

# 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; 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)

# GPP in CZ



## 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

# GPP in CZ



- SOPs for repeated activities
- Technological prescription (master formula sheet):

Required for repeated preparing

# GPP in CZE



Technological prescription for preparing :

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

# 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)

# Scope of Czech law for pharmacy practice



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



# Scope of Czech law for pharmacy practice



- **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;

# Scope of Czech law for pharmacy practice



- **Act No 167/1998 Coll, on addictive substances and amending** certain other acts, as amended
  
- **Act No 268/2014 Coll. on Medical Devices**

# Scope of Czech law for pharmacy practice



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

# Scope of Czech law for pharmacy practice



- **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 practice





- SOPs needed in the GPP
- All activities 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



# Limatation



# How to write SOPs?



- SOPs should be written in a concise, step-by-step, easy-to-read format.
- Paper or electronic form

# References:



- *Guidance for Preparing Standard Operating Procedures*