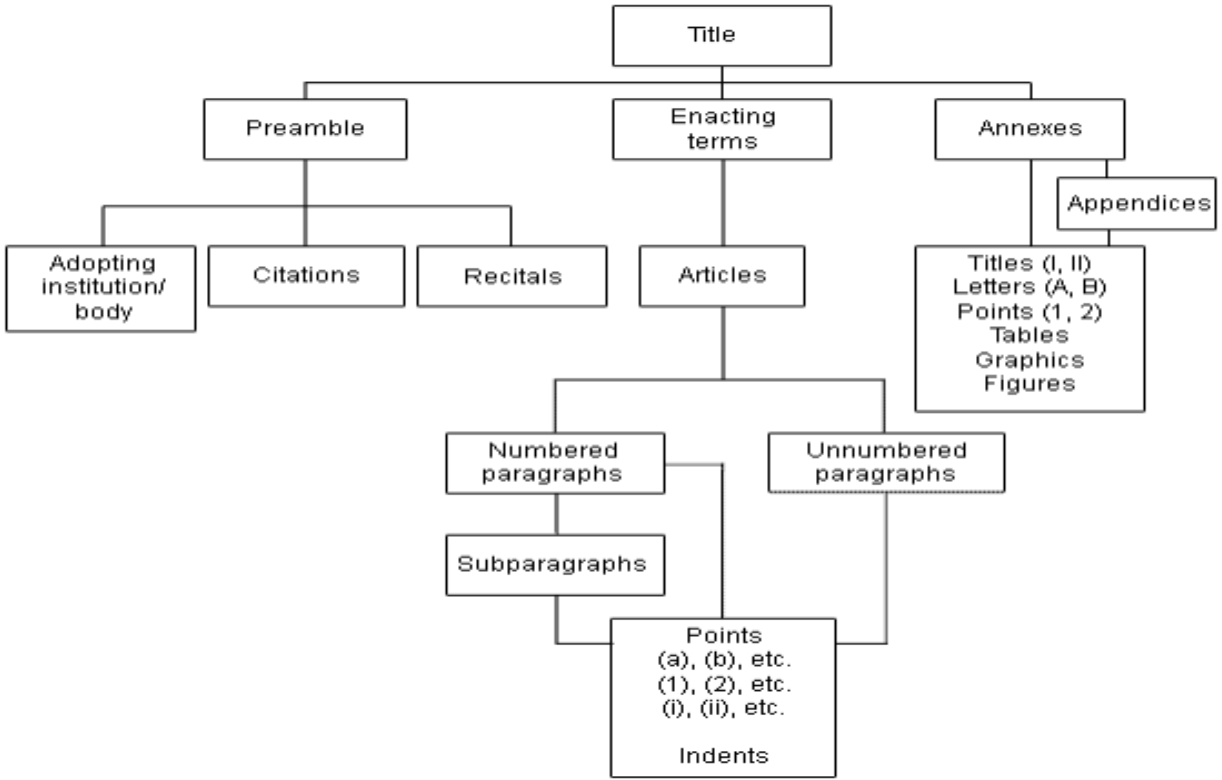
EU – sturcture of legal provision


Title
Preamble
Enacting terms
Annexes
Appendices
Adopting institution/ body
Citations
Recitals
Articles
Titles (I, II)
Letters (A, B)
Points (1, 2)
Tables
Graphics
Figures
Numbered paragraphs
Unnumbered paragraphs
Subparagraphs
Points
(a), (b), etc.
(1), (2), etc.
(i), (ii), etc.
Indents

Title

The complete title of an act comprises:

- the type of act
- the number, the year and the sequential number of the act,
- the name of the author of the act,
- the date of adoption
- the subject matter

Preamble

Preamble - citations

Citations indicate:

the **legal basis** for the act:(a)

- primary acts that constitute the general basis for the text in question.
- Primary acts are cited without a footnote reference. International agreements and protocols to international agreements may be cited in their short form with a footnote reference.

- where applicable, secondary acts that constitute the specific basis for the text.

Preamble - recitals

set out the reasons for the contents of the enacting terms (i.e. the articles) of an act.

- Recitals are introduced by the word ‘Whereas:’.
- They are numbered and each sentence in each recital starts with a capital letter and ends with a full stop, except the last sentence of the concluding recital, which ends with a comma.

Articles

- The enacting terms, which constitute the normative part of the act, are divided into articles.
- Articles may be grouped in ‘parts’, ‘titles’, ‘chapters’ and ‘sections’
- Articles may be subdivided into paragraphs, subparagraphs, points, indents and sentences.
- Paragraphs may be unnumbered or numbered with Arabic numerals and may contain points or indents, which may be preceded by a dash.

NB:

In French, numbered paragraphs are termed ‘paragraphe’ and unnumbered paragraphs are termed ‘alinéa’.)

Final article (in directives and decisions)

- the addressees are specified in this last article.

Compulsory character of regulations

- In regulations, after the final article, the following formula is used:

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Concluding formulas

Place, date and signature

- The act ends with the following:

- followed by the signature(s).

- In treaties, international agreements, etc. the full date is written in words

Annexes

- rules or technical data that - frequently take the form of a list or table in annexes
- The enacting terms must always indicate clearly, by means of a reference

- In annexes, any appropriate system of numbering or subdivision may be used.

Rules on drafting documents

- Acts published in the Official Journal follow strict drafting rules.

- Texts for publication in the Official Journal must exist in each of the official languages of the European Union

- When published, the texts in all language versions of the Official Journal are synoptic, meaning that the same text can be found on the same page of the same OJ in all official languages.

Amendments

- 1. Where a **whole article** is replaced, the new text starts with the designation of the article:
- *Regulation (EC) No XX/20ZZ is amended as follows:*

(1)

*in Article 3, **point (g)** is replaced by the following:‘**(g)***

“state of processing” means the way the fish is preserved (fresh, fresh salted and frozen).’;

Amendments

- if **a sentence** is being replaced, no subdivision marker is repeated, even if the first sentence of a numbered paragraph is subject to an amendment:

in paragraph 4, the first sentence is replaced by the following:

Czech legal system

Week 7+8, part I

Czech Republic

- The Czech Republic is one of the two successor states established in 1993

- **Since 1 st May 2004, the Czech Republic is a member of the European Union**

Czech Republic

- The political system is recognised as a **parliamentary democracy**

Czech legal system

- The Czech legal system is a **“continental” legal system**

- more specifically, *due to common historical roots*, it can be said it belongs to the “Germanic” legal culture.

The state power

- divided into the classical three powers, namely:

- **Legislature** = the Parliament of the Czech Republic
- **Executive** = the head of state and the government

- **Judiciary** = the courts of general jurisdiction (civil and criminal), administrative courts and the Constitutional Court.

- *There are also self-governing units*

The Legislative Power *in CZE*

- is vested in the Parliament

- The Parliament - two chambers:

  the Lower House: Chamber of Deputies (*Poslanecká sněmovna*)

  the Upper House: Senate (*Senát*)

- **The Chamber of Deputies:**
- 200 members who are elected every 4 years

- The renewal of the Chamber is always complete

The Legislative Power *in CZE*

The Senate:

- 81 senators, who are elected to a six-year term of office
- partial renewal of the Senate every 2 years

- The Senate has a stabilising role in the constitutional system.
- Eg.: if the Chamber of Deputies is dissolved the Senate is empowered to adopt legislative measures on matters which cannot be delayed

The Executive power

shared between:

- the President of the Republic and the Government.

- the President of the Republic - directly elected. The functions of the head of state - mostly representative

The Government

- highest body of **executive power**

- consists of:

  the Prime Minister,

  deputy prime ministers

  ministers

- The government is politically responsible to the Chamber of Deputies

Ministries

- **The Ministry of Finance**
- **The Ministry of Health**
- The Ministry of Education, Youth and Sports
- The Ministry of Foreign Affairs
- The Ministry of Culture
- The Ministry of Labour and Social Affairs
- The Ministry of Justice
- The Ministry of Interior
- The Ministry of Industry and Trade
- The Ministry for Regional Development
- The Ministry of Agriculture
- The Ministry of Defence
- The Ministry of Transport
- The Ministry of Environment

Ministries

- The ministers are appointed by the President of the Republic upon the proposal of the Prime Minister

- The President of the Republic will also recall a minister if the Prime Minister so proposes

The Judiciary

- The judiciary in the Czech Republic is defined by the Constitution so that the courts perform their duties as independent authoritie.

- The system of ordinary courts is made up of District, Regional, High courts and the Supreme
- General (civil and criminal), administrative and constitutional judiciary.

The Public Defender of Rights

- The office of the Public Defender of Rights (the Ombudsman) has been established by the law: Act no. 349/1999 Coll., the Public Defender of Rights)

- He/she is elected by the Chamber of Deputies for a term of 6 years

The Public Defender of Rights

- His/her task is to defend individuals against such conduct of authorities that does not comply with principles of a democratic state, rule of law and good administration, as well as against illegal inactivity of those authorities

- In order to protect public interest he/she has the special legitimation to challenge a decision of an administrative authority at an administrative court…

Idea of separation of powers

- The legislature, the head of state and most of the executives:

  located in the capital.
- Both Supreme courts and the Constitutional Court:
- located in Brno.

- Brno is also the seat of the Public Defender of Rights - Ombudsman.

Central agencies of state administration under governmental control

- There are a considerable number of other central agencies, that perform necessary administrative tasks.
- These agencies - enjoy a certain degree of independence of government.
  -

Self-Government

There are two types of self-government in the Czech Republic:

- territorial
- professional

Chambers

- typically exercise regulatory and disciplinary powers vis-à-vis its members
- membership is being the precondition for the the respective regulated profession.

- (establishment … by law…)

Czech legal system

- Only written law is recognised as a formal source of law.

- … judgments… = Judikáty

Czech legal system

The characteristics:

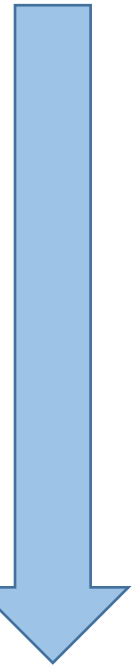
- Principle areas of law and procedures are **codified**

- (Civil and Criminal Codes, Administrative Procedure etc.);

Sources of law

- The legal order is assorted in a pyramidal-type structure:

- The lower levels of the pyramid have to be compatible with the higher ones.



- Constitution and constitutional laws

(including the Charter of Fundamental Rights and Freedoms)

- International treaties
- Statutes adopted by the Parliament
- Derived legislation and legislative acts of territorial self-governing units

Since the Czech Republic’s accession to the European Union:

- EU law and its legislative sources
  part of the Czech legal order...

Who can adopt a legislative act?

- The Parliament
- The government, ministries or authorities of state administration;
- Self-governing units within the delegated competence
- Self-governing units within the independent self-governing competence

Constitutional statutes

- are legislative acts of the highest legal force.
- passed by a special majority being necessary in both Chambers of Parliament and with the agreement of both chambers

- The most important constitutional laws are:
- **Constitutional law no. 1/1993 Coll., the Constitution of the Czech Republic**
- Resolution no. 2/1993 Coll. of the Presidium of the Czech National Council of 16 December 1992 on the declaration of the **Charter of Fundamental Rights and Basic Freedoms as a part of the constitutional order of the Czech Republic**
- …

Czech legal system

- The Constitution of the Czech Republic founded on **respect for rights and freedoms of a man and citizen**

- An important part of the Constitution and constitutional order is the Charter of Fundamental Rights and Freedoms
- *Albeit being in a separate constitutional law, it has the same legal force as the Constitution itself*.

International treaties

- Priority over ordinary statutes

Ordinary statutes -Act

- The universal form of legislative decision making adopted by the Parliament.

- Published in the **Collection of Laws of the Czech Republic:**

- Collection of laws (Coll) (*Sbírka zákonů* , abbreviated in Czech as *“Sb.”*)

Ordinary statutes

the standard form of citation is:

“number of the document” / ”year of the publication” Coll.

The number of every document is unique.

- The document number 1/1993 Coll. thus refers to the first document published in the Collection of laws in the year 1993

Senate’s legislative measure

- special type of legislation with the force of statute

Governmental order

- is a form of legislation adopted by the government
- legal force is lower than the force of a statute
- purpose is to implement a statute (derived legislation)

Regulations

- Decree
- other principal form of secondary derived legislation
- adopted by ministries and other administrative agencies (central, regional and local) or bodies of territorial self-governing units.

- **regulations can be adopted only upon an express empowerment contained in the respective law.**

- **stay within the bounds of the law .**

Generally binding ordinances

- adopted by territorial self-governing units within their self-governing competence
- a form of secondary legislation
- must comply with ordinary and constitutional statutes.

Types of legal norms in CZE - conclusion

- Following are the types of the generally binding legal regulations applicable in the CZE
- **EU regulations, directives , decisions** (published in the Official Journey of the European Union)
- **international treaties** (published in the Collection of International Treaties of the Czech Republic),
- **laws, government orders and regulations** (published in the Collection of Laws of the Czech Republic),
- regulations issued by regional and municipal authorities (published in the regions' journals of legal enactments, Collection of Legal Enactments of the Capital City of Prague, on official information boards of municipal authorities),
- some other instruments referred to by legal enactments…

Relations between legal norms, adopting of legal norms - conclusion

- international treaty over national legislation
- EU directives and regulations enjoy the same status as international treaties
- law must not contradict CZE Constitution and the Charter of Human Rights and Freedoms

---

- laws are adopted by the CR Parliament
- regulations and government orders are not adopted by Parliament; they are issued by relevant ministries or the government

Promulgation and publication of the legislation

- to be valid: it must be duly promulgated
- act in the Collection of laws (Coll) – Czech language only
- International - Collection of International Treaties, where the authoritative foreign version, as well as the Czech version, is published simultaneously.
- *The publication in the Collection of International Treaties (Sbírka mezinárodních smluv , abbreviated in Czech as "Sb.m.s.") follows the same numbering principles.*

Collections

- Both Collections are published in a printed version by the Ministry of Interior.
- They are also fully accessible online in a “PDF” format from 1945 onwards at the Ministry of Interior web page

- **The only authentic version of Czech legislation is in the Czech language.**

Law – valid/comes into force…

- A law is valid from the day it is published in the Collection of Laws.

- The day when a law comes into force is usually specified by the text of the law itself.

Law amendments

- Laws can later be **amended.**
- Such amendments are also published in the Collection of Laws and are **also allocated a number.**
- Amendments include information on which part of the law is being amended, as well as on how and when this change takes effect.
- **Changes only are published with the amendment, not the entire modified text of the original law!**

Structure

- Number/Year Coll, Name:

- Hypothesis
- Disposition
- Sanction
- Repealing provisions
- Legal Force/Effect (date)
- annex

The overview of legal regulations governing pharmaceuticals/pharamacy practice in the EU

- **Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use**

- **In force**

- Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for **good clinical practice** as regards investigational **medicinal products for human use**, as well as the requirements for authorisation of the manufacturing or importation of such products

- In force

- Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of **good manufacturing practice** in respect of medicinal products **for human use and investigational medicinal products for human use**

- In force

- Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of **human blood and blood components** and amending Directive 2001/83/EC
- In force
- Commission Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for **blood and blood components**

- In force

- Commission Directive 2005/62/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards Community standards and specifications relating to a quality system for **blood establishments**
- In force

- Directive 2004/9/EC of the European Parliament and of the Council of 11 February 2004 on the inspection and verification of **good laboratory practice**

In force

- Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of **good laboratory practice** and the verification of their applications for tests on chemical substances
- In force

- Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of **genetically modified organisms** and repealing Council Directive 90/220/EEC - Commission Declaration

In force

- Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010 amending, as regards **pharmacovigilance**, Directive 2001/83/EC on the Community code relating to medicinal products for human use

In force

- Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012 amending Directive 2001/83/EC as regards pharmacovigilance

In force

- Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning **unfair business-to-consumer commercial practices** in the internal market and amending Council Directive 84/450/EEC, Directives 97/7/EC, 98/27/EC and 2002/65/EC of the European Parliament and of the Council and Regulation (EC) No 2006/2004 of the European Parliament and of the Council (‘Unfair Commercial Practices Directive’)
- In force

- 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**
- In force

- Commission Implementing Directive 2012/52/EU of 20 December 2012 laying down measures to facilitate the **recognition of medical prescriptions** issued in another Member State
- In force

- Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of **falsified medicinal products**
- In force
- Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 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
- In force

- Commission Directive 2005/61/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and **notification of serious adverse reactions and events**
- In force

- Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use

- No longer in force

- Directive 2009/35/EC of the European Parliament and of the Council of 23 April 2009 on the colouring matters which may be added to medicinal products (recast)

In force

- others

- Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community **procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency**
- In force
- Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products
- In force

- Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal **products for paediatric use** and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004
- In force

- Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on **orphan medicinal products**
- In force

- Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 **on advanced therapy medicinal** products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004
- In force

- Regulation (EU) 2016/793 of the European Parliament and of the Council of 11 May 2016 to avoid trade diversion into the European Union of **certain key medicines**
- In force

- Commission Regulation (EC) No 847/2000 of 27 April 2000 laying down the provisions for implementation of the **criteria for designation** of a medicinal product as an orphan medicinal product and definitions of the concepts '**similar medicinal product**' and **'clinical superiority'**
- In force

- Commission Implementing Regulation (EU) No 520/2012 of 19 June 2012 on the performance of **pharmacovigilance activities** provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council

- In force

- Commission Regulation (EC) No 540/95 of 10 March 1995 laying down the arrangements **for reporting suspected unexpected adverse reactions which are not serious**, whether arising in the Community or in a third country, to medicinal products for human or veterinary use authorized in accordance with the provisions of Council Regulation (EEC) No 2309/93
- In force

- Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on **clinical trials** on medicinal products for human use, and repealing Directive 2001/20/EC
- In force

- Commission Implementing Regulation (EU) 2017/556 of 24 March 2017 on the detailed arrangements for the **good clinical practice inspection procedures** pursuant to Regulation (EU) No 536/2014 of the European Parliament and of the Council
- In force

- Commission Delegated Regulation (EU) No 1252/2014 of 28 May 2014 supplementing Directive 2001/83/EC of the European Parliament and of the Council with regard to **principles and guidelines of good manufacturing practice for active substances** for medicinal products for human use
- In force

- Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on **drug precursors**
- In force

- Council Regulation (EC) No 111/2005 of 22 December 2004 laying down rules for the monitoring of **trade** between the Community and third countries in **drug precursors**
- In force
- Commission Delegated Regulation (EU) 2015/1011 of 24 April 2015 supplementing Regulation (EC) No 273/2004 of the European Parliament and of the Council on drug precursors and Council Regulation (EC) No 111/2005 laying down **rules for the monitoring of trade between the Union and third countries in drug precursors**, and repealing Commission Regulation (EC) No 1277/2005
- In force

- International treaties:
- Single convention on Narcotic drugs
- Convention on Psychotropic substances

- Commission Delegated Regulation (EU) No 357/2014 of 3 February 2014 supplementing Directive 2001/83/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council as regards situations in which **post-authorisation efficacy studies** may be required
- In force

- Directive 2001/104/EC of the European Parliament and of the Council of 7 December 2001 amending Council Directive 93/42/EEC concerning **medical devices**

- Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on **in vitro diagnostic medical devices**
- In force

- Directive 2000/70/EC of the European Parliament and of the Council of 16 November 2000 amending Council Directive 93/42/EEC as regards **medical devices incorporating stable derivates of human blood or human plasma**

- Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to **active implantable medical devices**, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the marke

- Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

- Commission Regulation (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices

- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

Directive 2001/83/EC (32001L0083) of the European Parliament and of the Council on the Community code relating to medicinal products for human use

Week 7 +8 part III

Directive 2001/83/EC

- Aim:

rules governing the production, distribution and use of medicinal products must be to safeguard public health

Directive 2001/83/EC

- The aim attained by means which will **not hinder** the development of the pharmaceutical **industry or trade** in medicinal products

Directive 2001/83/EC

- approximation of the relevant national provisions

Directive 2001/83/EC

- Documents which must accompany an application for marketing authorization for a MP:

demonstrate that **potential risks are outweighed by the therapeutic efficacy** of the product.

Directive 2001/83/EC

- The adoption of the same standards and protocols by all the Member States

Directive 2001/83/EC

- Committee for Proprietary Medicinal Products - to EMA

Directive 2001/83/EC

Announced:

necessary to adopt specific provisions for:

- immunological medicinal products,
- homeopathic medicinal products,
- radiopharmaceuticals,
- medicinal products based on human blood or human plasma

Directive 2001/83/EC

- necessary to exercise control over the entire chain of distribution of MP,

- to guarantee products are stored, transported and handled in suitable conditions
- To combat with counterfeit MP

Directive 2001/83/EC

- Pharmacists should be exempt from obtaining special authorization/licence.

- But: keep records showing transactions in products

Directive 2001/83/EC

- Rules should be laid down as to how the labelling and package leaflets are to be presented -
- high degree of consumer protection

Directive 2001/83/EC

- *Medicinal product*

- *Substance:*
  - *Active substance:*
  - *Excipient:*

Directive 2001/83/EC

- *Adverse reaction:* A response to a medicinal product which is noxious and unintended.
- *Serious adverse reaction:* An AR which results in death, is life-threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly/birth defect.

- *Unexpected adverse reaction:* An AR, the nature, severity or outcome of which is not consistent with theSmPC.

Directive 2001/83/EC

- *Abuse of medicinal products:* Persistent or sporadic, intentional excessive use of medicinal products which is accompanied by harmful physical or psychological effets

- *Medicinal Prescription:* Any medicinal prescription issued by a professional person qualified to do so.

- *Name of the medicinal product:*
- *Common name:*
- *Strength of the medicinal product:*
- *Immediate packaging/Outer packaging*
- *Labelling:*
- *PIL*

- *Pharmacovigilance system:*
- *Herbs*
- *Falsified*

- shall apply to MP for human use intended to be placed on the market in MS and either **prepared industrially** or manufactured by a method involving an industrial process

- not apply to

- **PLACING ON THE MARKET**

Marketing authorization

No medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities

- **Marketing authorization**

- The application shall be accompanied by the documents, see Annex

- reference medicinal product

- generic medicinal product

- **Procedures relevant to the marketing authorization**

- **Mutual recognition and decentralised procedure**

- particulars at least appear on packagings

laid down requirements

- Name MP, name of the holder of the authorisation, expiry date, batch,
- method of administration,
- contents by weight, by volume or by unit

- easily legible, clearly comprehensible and indelible.

- Braille format

- authenticity and identification

- ...this medicinal product is subject to additional monitoring..

- **CLASSIFICATION OF MEDICINAL PRODUCTS**

Holders of distribution authorization

- minimum requirements:…
- Equipment, personell,…
- they must verify that the medicinal products received are not falsified by checking the safety features on the outer packaging, in accordance with the requirements laid down in….

- **SALE AT A DISTANCE TO THE PUBLIC**

- advertising of medicinal products
- Article 86

- the general public,

- persons qualified to prescribe or supply them,

- medical sales representatives
- supply of samples,

Advertising

- shall encourage the rational use of the medicinal product, by presenting it objectively and without exaggerating its properties,
- shall not be misleading.

- Member States shall prohibit any advertising of a medicinal product in respect of which a marketing authorization has not been granted in accordance with Community law.

- The end:
- **GENERAL PROVISIONS and**
- **FINAL PROVISIONS**

- Member States shall take all appropriate measures to ensure that the competent authorities concerned communicate to each other such information as is appropriate

- Directives – repealed

- enter into force
- Whom is addressed

CZE legal regulations governing pharmaceuticals, health care services

Week 7 +8 part IV

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

- This Act incorporates the relevant legal provisions of the EU, with a view to directly applicable regulations of the EU:

a) the research, manufacture, preparation, distribution, control, and elimination of MP and active substances

b) the marketing authorisation, post-marketing surveillance, prescribing and supply of MP, sale of selected medicinal products, and the provision of information;

c) international cooperation in the assurance of public health protection and the development of a uniform market of MP in the EU;

d) record-keeping on the activities listed…

General Provisions

Definition: What is?

- Medicinal product
- Substance: active substance, excipient
- Summary of the Product Characteristics
- Pharmacovigilance
- ADR
- ADE

General Provisions

Definition: What is?

- The name of a medicinal product
- Strength of the medicinal product
- Package leaflet

- Handling of pharmaceuticals
- Distribution of pharmaceuticals

- Dispensing of medicinal products
- The use x Abuse of medicinal products x Off-label use

- Counterfeit medicinal product
- ……
- (pre-mix for medicatedfeeding stuffs, medicated feedingstuff, Withdrawal period)

General Provisions

Definition: What is?

- The provider
- GMP
- GDP
- GPP

- Use of medicinal products in the delivery of healthcare services and veterinary care

- Tasks of authorities performing state administration in the field of pharmaceuticals

SIDC/ Institute for State Control of Veterinary Biologicals and Medicine

- Qualification of persons handling pharmaceuticals - General prerequisites, Professional prerequisites

- **MARKETING AUTHORISATION OF MEDICINAL PRODUCTS AND ISSUES RELATED**

- medicinal product may not be placed on the market in the Czech Republic, unless it has been:
- a) authorised by the Institute, where a human medicinal product is concerned, or by the Veterinary Institute where a veterinary medicinal product is concerned
- b) authorised by a procedure compliant with a directly applicable EU regulation

- *Exceptions…*

- **Classification of human medicinal products for the purposes of dispensing and sale of selected Pharmaceuticals**

- **RESEARCH, MANUFACTURE, DISTRIBUTION, PRESCRIBING, DISPENSING AND DISPOSAL OF PHARMACEUTICALS**
- Clinical trial

- **Manufacture, preparation and distribution of pharmaceuticals**

- **Preparation of medicinal products**

- **Prescribing, dispensing of medicinal products and disposal of pharmaceuticals**
- The implementing regulation
- **Pharmacovigilance of medicinal products for human use**

- **Administrative delicts**
- a fine may be imposed of up to:
- …… CZK, where an offence referred to in paragraph……

- **Delegating provisions, Repealing provisions**
- **CHAPTER TWELVE**
- **EFFECT**

Implementing regulations:

- **Decree No 229/2008 Coll.**, on the manufacture and distribution of pharmaceuticals, as amended;
- **Decree No 228/2008 Coll.**, on the marketing authorisation of medicinal products, as amended;
- **Decree No 106/2008 Coll., on good practice of vendors of selected pharmaceuticals and a professional training for vendors of selected pharmaceuticals**
- **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;
- **Decree No 415/2017** Coll., on the implementation of certain provisions of the Pharmaceutical Act on **electronic prescriptions**

- **Decree No 226/2008 Coll.,** on good clinical practice and detailed conditions of clinical trials on medicinal products, as amended;
- **Decree No 86/2008 Coll.,** on the principles of good laboratory practice in the area of pharmaceuticals, as amended;
- **Decree No 143/ 2008 Coll.,** on defining detailed conditions to assure the quality and safety of human blood and its components (Decree on Human Blood), as amended;