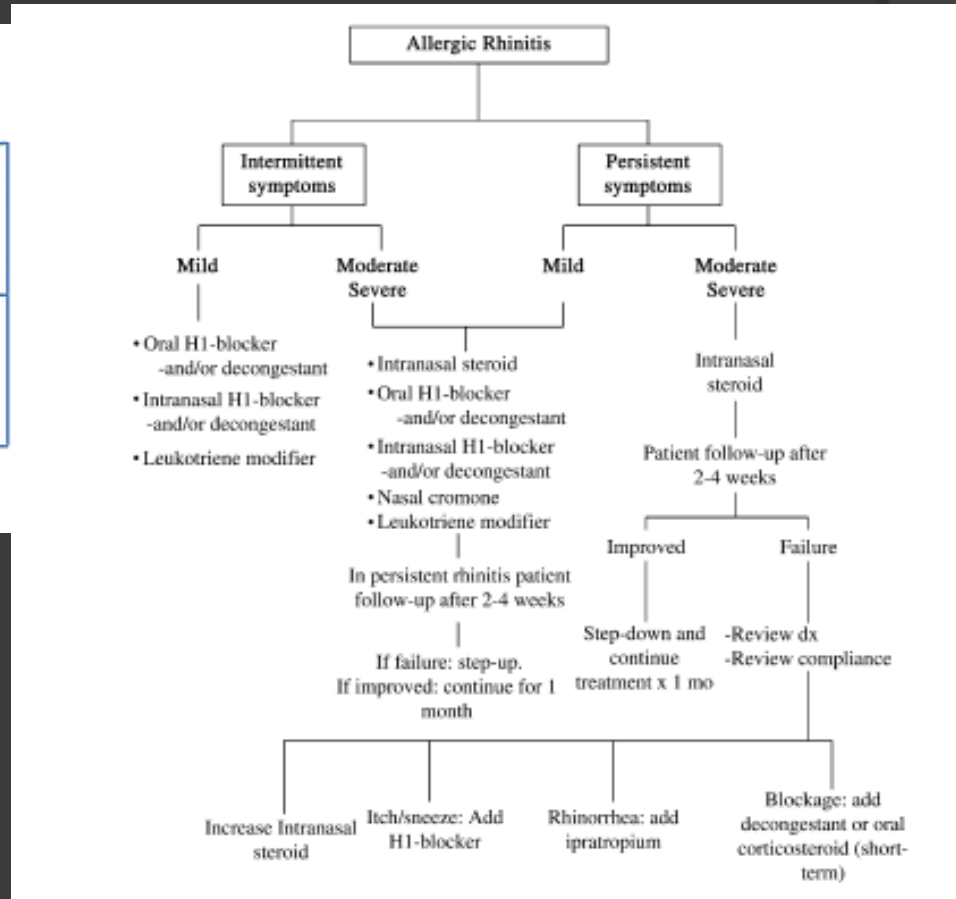
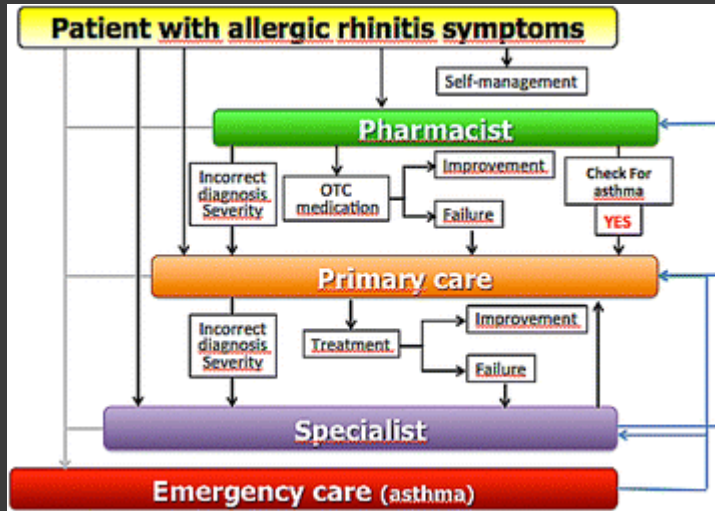
Provide **an area** suitable for delivering of basic information, counselling and pharmaceutical care →

Provide a separate **room** for these activities

3.8. Standards for Self medication

- ⦿ Protocols to ensure that advice is accurate and appropriate

3.8. Standards for Self medication



Greiner A.N., Meltzer E.O.: Pharmacologic rationale for treating allergic and nonallergic rhinitis, The Journal of Allergy and Clinical Immunology, Volume 118, Issue 5 , Pages 985-996, November 2006

3.9. Standards for Products

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

4. Legislation

- ⦿ The legislation for pharmacy practice must be practical, enforceable
- ⦿ 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

Guidelines for pharmacy practice

Good pharmacy practice in developing
countries

STANDARD OPERATING PROCEDURES and other
documentation in pharmacy practice

Application of Good pharmacy practice

Good pharmacy practice

- The concept of GPP – adopted in many countries

Draft

Practice



GOOD PHARMACY PRACTICE IN SOUTH AFRICA



ber 2005



Best
Eff
Me



1

/ 76



- The GPP standards: all practising pharmacists and other healthcare professionals providing a pharmaceutical-related service to patients.



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 practice

Standard Operating Procedures

- ◎ SOPs needed in the GPP
- ◎ All activities in the pharmacy - It is possible to describe in the SOP
 - staff
 - prescription problem solving
 - SOPs for laboratory..

Standard Operating Procedures

- Help to assure quality and consistency of pharmacy service:

Provide an opportunity to fully utilise the skills of all team members;

Help to avoid confusion over who does what (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