# 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

#### 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; Amendment 254/2013

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

#### Documents in the pharmacy

Store 5 years!

- Rx which aren't sent to insurance companies
- Record book for CD drugs
- Protocols (inspection, audits, tests..)
- Technological prescription / SOPs

SOPs for repeated activities

Technological prescription (master formula sheet):

Required for repeated praparing

#### Technological prescription for praparing:

- Medicinal product
- Ingredients
- Praparing directions
- Containers
- Labelling
- Storage
- Expiration date
- Tests
- Date signature
- Up dates signature
- Annulment date signature

- 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)

• Act No. 378/2007 Coll., on Pharmaceuticals, as amended,

- Decree No 54/2008 Coll., on the method of prescribing medicinal products, particulars to appear on medical prescriptions, and rules governing the use of medical prescriptions, as amended;
- **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;
- Decree No 85/2008 Coll., which lays down a list of active substances and excipients which may be used in the preparation of medicinal products, as amended;

 Act No 167/1998 Coll, on addictive substances and amending certain other acts, as amended

Act No 268/2014 Coll. on Medical Devices

• Act No 48/1997 Coll., on Public Health Insurance and on Amendments to Some Related Acts, as amended.

• Act No. 372/2011 Coll., on health services and the terms and conditions for the providing of such services, as last amended.

# SOPs in the pharmacy pracitce

SOPs needed in the GPP

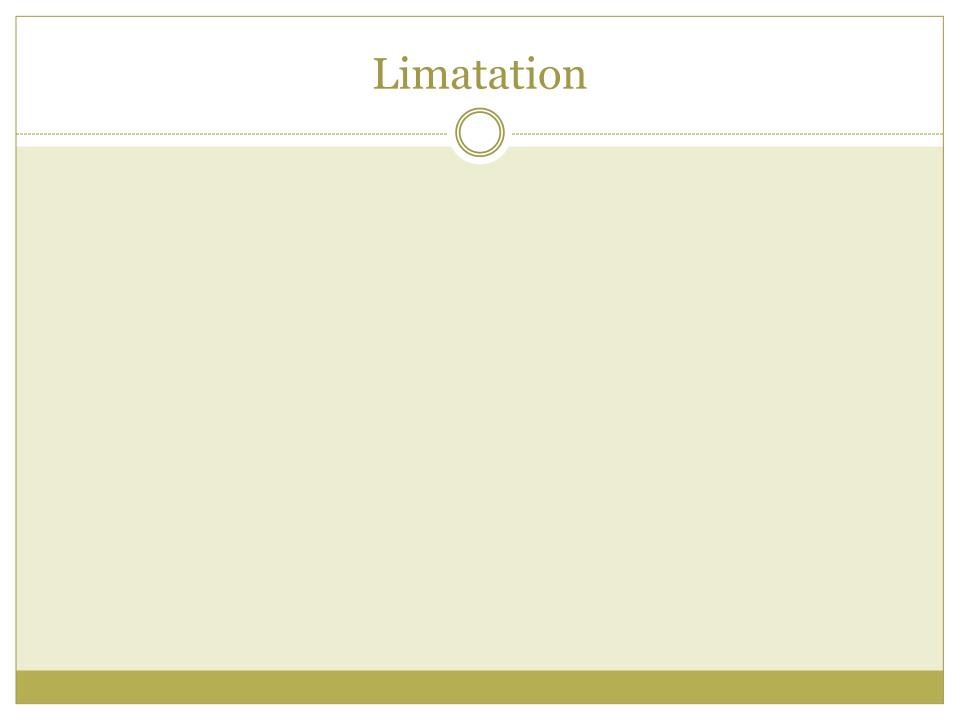
 All ativities in the pharmacy - It is possible to describe in the SOP  Help to assure quality and consistency of pharmacy service:

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

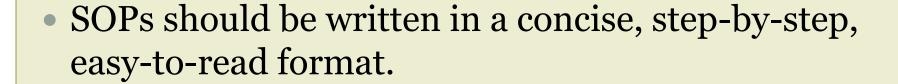
Role clarification

#### 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



## How to write SOPs?



Paper or electronic form

## References:

• Guidance for Preparing Standard Operating Procedures