

European union – law system

Patient rights international view

# European Union

- „transcending nation-states “

FOR THE PURPOSE OF COOPERATION → HUMAN  
DEVELOPMENT

EU represents „a new legal order of  
international law“

*(ref: According to its Court of Justice)*

Week 5+6, part Ia

# **EUROPEAN UNION – „IN A NUTSHELL“**

Week 5+6, part 1b

# **EUROPEAN UNION AND HEALTH**

# EU and public health

- works to protect and improve the health:  
of all Europeans throughout their lives

## main objectives of EU health policy:

- prevent disease,
- promote healthier lifestyles,
- promote well-being,
- protect people from serious cross-border threats to health,
- improve access to healthcare,
- promote health information and education,
- improve patient safety,
- support dynamic health systems and new technologies,
- set high quality and safety standards for organs and other substances of human origin,
- ensure high quality, safety and efficacy for MP, MD

# Eu and health organisation

- the organisation and delivery of HC is the responsibility of individual countries
- HOWEVER: the EU brings „added value“ =

# EU - Key challenges in health

- Sustainability:
  - Ageing population
- Reducing the incidence of preventable diseases:
- Health inequalities
- Life expectancy at birth



# EU - Key challenges in health

- New and emerging health problems:
- Health security

# Health strategy in EU

2007: the EU adopted its 'Health strategy'.

- Based on four key principles:

1. Europeans have shared health values;
2. Health is the greatest wealth;
3. Considerations about health must be included in all policies;
4. „EU's voice must be heard on all issues affecting global health“

# Health strategy in EU

- Identified three key objectives:
  1. fostering good health in an ageing Europe;
  2. protecting citizens from health threats;
  3. supporting dynamic health systems and new technologies

# EU financial support - health

- The EU's work will complement and support national efforts in four key areas:
  - disease prevention and health promotion measures;
  - protecting citizens from cross-border health threats;
  - innovative and sustainable health systems;
  - better and safer healthcare for citizens.
- All 28 EU countries plus Iceland and Norway participate in the programme

# What?

- coordination mechanism for communicable diseases to include all health threats caused by biological, chemical or environmental factors;
- EU alert systems
- EU Health Security Committee (HSC):
- European Centre for Disease Prevention and Control (ECDC)
- EU-wide research networks

# WHAT?

- Strengthening the quality, safety and efficacy of medicines
- Tackling the risk factors of chronic disease, cancer
- Promoting healthy and active ageing

# WHAT?

- Research and health expertise
- Sustainable, cost-effective health systems
- Increasing the use of e-health and telemedicine

# **EU LAW SYSTEM**



# European Union law

- system of rules operating within the member states of the EU
- to „promote peace, values and the well-being of its peoples“

# European Union law

- European Union law is the basis for European integration  
(European unification).
- on the basic historical experience of continental European law.
- It is an independent legal system that is superior to the national legal systems.

# European Union law

- EU has to operate among a plurality of national legal systems.
- ....the European Court of Justice resolve conflicts of laws between different systems.

# European Union

Within the EU itself the Court of Justice's view is that:

if EU law conflicts with a provision of national law:

**EU LAW HAS PRIMACY.**

# European law

- is organized in the so-called "Acquis communautaire"  
[a ,ki kɔmyno 'tɛ:v]
- the accumulated legislation, *legal acts*, and *court decisions*
- constitute the body of European Union law

# Acquis Communautaire

1. Free movement of goods
2. Freedom of movement for workers
3. Right of establishment and freedom to provide services
4. Free movement of capital
5. Public procurement
6. Company law
7. Intellectual property law
8. Competition policy
9. Financial services
10. Information society and media
11. Agriculture and rural development
12. Food safety, veterinary and phytosanitary policy
13. Fisheries
14. Transport policy
15. Energy
16. Taxation
17. Economic and monetary policy
18. Statistics
19. Social policy and employment (including anti-discrimination and equal opportunities for women and men)
20. Enterprise and industrial policy
21. Trans-European networks
22. Regional policy and coordination of structural instruments
23. Judiciary and fundamental rights
24. Justice, freedom and security
25. Science and research
26. Education and culture
27. Environment
28. Consumer and health protection
29. Customs union
30. External relations
31. Foreign, security and defence policy
32. Financial control
33. Financial and budgetary provisions
34. Institutions
35. Other issues

# European Union law

- Primary law
- Secondary law
- Supplementary law = Case law

# Primary law

- mainly of the Treaties of the EU
- Contain formal and substantive provisions, which frame the implementation of the policies of the European institutions.
- Determine the formal rules that allocate the division of competences between the European Union and Member States



# scope of primary law

- the founding Treaties establishing the European Union
- the major Treaties amending the EU
- the Protocols annexed to those Treaties
- additional Treaties making changes to specific sections of the founding Treaties
- the Treaties of accession of new Member States to the EU

# The treaties – basis for democratic cooperation built on law: example

1952	The European Coal and Steel Community
1958	The treaties of Rome: <ul style="list-style-type: none"><li>• The European Economic Community</li><li>• The European Atomic Energy Community (EURATOM)</li></ul>
1987	The European Single Act: the Single Market
1993	Treaty on European Union - Maastricht
1999	Treaty of Amsterdam
2003	Treaty of Nice
2009	Treaty of Lisbon

# The EU's legal foundations

- Treaty on European Union
- Treaty on the Functioning of the European Union

# Sources of secondary law

Secondary law comprises:

- **unilateral acts**
- **agreements**

# Unilateral acts

Two categories:

- **REGULATIONS, DIRECTIVES, DECISIONS, OPINIONS, RECOMMENDATIONS;**

*those listed in Article 288 of the Treaty on the Functioning of the EU*

- **"atypical" acts such as COMMUNICATIONS, RECOMMENDATIONS, white and green papers**

*those not listed in Article 288 of the Treaty on the Functioning of the EU, i.e*

# Convention and Agreements

- international agreements signed by the EU and a country
- agreements :
  - EU with non-member countries or
  - EU with international organizations within their areas of responsibility.
  - between Member States
- interinstitutional agreements

# Sources of supplementary law

- TO BRIDGE THE GAPS LEFT by primary and/or secondary law.

# Primary vs secondary law

- Treaties are the starting point for EU
- Every action taken by the EU is founded on the treaties.



## Legislative vs non-legislative acts

- Legislative acts are adopted following one of the legislative procedures set out in the EU treaties (*ordinary or special*).
- Non-legislative acts do not follow these procedures = can be adopted by EU institutions according to specific rules.

# Regulations

- are of general application
- binding in their entirety
- DIRECTLY APPLICABLE!!

# Regulations

- must be complied with fully by those to whom they apply
- directly applicable =  
in all the Member States as soon as they enter into force and do not need to be transposed into national law.
- They are designed to ensure the uniform application of Union law in all the Member States.

# Directives

- binding as to the result to be achieved
- but leave to the NATIONAL AUTHORITIES THE CHOICE OF FORM AND METHODS

# Directives

National legislators:

- must adopt a transposing act
- bring national law into line with their objectives
- to Member States are given some competences, in transposing directives - to take account of specific national circumstances.
- Transposition - within the period laid down in the directive.

# Decisions

- binding on those to whom it is addressed
- directly applicable

# Recommendations and opinions

do not confer any rights or obligations on those to whom they are addressed

May provide guidance as to the interpretation and content of Union law.

# recommendation

allows the institutions to communicate their views

- AND to suggest a line of action



# opinion

- allows the institutions to make a statement in a non-binding fashion, without imposing any legal obligation on those to whom it is addressed.
- It can be issued by the main EU

# Consolidated texts

- integration of its successive amendments and corrigenda
- *Note: that these texts have no legal value. For legal purposes please refer to the full texts.*

# Institutions and bodies

- European Parliament
- Council
- European Council
- European Commission
- Court of Justice
- Court of Auditors
- European Central Bank
- European Economic and Social Committee
- European Committee of the Regions

# European Parliament

The Parliament has 3 main roles:

1. **Legislative**
2. **Supervisory**
3. **Budgetary**

- The European Parliament is the EU's law-making body.
- The Lisbon Treaty gave Parliament significantly more legislative powers

# European Parliament

- **Role:** Directly-elected EU body with legislative, supervisory, and budgetary responsibilities
- **Members:** 751
- **President:** Antonio Tajani
- ***Established in:** 1952 as Common Assembly of the European Coal and Steel Community, 1962 as European Parliament, first direct elections in 1979*
- **Location:** Strasbourg (France), Brussels (Belgium), Luxembourg
- (Luxembourg - administrative offices, Meetings of the whole Parliament Strasbourg and in Brussels, Committee meetings - Brussels.)
- **Website:** [European Parliament](http://www.europarl.europa.eu)

# European Parliament

- It is **directly elected by EU voters** every 5 years.
- The last elections were in May 2019.

# European Parliament

## Legislative role

- Passing EU laws, together with the Council of the EU,  
*based on European Commission proposals*
- Deciding on international agreements
- Deciding on enlargements
- Reviewing the Commission's work programme and asking it to propose legislation

# European Council

- **Role:** Defines the general political direction and priorities of the European Union
- **Members:** Heads of state or government of EU countries, European Commission President, High Representative for Foreign Affairs & Security Policy
- **President:** Donald Tusk
- ***Established in:*** 1974 (*informal forum*), 1992 (*formal status*), 2009 (*official EU institution*)
- **Location:** Brussels (Belgium)
- **Website:** [European Council](#)



# What does the European Council do?

- Decides on the EU's overall **direction** and political **priorities**

# The Council of the European Union

- **Role:** Voice of EU member governments, adopting EU laws and coordinating EU policies
- **Members:** Government ministers from each EU country, according to the policy area to be discussed
- **President:** Each EU country holds the presidency on a 6-month rotating basis
- **Established in:** 1958 (as Council of the European Economic Community)
- **Location:** Brussels (Belgium)
- **Website:** [Council of the EU](#)

# The Council of the European Union

- Together with the [European Parliament](#), the Council is the **main decision-making body** of the EU.

# The Council of the European Union

- 1. Negotiates EU laws**
2. Coordinates member states' policies
3. Develops the EU's common foreign and security policy
4. Concludes international agreements
5. Adopts the EU budget - jointly with the European Parliament.

# Court of Justice of the European Union (CJEU)

- Role: Ensuring EU law is interpreted and applied the same in every EU country; ensuring countries and EU institutions abide by EU law.
- Court of Justice: 1 judge from each EU country, plus 11 advocates general
- Location: Luxembourg
- Website: Court of Justice of the European Union (CJEU)

# The Court of Justice of the European Union (CJEU)

- settles legal disputes between national governments and EU institutions
- 2 courts

# European Commission

- **Role:** Promotes the general interest of the EU by proposing and enforcing legislation *as well as by implementing policies and the EU budget*
- **Members:** A team or 'College' of Commissioners, 1 from each EU country
- **President:** Jean-Claude Juncker
- **Year established:** 1958
- **Location:** Brussels (Belgium)
- **Website:** [European Commission](https://ec.europa.eu/)

# European Commission

- **politically independent executive arm**
- responsible for drawing up proposals for new European legislation,





Citizens, interest groups, experts: discuss, consult



Commission: makes formal proposal



Parliament and Council of Ministers: decide jointly



National or local authorities: implement



Commission and Court of Justice: monitor implementation

# European Ombudsman

- **Ombudsman:** Emily O'Reilly
  - **Established in:** 1995
  - **Location:** Strasbourg (France)
  - **Website:** [European Ombudsman](#)
- **Role:** investigates **complaints** about **poor administration** by EU institutions or other EU bodies.
- ... **citizens** or **residents** of EU countries or by **EU-based** associations or businesses.

# What does the Ombudsman do?

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# How does the Ombudsman work?

- **launches investigations**
- **make recommendations** to the institution

# Human rights

# Patient rights

Week 5+6 part II

# Universal Declaration of Human Rights

- UN
  - Formalized in 1948
  - Recognition:
    - THE INHERENT DIGNITY
    - EQUAL AND UNALIENABLE RIGHTS OF ALL MEMBERS OF THE HUMAN FAMILY
- is the foundation of freedom, justice and peace in the world,

# Fundamental rights in the EU:

There are three sources:

- the EU's Charter of Fundamental Rights;
- the European Convention on Human Rights (ECHR);
- the constitutional traditions of Member States.



# EU Charter of Fundamental Rights

*The Charter contains rights and freedoms under six titles:*

- 1. Dignity,*
- 2. Freedoms,*
- 3. Equality,*
- 4. Solidarity,*
- 5. Citizens' Rights,*
- 6. Justice.*

# Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine

- was opened for signature on 4 April 1997  
in Oviedo
- <https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/164>
- [https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/164/signatures?p\\_auth=WCYHJ1W](https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/164/signatures?p_auth=WCYHJ1W)

Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine

- Art. 3 – equal access to health care of appropriate quality
- Art. 4 – professional standards
- Art. 5 – free informed consent
- Art. 6 – Protection of persons not able to consent
- Art. 8 – emergency requiring urgent solutions
- Art. 9 – previously expressed wishes
- Art.10 – privacy and right for information

# Patients' rights

- vary in different countries and in different jurisdictions,
- often depending upon prevailing cultural and social norms.

# Patients' rights

Growing international consensus:

ALL PATIENTS HAVE A FUNDAMENTAL RIGHT TO:

- privacy,
- confidentiality of their medical information,
- consent to or to refuse treatment,
- be informed about relevant risk to them of medical procedures.

Patient's rights have no borders

# CHARTER OF FUNDAMENTAL RIGHTS AND FREEDOMS (1993) CZE

## Constitution

- Everyone has the right to live.
- No one shall be deprived of life.
- Everyone has the right to maintain his human dignity .....
- Everyone has the right to be protected from unauthorized collection, disclosure or other misuse of his personal data.
- *Note:.....General Data Protection Regulation*

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

**THE POSITION:**

**OF THE PATIENT AND OTHER PERSONS**

**IN CONNECTION WITH THE PROVISION OF HS**



# **Act No. 372/2011 Coll**

## **Definition:**

- **What is HCS**
- **Who is a patient**
- **Types and forms of HCS**

# Health services:

• § 2

- **the provision of HC by HP**
- **The consultation services to assess the individual treatment process**
- **medical rescue service**
- **(transporting patients, anti-toxikomanic seizure service, services within the scope of the operation of blood transfusion services ,.... etc)**

# Health care

- set of activities and measures implemented for natural persons for the purpose:
  - prevention, detection and eradication of illness, defect or health statute
  - maintenance, restoration or improvement of the health statute
  - maintaining and prolonging life and alleviating suffering,
  - assistance in reproduction and childbirth,
  - health assessment,
- preventive, diagnostic, medical, medical, rehabilitation, nursing or other healthcare provided by healthcare professionals for the above listed purposes
- medical examination

# Patient

- means a natural person to whom is provided with a health service.

# Types of health care according to the timing of its provision

- urgent care to prevent or reduce the occurrence of sudden conditions that directly endanger life or could lead to sudden death or serious health hazards
- acute care
- the necessary medical care required by the medical condition of the patient who is a foreign insured person,
- planned care

# types of healthcare provided by the purpose of its provision

- preventive care
- Diagnostic care

# types of healthcare provided by the purpose of its provision

- dispensary care,  
the active and long-term monitoring of the state of health of a patient at risk of or suffering from a disease
- medical treatment intended to have a favorable effect on the state of health through the implementation of an individual treatment procedure in order to cure or mitigate the consequences of the illness and to prevent or reduce the degree of disability or disability

# types of healthcare provided by the purpose of its provision

- assessment care
- rehabilitative care
- nursing care
- palliative care
- pharmacy care (pharmaceutical care) 😊



# Act No. 372/2011 Coll

## Part 4:

- **The position of the patient and other persons in connection with the provision of HS**
- **Rights and duties of patient**

# Rights of the patient

- Provision of HS on adequate professional level
- the least restrictive environment
- Respect
- Informed consent

# Rights of the patient

- patient has right to choose **providers of health services to meet the health needs**
  - *There are some exceptions*
- „Guardian“

# Rights of the patient

- Right to ask for consultation service (second opinion)

# Rights of the patient

- Information secrecy HCP
- obligation for providers to disclose health information in medical records, which are necessary to provide consulting services
- (The **General Data Protection Regulation (GDPR)** (Regulation (EU) 2016/679))

# Rights of the patient

be informed in advance about the price provided by HS

the manner of their payment

# Rights of the patient

To know the name of :

- Health care professionals
- Other professionals involved in the provision of HS and

# Rights of the patient

Deny presence of

- persons who are not directly involved in the provision of HS



# Rights of the patient

## Right for presence of

- Legal guardian or a person designated by him - *for minors, patients deprivation of legal capacity*
- close relatives or a person designated by the patient

*Under certain conditions*

# Rights of the patient

- To receive visitors in a hospital inpatient and day care
- To receive pastoral care visitors in a hospital inpatient and day care

# Information to patient

- **Information about the patient's condition and the proposed**

*HS Act No. 372/2011 Sb. - § 31 - 33*

- **Information about health condition/state and about the proposed individual treatment including any changes → TO the patient or guardian**
- **In understandable way and sufficient extent**
- **Given by HCP who delivers the care**
- **Recorded in the medical records**

# Information to patient

- To enable to give **additional questions related to health status**

**To the patient or To person chosen by him**

Q must be clearly answered

# Information to patient

## The content of information - in particular:

- The cause and origin of disease, stage and expected development
- Purpose, nature, anticipated consequences and risks of the proposed HC
- Provide/explain other options of the HS, suitability, benefits and risks
- other necessary treatment
- Restrictions and recommendations in the way of life with respect to health state

# Patient option

- **to give up** to communicate information about health

.... disable reporting

(exemption)

# Patient option

## Exception:

- infectious disease or any other disease - risk to life or health other persons
  - *the information can be given without the patient's consent under the law*

# Information

The Provider is entitled to tell the person who will personally take care of the patient, **the necessary information:**

- To secure the care to the patient
- To protect their health



# Underage patient and the patient deprived of legal capacity

Right to information and the right to ask questions:

- **Legal representative** and
- **Also underaged patient** - in a way that takes into account:
  - His intellectual maturity
  - His ability to understand current information

# Note

→ Information on **unfavorable diagnosis or prognosis**

- may be retained:....under special condition

Only for limited period

# Note:

## Can not be applied:

- If it is the only way to take preventive measures or undergo early treatment
- There is a risk to the patient's surroundings
- ?
- When patient explicitly asks

# Information

**Information about the patient** - patient can:

- Identify persons who may be informed (and how)
- access to Medical Records (MR)
- make notes or copies of extracts from MR

# Patient's duties

- **The patient is obliged to (§ 41):**
- to comply with an individual treatment procedure if agreed with him;
- *Consequences: deliberate / systematic failure → termination of patient care*

# Patient's duties

- Follow the **internal rules** of HCF
- pay the price of the HS to the provider when not covered or partially covered by public health insurance

# Patient's duties

## Truely inform about:

- current state of health,



- HS provided by other providers,



- Use of medicines and Addictive Substances

- Other facts essential for provission of HS

# Patient's duties

- **Duty to identify with ID card**
- **?**



# Informed consent

(§ 34 a 35)

- HS can be provided **only with patient's free and informed consent**
- IC can be anytime cancelled
- **Written form needed**

?

- → Consent is a part of the medical record
- Signature of patient, ev. Witness and HCP

# Informed consent

When patient is not able to write, speak ?

- **unmistakable expression of will**

# Informed consent

- **Underage patient and the patient deprived of legal capacity**

(§ 35)

*Find out his opinion + recorded in the documentation*

*Legal representative*

# Reverse

- = Refusal to consent to HS (§ 34/ 4)
- **W**ere given patient health information
- **P**atient refuses to consent with HS
- **I**nformation must be given repeatedly,
- in the manner from which it is clear that the absence of HS can seriously damage his health or life-threatening
- **B**UT Patient still disagrees
- → the patient's written declaration (**reverse**) – to be attached in his medical record

# Previously expressed wishes

- (§ 36)
- Written form  
(informed about consequences and context of the „wish“)
- Certified signature of the patient and...
- Validity 5 years
- → provider will take into account

S.

# Previously expressed wishes

can not respect:

e.g. active cause of death, threats to others

Progression in HCS

- not applicable (patients minors and deprivation of legal capacity)

# Providing health care services without consent and restraints

## Hospitalisation without consent

Possible – reasons (§ 38)

- Without the consent of the patient can only provide emergency medical care
- Protective treatment - court judgment,
- Quarantine, isolation...
- 
- ***Restrictions on the free movement of the patient - can be used restraint***
- § 39
- *Conditions of use*

- Duties and righth's of HP