EU and CZE legal regulations governing pharmaceuticals, pharmacy pracitce

Directive 2011/62/EU -

Medicines verification in Europe:

2019, what to expect in 2020

Directive 2011/62/EU

Falsified MP:

Any MP with a false representation of:

- its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients;

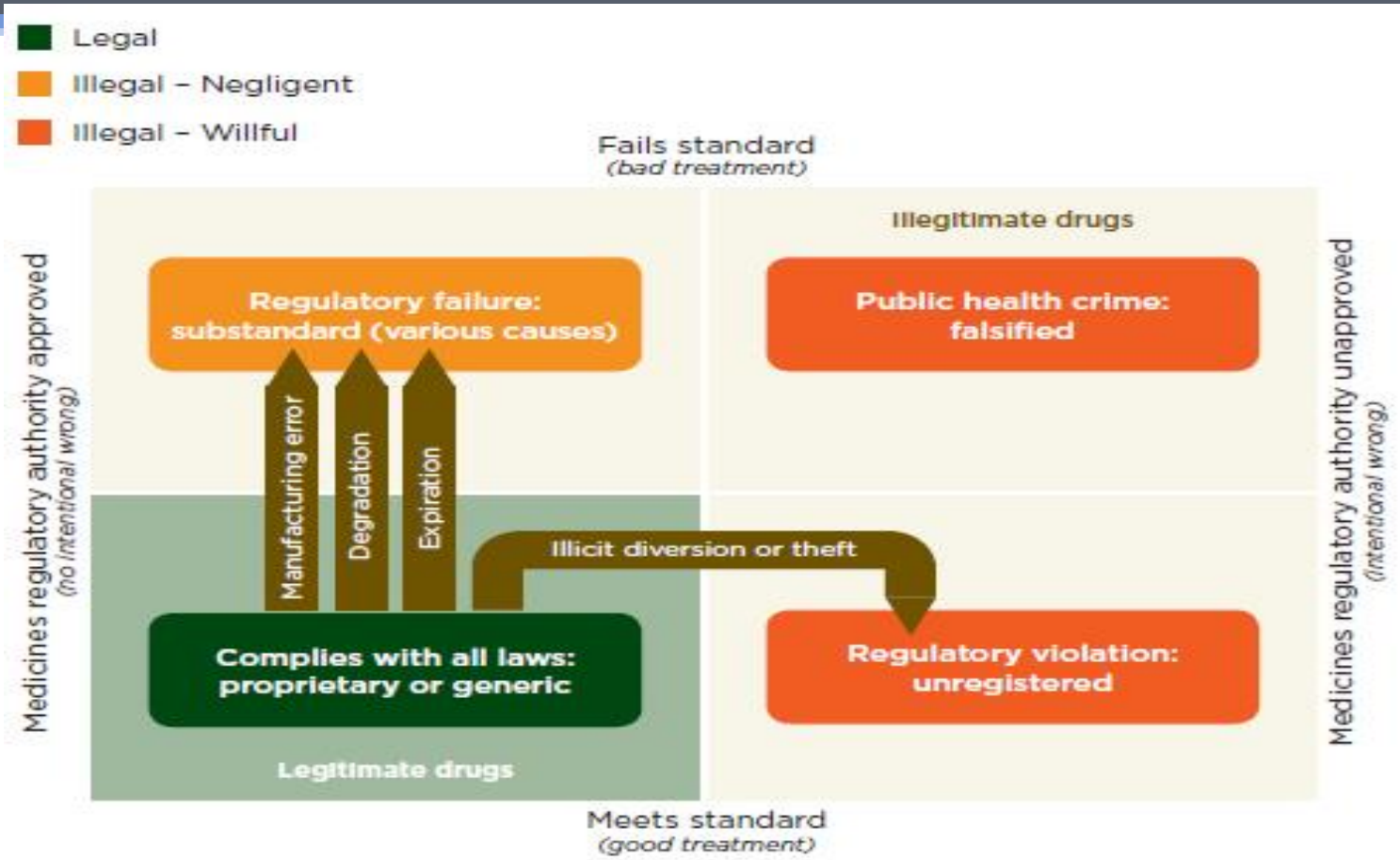
Directive 2011/62/EU

Falsified MP:

Any MP with a false representation of:

- its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder;
- its history, including the records and documents relating to the distribution channels used.

- Note:
- This definition does not include unintentional quality defects…


Legal
Illegal – Negligent
Illegal – Willful
Fails standard
(bad treatment)
Illegitimate drugs
Regulatory failure:
substandard (various causes)
Public health crime:
falsified
Medicines regulatory authority approved
(no intentional wrong)
Manufacturing error
Degradation
Expiration
Illicit diversion or theft
Complies with all laws:
proprietary or generic
Regulatory violation:
unregistered
Legitimate drugs
Medicines regulatory authority unapproved
(intentional wrong)
Meets standard
(good treatment)

- *Counterfeit: A counterfeit drug bears an unauthorized representation of a registered trademark on a product identical or similar to one for which the trademark is registered.*
- *Falsified: A falsified drug is one that falsely represents the product's identity or source or both.*
- *Substandard: A substandard drug is one that fails to meet national specifications cited in an accepted pharmacopeia or in the manufacturer's approved dossier.*
- *Unregistered: An unregistered product lacks market authorization from the national regulatory authority. Though it may be of good quality, an unregistered product is illegal.*

Directive 2011/62/EU

Safety features for MP:

- Those should allow **verification** of the authenticity and **identification** of **individual packs**, **and provide evidence of tampering.**

Directive 2011/62/EU

- **MP subject to prescription** should as a general rule bear the safety features. …
- the possibility to exclude certain MP or categories of MP subject to prescription from the requirement …..by way of a delegated act, following a risk assessment

Directive 2011/62/EU

Safety features:

- **should not** be introduced for MPs or categories of MPs **not subject to prescription**
- exception, an assessment shows the risk of falsification, which leads to serious consequences.
- Those MPs listed in a delegated act…

Directive 2011/62/EU

The risk assessments consider aspects:

- the price of the MP;
- previous cases of falsified MPs being reported in EU and in third countries;

- the implications of a falsification for public health, taking into account the specific characteristics of the products and the severity of the conditions intended to be treated

COMMISSION DELEGATED REGULATION (EU) 2016/161

supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use

- **of 2 October 2015**

- shall apply from 9 February 2019.

Verify – what?

- the authenticity of the unique identifier;
- the integrity of the anti-tampering device.

Unique identifier

- **2D code**

should be avoided mulitple 2D

UI - data

Consist of:

- a code allowing the identification, a numeric or alphanumeric sequence of maximum 20 characters, generated by a deterministic or a non-deterministic randomisation algorithm : PC, SN

- the batch number LOT
- the expiry date. EXP

COMMISSION DELEGATED REGULATION (EU) 2016/161

- Which data elements of the UI on the packaging in human-readable format:

Decommissioning of a unique identifier

- means the operation changing the active status of a UI stored in the repositories system to a status impeding any further successful verification of the authenticity of that UI

COMMISSION DELEGATED REGULATION (EU) 2016/161

- Shall not release the product for sale or distribution:
  - reason to believe that the packaging of the MP has been tampered with,
  - the verification of the safety features shows that the product may not be authentic –

.....and shall immediately inform the relevant competent authorities....

COMMISSION DELEGATED REGULATION (EU) 2016/161

To avoid an excessive impact on HC institutions - Member States may to allow:

- persons authorised or entitled to supply MPs to the public operating **within healthcare institutions** to perform the verification of the authenticity and the decommissioning of a unique identifier **earlier than the time the MPs is supplied to the public**,
- exempt them from such an obligation, subject to certain conditions..

COMMISSION DELEGATED REGULATION (EU) 2016/161

….a wholesaler verifies the safety features and decommissions the unique identifier of a MP before he supplies that MP to any of the following persons or institutions:

COMMISSION DELEGATED REGULATION (EU) 2016/161 Decommissioning - exceptions

- persons authorised or entitled to supply MPs to the public who do not operate within a healthcare institution or within a pharmacy;
- veterinarians and retailers of veterinary MPs;
- dental practitioners;
- optometrists and opticians;
- paramedics and emergency medical practitioners; hospices;
- nursing homes. ,...

Decommissioning - exceptions

- general rule - the decommissioning of the UI takes place at the time the MP is supplied to the public.
- Exceptions: Hospitals can decommission the UI at any time the MP is in their physical possession (for example, when they receive the product).
- When only part of a pack is supplied, the UI should be verified and decommissioned when the pack is opened for the first time.

Decommissioning - exceptions

- **Member States cannot exempt pharmacies nor healthcare institutions.**

Anti-tampering device (ATD)

- the content of the packaging is authentic.
- device allowing the verification of whether a pack has been opened/tampered with.
- Set by manufacturer

COMMISSION DELEGATED REGULATION (EU) 2016/161

- Establishment of the repositories system
- Data protection

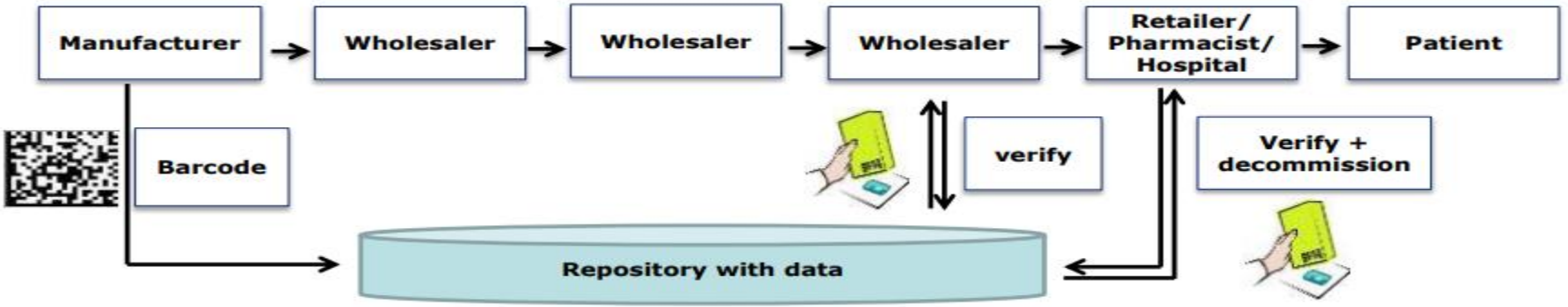
In practice:

- The obligation to verify the authenticity of MP by scanning :

of the two-dimensional code **before dispensing it to the patient**

- The obligation to verify the authenticity of ATD feature

End-to-end verification system + risk based verifications



European Medicines Verification Organisation

- The European Federation of Pharmaceutical Industries PGEU
- GIRP
- The European Association of Euro-Pharmaceutical Companies
- …
- EMVO's affiliate stakeholders are EAHP (European Association of Hospital Pharmacists) and HOPE (European Hospital and Healthcare Federation).

Which MP??

All human MP - Rx
Exception: Whitelist

Humen OTC MP - : No
Exception: **Blacklist**

do not apply to food supplements, medical supplies, veterinary LPs, etc.

Alert

The system is designed to trigger an alert, if:

a verification/decommissioning event reveals a suspicion that the MP is falsified.

FMD - Stabilisation period in 2019

- the current expectation:
  - the number of alerts triggered will in no way reflect the number of falsified products,
  - alerts may be generated by technical or procedural mistakes.
- … stabilisation period: why, how, goals, end of ?

Directive 2011/62/EU

- *The illegal sale of MPs to the public via the Internet is an important threat to public health as falsified MPs may reach the public in this way….*

Directive 2011/62/EU

- *the fact that specific conditions for retail supply of MPs to the public have not been harmonised at EU*

- *Member States may impose conditions for supplying MPs to the public within the limits of the Treaty on the Functioning of the European Union (TFEU).*

Directive 2011/62/EU

- The public should be assisted in identifying websites which are legally offering MPs for sale at a distance to the public

- common logo should be established

COMMISSION IMPLEMENTING REGULATION (EU) No 699/201

- of 24 June 2014 on the design of the **common logo to identify persons offering medicinal products for sale at a distance to the public** and the technical, electronic and cryptographic requirements for verification of its authenticity

DIRECTIVE 93/42/EEC concerning medical devices Consolidated version

Definitions, scope

‘medical device’

- any **instrument, apparatus, appliance, software, material or other article**, whether used alone or in combination,
- including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application,
- intended by the manufacturer to be used for human beings for the purpose listed in the Directive..

- custom-made device

- ‘intended purpose’: the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials;

MD / MP

Where a device incorporates, as **an integral part**, a substance which, if used separately, may be considered to be a **MP** and which is liable to act upon the body with action ancillary to that of the device, **that device shall be assessed and authorized in accordance with this Directive**

This Directive shall not apply to:

- in vitro diagnostic devices;
- cosmetic products covered by Directive 76/768/EEC
- human blood, blood products, plasma or blood cells of human origin…
- transplants or tissues or cells of human origin

- Essential requirements
- Free movement, devices intended for special purposes
- CE marking

MD information to public

- information, which must be made available to the user and the patient
- in their national language(s), regardless of whether it is for professional or other use…

Standards

- Reference to standards
- relevant national standards adopted

MD classification

- Devices shall be divided into Classes I, IIa, IIb and III.

- Classification shall be carried out in accordance with Annex IX.

Reporting

- Information on incidents occuring following placing of devices on the market

European databank

EUDAMED – EUDAMED2

NCAR

- The Medical Devices Directives provide that adverse incidents are evaluated and, where appropriate, information is disseminated in the form of a National Competent Authority Report (NCAR).

- Clinical investigation

- Conformity assessment procedures

CE marking

Devices, *other than devices which are custom-made or intended for clinical investigations*:

- considered to meet the essential requirements referred to…

- must bear the CE marking of conformity when they are placed on the market

The CE marking of conformity

- must appear in a visible, legible and indelible form on the device or its sterile pack,
- where practicable and appropriate, and on the instructions for use.
- where applicable, the CE marking must also appear on the sales packaging

- ANNEX I ESSENTIAL REQUIREMENTS I. GENERAL REQUIREMENTS

Safety of patients

MD must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended:

- **will not compromise the clinical condition or the safety** of **patients**, or the safety and health of **users** or, where applicable, **other persons**, provided that any risks which may be associated with their intended use constitute **acceptable risks** when weighed against the **benefits to the patient** and are **compatible with a high level of protection of health and safety.**

What does it mean???

…..consideration of the technical knowledge, experience,

… education and training

…where applicable the medical and physical conditions of intended users

…design for lay, professional, disabled or other users

REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION

Chemical, physical and biological properties

- Toxicity
- flammability,
- compatibility between the materials used and biological tissues
- minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use
- microbial contamination

- Construction properties

And

- Environmental properties

MD

…must be designed and manufactured in such a way as to **provide sufficient accuracy and stability within appropriate limits**

- ……The limits of accuracy must be indicated by the manufacturer.

DECLARATION OF CONFORMITY

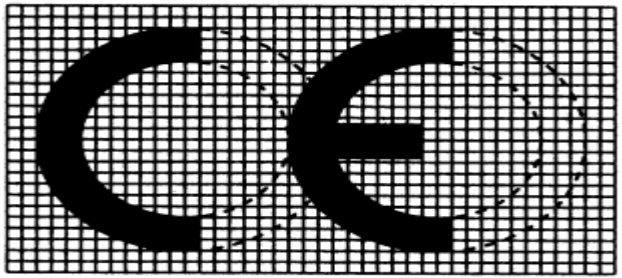
- Quality system: The manufacturer must lodge an application for assessment of his quality system with a notified „item“

- quality assurance techniques at the manufacturing stage
- Examination of the design of the product

Surveillance:

- The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations imposed by the approved quality system…

- ANNEX XII CE MARKING OF CONFORMITY



Food, food supplements, nutrients, health claims

DIRECTIVE 2002/46/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

- of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements

- Food supplement:…
- Nutrient:…….

Regulation (EU) No 1169/2011 of the European Parliament and of the Council

of 25 October 2011 on the provision of food information to consumers

- ANNEX II SUBSTANCES OR PRODUCTS CAUSING ALLERGIES OR INTOLERANCES
- ANNEX XIII REFERENCE INTAKES PART A — DAILY REFERENCE INTAKES FOR VITAMINS AND MINERALS (ADULTS)

Regulation (EC) No 1924/2006 of the European Parliament and of the Council

- of 20 December 2006
- on nutrition and health claims made on foods

Why… summary

Therefore, should be established:
general principles applicable to all claims made on foods

- to ensure a high level of consumer protection,
- give the consumer the necessary information to make choices in full knowledge of the facts,
- creating equal conditions of competition for the food industry

Apply to

all nutrition and health claims made in commercial communications, including

- advertising of food *and promotional campaigns, such as those supported in whole or in part by public authorities*.

- also to trade marks and other brand names which may be construed as nutrition or health claims.

Claim should not be made:

nutrition or health claim should not be made if:

- *it is inconsistent with generally accepted nutrition and health principles*

- if it encourages or condones excessive consumption of any food or disparages good dietary practice…

List of claims

- permitted nutrition claims and their specific conditions

- agreed at national or international level and EU

Claim:

- „message“

including pictorial, graphic or symbolic representation

- **which states, suggests or implies that a** food **has particular characteristics;**

Claims shall not:

- be false, ambiguous or misleading;
- give rise to doubt about the safety and/or the nutritional adequacy of other foods;

ANNEX:

- Nutrition claims and conditions applying to them

Commission Regulation (EU) No 432/2012

of 16 May 2012 establishing a list o
f permitted health claims made on foods, other than those referring to the reduction of disease risk and to **children's development**

DIRECTIVE 2001/82/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 November 2001 on the Community code relating to veterinary medicinal products

The primary purpose

- rules for the production and distribution of VetMP: safeguarding of public health.

The purpose

- from the point of view of public health and the free movement of VetPM

the competent authorities to have:

all useful information on authorized veterinary medicinal products in the form of approved summaries of the characteristics of products.

Committee for Veterinary Medicinal Products

- set up in accordance with the European Agency for the Evaluation of Medicinal Product

Veterinary medicinal product:

- any substance or combination of substances presented as having properties for **treating or preventing disease in animals;**
- any substance or combination of substances which may be used in or administered to animals with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic ction, or to making a medical diagnosis.

Withdrawal period

- The period necessary between the last administration of the VetMP to animals,

under normal conditions of use and in accordance with the provisions of this Directive,

and the production of foodstuffs from such animals, in order to protect public health by ensuring that such foodstuffs do not contain residues in quantities in excess of the maximum residue limits for active substances laid down pursuant to *Regulation (EEC) No 2377/90*.

Veterinary prescription

- Any prescription for a veterinary medicinal product issued by a professional person qualified to do so in accordance with applicable national law

Package leaflet:

- The leaflet containing information for the user that accompanies the medicinal product.

Homeopathic veterinary medicinal products:

- manufacture, control and inspection

Quality of Vet MP

- compliance with the principles of GMP for all medicinal products irrespective of the final destination

Distributors of VetMP

- authorization by Member States

- maintain adequate record

VetMP - pharmacovigilance

- systems should consider the available data on lack of efficacy

VetMP - ADR

- collection of information on adverse reactions due to off-label use,
- investigations of the validity of the withdrawal period
- on potential environmental problems

….regular monitoring of good usage of veterinary medicines.

VetMP

- increasing use of electronic means of communication of information

Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare

Notwithstanding the possibility for patients to receive cross-border healthcare under this Directive:

- Member States retain responsibility for providing safe, high quality, efficient and quantitatively adequate healthcare to citizens on their territory

- Respects the freedom of each Member State to decide what type of healthcare it considers appropriate

- rules for facilitating the access to safe and high-quality cross-border healthcare
- promotes cooperation on healthcare between Member States,
- in full respect of national competencies in organising and delivering healthcare.

shall not apply to

- services in the field of long-term care the purpose of which is to support people in need of assistance in carrying out routine, everyday tasks;
- allocation of and access to organs for the purpose of organ transplants;
- with the exception of Chapter IV, public vaccination programmes against infectious diseases which are exclusively aimed at protecting the health of the population on the territory of a Member State and which are subject to specific planning and implementation measures.

- national contact point - relevant information
- healthcare providers provide relevant information to help individual patients to make an informed choice
- ensure continuity of care

CHAPTER III

- REIMBURSEMENT OF COSTS OF CROSS-BORDER HEALTHCARE

- Article 11

Recognition of prescriptions issued in another Member State

CZE legal provisions for pharmacy practice II

Good pharmaceutical practice

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 MPs, as amended

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

One of the legal provision: implementing Act on Pharmaceuticals

„Practical application“ of general requirements

Scope of topics in GPP

Pharmacies – mainly Chapter II
1) Praparing of MPs in the pharmacy:

- Individual – individual medical prescription
- without individual medical prescription

Scope of topics in GPP

- Which substances can be used for preparing MP?
- Substances listed in:
- Pharmacopoeia – Note New: Czech pharmacopeia **Decree No 85/2008 Coll.,** which lays down a list of active substances and excipients which may be used in the preparation of MPs, as amended ..
- MP with marketing authorisation: under special conditions

Scope of topics in GPP

- How to behave if praparing proceed?

- What to do if wrong dose of any substance is prescribed

Scope of topics in GPP

- How to label pharmaceuticals prepared in the pharmacy:
- Control and Documentation for praparing, Tests, Identification

Scope of topics in GPP

2) Dispensing –

e.g. Practical details like:
a part of dispensing is sharing of information for right and safe using and storing

GPP in CZ

- Communication with Central repository of electronic prescriptions;
- central repository - MP with restriction
- E-pharmacy - requirements

GPP in CZ

Documents in the pharmacy

- Store 5 years!

- Rx which aren‘t sent to insurance companies
- Record book for CD
- Protocols (inspection, audits, tests..)
- Technological prescription / SOPs

GPP in CZ

- SOPs for repeated activities

- Technological prescription (master formula sheet):

Required for repeated praparing

GPP in CZE

Technological prescription for praparing :

- MP
- Ingredients
- Praparing directions
- Containers
- Labelling
- Storage
- Expiration date
- Tests
- Date - signature
- Up dates - signature
- Annulment – date - signature

- Annex I:
- DETAILED CLASSIFICATION OF PHARMACEUTICAL FORMS WITH REGARD TO THE COMPOSITION AND ROUTE OF ADMINISTRATION

Act No. 167/1998 Coll

- on Dependency Producing Substances and on Amending Certain Other Acts, as subsequently amended
- (sometimes translated: on addictive substances)

Implementing legal provision:

- Decree No. 53/2014 Coll.

on forms according to the Act on Dependency Producing Substances

- Decree No.123/2006 Coll.

on records and documentation of dependency producing substances and preparations

- Order of the Government No. 463/2013 Coll.

regarding the lists of dependency producing substances
Devided substances in 8 Annexes (tables)

Subject of Regulation

- handling of dependency producing **substances**/addictive substances,
- export and import, and transit operations with them;

- the handling of **preparations containing dependency producing substances**, **preparations** containing **category 1 drug precursors**

- *the cultivation of poppy, cannabis, and coca bush, and the export, import, and destruction*

Definition of Terms

- Dependency producing substances: mean narcotic drugs and psychotropic substances listed in Annexes of Government Regulation Concerning a List of Dependency Producing Substances

Definition of Terms

- Handling and handling permit

- Without a handling permit, dependency producing substances set forth in Annex No. 1, 2, 5, 6 or 7 of Government Regulation Concerning a List of Dependency Producing Substances and preparations containing them, or medical preparations containing a scheduled substance of category 1:
- May be:
- prescribed by physicians within the provision of health care in health-care facilities and facilities providing social services,
- prescribed and used by veterinary doctors for the purposes of veterinary care
- used for therapeutic purposes by physicians and other health-care workers in in-patient and outpatient health-care facilities

- ELIGIBILITY FOR HANDLING
- General Qualification: legal capacity, over 18 years of age, clean criminal record

- Health Qualification: undergo a medical inspection

- Professional Qualification

- Storage: Section 10
- Transport: Section 11
- Prescription Forms and Order Forms *with Blue* Stripe : Section 13 (Details in Decree 54/2008)
- Notification Duty of Persons Operating Pharmacy: Section 27:
- SIDC by the end of February – report annually
- Competence of State Administrative Bodies: Ministry of Health , SIDC, International Narcotics Control Board

Act No. 272/2013 Coll.

On Drug Precursors

Implementing legal provision:

- Decree No. 71/2014 Coll.

on the contents, form and requisite details of record-keeping of activities with scheduled substances of category 1

- *Order of the Government No. 458/2013 Coll.*

regarding the list of initial and auxiliary substances and their annual quantity limits

:

- (Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors.)
- certain obligations of natural persons engaged in business, legal persons, and state administrative authorities that engage or intend to engage in an activity concerning a scheduled substance of category 1, 2, or 3, a non-scheduled substance, or a an initial or auxiliary substance
- the competences of administrative authorities in carrying out state administration

- LICENCE AND REGISTRATION
- LICENCE FOR ACTIVITIES WITH SCHEDULED SUBSTANCES OF CATEGORY 1: needed:
- e.g. for the purpose of the production of a medical preparation: scheduled substance of category 1
- Registration: category 2,3

- Implementig decree:
- Record book and Registration Details
- Stocktaking

Act No 268/2014 Coll, on Medical Devices and on Amendments to Some Related Acts, as amended

- Definition: medical devises
- Categorisation: I, IIa, IIb, III… (according to Directive 93/42/EEC……)
- Handling
- State authority: Ministry of health, SIDC
- Notification
- Medical prescription on medical devices – only paper form

Medical devices

Main important Implementing legal provision:

- Decree No. 62/2015 on the implementation of certain provisions of the Act on Medical Devices

- Government Regulation No 56/2015 Coll., on technical requirements for in vitro diagnostic medical devices
- Government Regulation No 55/2015 Coll., on technical requirements for in vitro diagnostic medical devices on technical requirements for active implantable medical devices
- Government Regulation No 54/2015 Coll., on technical requirements for medical devices

- **Act No 258/2000 Coll.**, on the Protection of Public Health and Amendments to Some Related Acts, as amended

- **Decree on** hygienic requirements governing cosmetic products,
- **Act** on Consumer Protection
- **Act** on the Donation, Procurement and Transplantations of Tissues and Organs and on Amendments to Some Acts (Transplantation Act), as amended

Legal regulations governing the areas bordering upon the area of MPs.

- **Act** on Foodstuffs and Tobacco Products
- **Implementing regulations:**
- **Decree** on labelling of foodstuffs and tobacco products,
- **Decree** which lays down the requirements for dietary supplements and fortification of foodstuffs;
- (health claims)

Legal regulations governing the areas bordering upon the area of MPs.

- **Act** on Advertising Regulation

- Act on the Operation of Radio and Television Broadcasting

Act No. 372/2011 Coll., on Health Services

- Not only about rights and duties of Patients/HC providers
- Types of Health services:
- like: preventive, diagnostic, medical/treatment care, pharmaceutical care and pharmaceutical-clinical care…
- Inpatient/ Hospital (or even part of the outpatient)

- GENERAL CONDITIONS FOR THE PROVISION OF HEALTH SERVICES

- Implementing regulation:
- **Decree No 92/2012 Coll.,** on requirements for material and technical equipment of health facilities

Implementig regulation

- **HS only in buildings:**
- allow a functional and safe operation in terms of:
- construction and technical requirements for premises and their function and layout arrangement
- HP form a closed operationally and functionally interconnected unit
- (departments under special conditions)
- be located in comercial space (not residential) which meet the general requirements for construction

Implementig regulation

Technical requirements:

- supply of drinking water and hot water
- waste water disposal
- system of natural or artificial ventilation
- heating system
- connection and distribution of electricity
- connection to the public telephone network, fixed or mobile
- *Connection to the internet…..*

Technical and material requirements specific for PHARMACY

- Annex 5:
- separate entry for: public and employees and receive supplies
- Primary premises/Basic workplaces:
- „Mandatory"
- (e.g. Premises for dispensing, preparation, stock, sanitary workplace, workplace for recieving supplies)
- "Possible"
- technical department for the dispensing of MD, Consultation room, analytical workplace...

Technical and material requirements specific for PHARMACY

- **<u>Secondary premises</u>:**
- for pharmacists‘ work - office
- facilities for employees
- for cleaning

- **For every workplace:** minimum area and structure, equipment

Professional competences

- Act No 95/2004 Coll., on the C**onditions of Achieving and Recognising Professional Competence and Specialised Competence** for the Conduct of the Healthcare Professions of a Doctor, Dental Practitioner, and **Pharmacist**, as amended by Act No 125/2005 Coll.
- Act No 96/2004 Coll., on the **Conditions of Achieving and Recognising Competence for the Conduct of NonMedical Healthcare Professions** and for the Conduct of Activities Associated with the Delivery of Health Care and on Amendments to Some Related Acts (Act on Non-Medical Healthcare Professions), as amended by Act No 125/2005 Coll. 30)
- on the **Recognition of Professional Qualifications** and other Competence of the Nationals of the Member States of the European Union and on Amendments to Some Acts (Act on Professional Qualification Recognition
- (based on: DIRECTIVE 2005/36/EC on the recognition of professional qualifications)

Pharmacists:

- Required education (basic):
- 5 years of University study that includes 6 - months (26 weeks) of practical training in the pharmacy
- Competence of dispensing, preparing, controling, stocking drugs and information giving **WIHTOUT SUPERVISION**
- Specialized education (postgraduate):
- Certification for beeing the pharmacy head (boss), for special activities (preparing cytostatic drugs,...)
- Continuing education (whole- life) reqiured
- According to the rules of The Czech Chamber of Pharmacists

Pharmaceutical assistant

- **Required education (basic):**
- 3- year „higher“ education (after passing school- leaving exam)
- Competence of dispensing (OTC), preparing, analysis, stocking drugs and
- information giving **UNDER SUPERVISION**

- **Further education needy to get the competence of working**
- **WITHOUT SUPERVISION:**
- Working 3 years in the pharmacy + meeting requirements in further education

- **Specialized education:**
- Certification (or other) not needy for working in pharmacy

- **Supervising pharmacy assistent before completing further education:**

-Pharmacist
-Pharmaceutical assistant with specialized education

- **Pharmacist**
- Dispensing drugs on medical prescription (Rx drugs),
- OTC with restriction
- Weighing addictive substances (when preparing drugs)

- **Vs.**

- **Pharmacy assistant**
- Dispensing OTC drugs, dietary supplements,……
- Processing addtictive substances into the final drug
- Weighing all other substances and processing them into the final drug

Legal impact on health systém in CZE – establishment

- **Non-state-owned medical facility**
- **(private)**
- **X**
- **State-owned medical facility**

- **Non-state-owned medical facility (NSMF) = private health care facility:**
- = not owned by state
- Operator – individual OR a legal entity

HCP: main duties

- can provide the health care only within the conditions set in the registration. (x …. emergency)
- must cooperate with other medical facilities if necessary for provision of care.
- Keep records

Ownership:

- **Individual:**
- must be fully qualified to perform legal acts (legal capacity) = ??
- Integrity (clear criminal record)
- professional competence
- *medical fitness*

- **Legal entity:**
- is obliged to appoint a professional representative for professional competence

Registration form - briefly

1)Name, surname, residence and personal identification number – INDIVIDUAL

2)Name of LEGAL ENTITY, residence, registration number

3)type and extent of provision of health care

4)Place

5)Date of starting provision

Registration form - briefly

- Annexes:
- **Professional certification from the professional body *(by the Czech Chamber of Pharmacists)***
- **2)Approval of the competent authority for registration**
- **3)Certificate of professional competence**
- *Act No 95/2004 Coll., on the Conditions of Achieving and Recognising Professional Competence and*
- *Specialised Competence for the Conduct of the Healthcare Professions of a Doctor, Dental Practitioner, and*
- *Pharmacist*
- **4)Approval from hygiene department**
- **5)Approval from the State Institute for Drug Control** (Material and technical base for the operation of a pharmacy)
- **6)Criminal record**

Decree No 306/2012 Coll., which governs the prevention and spread of infectious diseases and hygiene requirements for the operation of medical facilities and social care

- Sterilization, higher level of disinfection, disinfection
- Cleaning of the premises preventive health care and social care

- Reporting

Annex No. 2 to Decree No. 306/2012 Coll.

- List of infectious diseases in which isolation is carried out in hospital wards or treatment institutes and diseases the treatment of which is mandatory Task

- **Pharmacy**
- Pharmacy - Pharmaceuticals dispensary – dependent on the „mother pharmacy“ – „distant unit of the pharmacy “

- Dispensary of Medical Devices

- **„Chain“ pharmacies**
- **„Virtual chains“**
- **Mail - ordering pharmacies**

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

- Main Implementing regulations:
- **Decree No 384/2007 Coll.,** on the list of reference groups;
- **Decree No 385/2007 Coll.,** on the list of active substances for adjuvant or add-on therapy;

- Act No. 592/1992 Coll., on premiums for general health insurance, as last amended.
- Act No. 551/1991 Coll., on the General Health Insurance Company of the Czech Republic [in Czech, "*VZP*"], as last amended.

- …

- a public health insurance
- the extent and conditions under which medical services are covered by this Health Insurance "paid services"
- the method of pricing and reimbursement of MPs and foodstuffs for special medical purposes covered by health

- *directly applicable European Union rules governing system coordination*

Health Insurance in CZE - briefly

- All individuals have to have insurance – it is mandatory and no qualifying individual can be denied coverage by a public health insurance company.
- In the case of an employment relationship, the employer pays for the health insurance at the rate given by legal provision - calculated of income

(of which one part is paid by the employee and the second by the employer).

- In certain cases, the insurance premiums are paid by the state (dependent children, pensioners, etc.).

Health Insurance in CZE

- Foreign person participates in the public health insurance program and obtains the same rights to receive the care, which is paid for by a public health insurance company

- ("**covered healthcare services**") as any other insured person, if they are either of the following:
- a person with a ‘permanent resident’ status in the Czech Republic;
- persons working as an employee of an employer (company, etc.) with a ‘registered address’ /‘permanent residence’ in the Czech Republic.

- Others?

Health Insurance in CZE

- "covered healthcare services"
- preventive, dispensary, diagnostic, therapeutic, therapeutic-rehabilitative, spa therapeutic-rehabilitation care, including examinations, nursing and palliative care and care for the donors of blood, tissues or organs and cells in relation to their removal – pursuant to the provisions of the Health Services Act;

- (note in certain situations, the services **<u>may not be fully covered</u>** by the public health insurance provider)

Health Insurance in CZE

Covered healthcare services:

- are paid for by the health insurance company **on the basis of a contract** between:

- the provider of the healthcare services and the health insurance company of the insured person.

Health Insurance in CZE

- This **does not apply to pharmacies** because the insured person can pick up their prescriptions at any pharmacy, irrespective of the pharmacy's having a contract with the health insurance company.

- However, the prescription must generally be written by a doctor who has a contract with the health insurance company, through which the patient is insured.

Health Insurance in CZE – impact on pharmacy practice

- Patients are asked to make a co-payment towards the cost of certain pharmaceuticals.

- MP are categorized into groups, where in each group of drugs
- (the so-called “indicative group” – based on the type of illness), at least one drug in the group must be fully covered by health insurance (i.e. the MP has no co-pay required).
- *Details about principles of reimbursement of MP – calculation by SIDC - social pharmacy*
- During hospitalization, an insured person does not pay any of the cost for medicines or medical devices. - These costs are fully covered by the health insurance company.

Procedure for filing a complaint against healthcare received

A person has an absolute right to file a complaint against any healthcare services received - if they feel that:

- the level of care was inadequate,
- unreasonably delayed,
- of an inadequate quality or
- if care was denied.
- If a person is dissatisfied with the conduct of a physician or with his/her approach,
- if the patient feels they were given insufficient information
- if there is a suspicion of malpractice or misconduct during an operation

- (HCP: Insurance for such situation)

Procedure for filing a complaint against healthcare received

Before filing a formal complaint,

- it is recommended that a patient exhaust all other options.

Procedure for filing a complaint against healthcare received

- Under “The Act on Healthcare Services”, a complaint is submitted to the respective **provider** – which could be a doctor or the management of a healthcare facility.

- In a case of any suspected professional misconduct or unethical conduct on the part of a doctor or dentist, a complaint can be submitted to the Czech Medical Chamber or to the Czech Dental Chamber or, as applicable, to Czech Chamber of pharmacists.

Note:

- Chambers: Act No **220/1991** Coll., on the Czech Medical, Czech Dental chamber, Chamber of pharmacisst