

EU Health Issues

- EU Health Legal Framework
- Right to Health as Socio-Economic right
- Right To health as International and Human Right

EU Legislation

- Primary and Secondary Legislation

Types of EU legal acts

- EU treaties. The treaties lay down the objectives of the European Union, the rules for EU institutions, how decisions are made and the relationship between the EU and its member countries.
- Regulations.-binding
- Directives-binding
- Decisions-binding
- Recommendations-non binding
- Opinions-nonbinding
- Delegated acts.
- Implementing acts.

EU Health Legal Framework

Very broad concept and it contains all these disciplines: Pharmaceutical, public health, the state of health, tobacco, reproductive health etc

Does the EU regulate healthcare?

The European Union has no major administrative responsibility in the field of healthcare. Both the World Health Organization Regional Office for Europe (WHO/Europe) and the European Centre for Disease Prevention and Control are involved in public health development in Europe.

Definition: What else does cover the EU Health leg Framework?

The European Union (EU) legal framework for pharmaceuticals is aimed at ensuring a high level of protection of public health. It is based on the principle that the placing of a medicine on the market is subject to the granting of a marketing authorization by the competent authorities.

Public Health

The following elements should be considered to be essential for inclusion in a single public health act:

- ☐ a clear philosophical framework;
- ☐ definition of public health law;
- ☐ definition of common terms in public health law;
- ☐ establishment of essential public health functions;
- ☐ due importance paid to the international public health law context;
- ☐ clear demarcation of the roles and responsibilities and establishing coordinative mechanisms in the system;
- ☐ improvement of existing services, inclusion of accountability and enhancement of quality assurance;
- ☐ use of internationally agreed disease classifications;
- ☐ public health decisions to be based on the best scientific evidence of significant risk;
- ☐ establishment of good enforcement and adequate powers to deal with public health risks;

- ☐ provision of fair procedures;
- ☐ establishment of statutory advisory bodies;
- ☐ setting-up of impact-oriented monitoring and evaluation systems and reporting mechanisms;
- ☐ establishment of a legal basis for partnerships in public health activities;
- ☐ provision of public health legal services;
- ☐ provision of funding;
- ☐ setting of adequate penalties, as appropriate.
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➤ **How does the EU deal with diseases?**

- The Strategy focuses on four principles and three strategic themes for improving health in the EU.
- The principles include taking a value-driven approach, recognizing the links between health and economic prosperity, integrating health in all policies, and strengthening the EU's voice in global health.
- The strategic themes include Fostering Good Health in an Ageing Europe, Protecting Citizens from Health Threats, and Dynamic Health Systems and New Technologies.
- Fostering good health – to prevent diseases and promote healthy lifestyles by addressing the issues of nutrition, physical activity, alcohol, tobacco and drug consumption, environmental risks and injuries.

- What is the National Health Initiative of EU?
- The European Health Information Initiative (EHII) is a WHO network committed to improving the information that underpins health policies in the European Region. It fosters international cooperation to support the exchange of expertise, build capacity and harmonize processes in data collection and reporting.

EU legal Instruments

European legal instruments related to e-health

A. The Data Protection Directive 95/46/EC “On the protection of individuals with regard to the processing of personal data and on the free movement of such data (the Data Protection Directive)”.

➤ This Directive contains several important principles that require compliance from e-health actors that process personal data concerning health.

If national health care systems or other e-health actors create health grids, electronic national records or information systems that may be used for treatment, quality review or research purposes, they have to comply with the principles of the Data Protection Directive.

The European directive on patients' rights

- Directive No. 2011/24/EU of March 9, 2011 on patients' rights in cross-border healthcare aims to guarantee patient mobility and the free provision of healthcare services.
- It has been applicable in the European member States since October 25, 2013, and in the European Economic Area* (Iceland, Liechtenstein, and Norway) since August 1st, 2015. However, it does not apply to Switzerland. It no longer applies to the United Kingdom as of 01/01/2021.

Background information

- The European Union's coordination rules guarantee that an insured individual who travels within the European Union will receive the same healthcare as if s/he were a member of the healthcare system of the State in which treatment is provided.
- Coordination regulations (EC) Nos. 883/04 and 987/09 entitle insured individuals to receive healthcare elsewhere within the European Union or the European Economic Area (Iceland, Liechtenstein, and Norway), as well as in Switzerland, and be covered for the care received by their home country's healthcare system according to that system's specific guidelines.
- Legal precedent from the European Court of Justice has subsequently reinforced patients' rights. Indeed, by taking account of legal precedent (Kohll, Decker, Smits and Peerbooms, and Watts rulings), the directive reaffirms the principle of free movement of people.
- This directive includes social security coordination rules which work together with those provided by (CE) regulations Nos. 883 and 987.

Content of the directive

- The Directive aims to facilitate access to safe, high-quality cross-border healthcare and to promote healthcare-related cooperation between EU and EEA (Iceland, Liechtenstein, and Norway) member States, while maintaining each State's independent authority to organize and provide healthcare services:
- The patient is free to choose a healthcare provider or facility in either the public or the private sector;
- The patient is reimbursed by the member State of affiliation for at least the amount reimbursed for identical care provided in the State of residence, insofar as the treatment received abroad is covered by that State's healthcare system;
- Cross-border prescriptions for medications or medical devices: the patient's home country must provide follow-up care of equal quality, regardless of where treatment was initially provided;

- Creation of a National Contact Point in each country to inform patients of all of their rights. Example: The Cleiss is France's National Contact Point;
- Formation of a network of national authorities in charge of "e-health" to improve continuity of care and guarantee access to high-quality care;
- Establishment of a network of authorities or bodies in charge of assessing healthcare technologies as a way of promoting cooperation among the competent authorities from each State;
- Member States are encouraged to work together to improve treatment of rare diseases by developing new diagnostics and treatment solutions;
- Support for creating European healthcare provider reference networks, promoting mobility of expertise in Europe and access to highly specialized care by concentrating and combining available resources and expertise.

- The directive does not apply to:
- Long-term care (home care services),
- Organ donations,
- Public vaccination programs

Socio-Economic rights

- Economic and Social Rights
- Socio-economic rights provide protection for the dignity, freedom and well-being of individuals by guaranteeing state-supported entitlements to education, public health care, housing, a living wage, decent working conditions and other social goods.

What are examples of socioeconomic rights?

Economic, social and cultural rights are socio-economic human rights, such as the right to education, right to housing, right to an adequate standard of living, right to health, victims' rights and the right to science and culture.

Right to Health

Right to Health: An Inclusive Right for All

- The World Medical Association (WMA) is committed to protecting and promoting the right to health in an inclusive manner. This includes essential aspects such as the availability of quality and affordable health services, safe environment and working conditions, adequate housing and nutritious food.

What is the importance of the right to health?

- Understanding health as a human right creates a legal obligation on states to ensure access to timely, acceptable, and affordable health care of appropriate quality as well as to providing for the underlying determinants of health, such as safe and potable water, sanitation, food, housing, health-related information etc.

Right to Health as according to EU

- Charter of Fundamental Rights and Freedoms
- Article 31: Everyone has the right to the protection of her health. Citizens shall have the right, on the basis of public insurance, to free medical care and to medical aids under conditions provided for by law.
- Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.

What is the legal basis for the right to health?

- The legal basis for the right to health is found within international law and agreements. The 1948 Universal Declaration of Human Rights (UDHR) contends in Article 25 that "everyone has the right to a standard of living adequate for the health and well-being of himself and his family," including medical care.

What are the key elements of right to health?

➤ Essential Elements of the Right to Health

- Non-discrimination. Health facilities, goods and services accessible to all, especially marginalized and vulnerable;
- Physical accessibility;
- Economic accessibility (affordability);
- Information accessibility.

Is health care a right or a privilege?

- Those who see healthcare as a privilege will often use the rhetoric of negative rights.
- There is a major global consensus that health—and all the circumstances that mediate health—is a fundamental human right (see the UN Universal Declaration of Human Rights and the World Health Organization's Constitution).
- (Positive Rights and Negative Rights0

Human Rights/ Health Rights

- The discourse of human rights has pervaded the regulation of healthcare across jurisdictions.
- This has been particularly the case following the Nuremberg trials and the development of the Universal Declaration of Human Rights.
- Human rights can be loosely divided into ‘negative’ and ‘positive’ rights.
- Negative rights are typically contained in traditional so-called civil and political statements of human rights. These rights statements have been in existence for considerable periods of time – in some cases, several hundred years, as in the case of the United States Bill of Rights. Such rights include the right to life and rights to privacy of home and family life. They
- do not usually involve expenditure of public resources.

- Positive rights
- Positive rights are to be found in more modern, frequently termed 'socioeconomic', human rights statements.
- Examples include the right to health and right to education. Positive rights typically involve expenditure of public money and tend to be characteristic of more affluent societies.

International human rights documents refer to rights applicable in the context of health law and health policy.

- Preamble of the World Health Organization (WHO) Constitution in 1946
- Council of Europe's Convention on Human Rights and Biomedicine
- Article 25, Universal Declaration of Human Rights, adopted 10 December 1948 under General Assembly Resolution 217 A (III), UN Doc. A/810, 71. 6
- Article 12(1), International Covenant on Economic, Social and Cultural Rights, New York, 19 December 1966, in force 3 January 1976, 993 UNTS 3; 6 ILM 360. 7 Article 6, Universal Declaration of Human Rights, above n.5. 8 See Article 3, Universal Declaration of Human Rights, above n.5; and Article
- International Covenant on Civil and Political Rights, New York, 19 December 1966, in force 23 March 1976, 999 UNTS 171; 6 ILM 368. 9 Article 5, Universal Declaration of Human Rights, above n.5.

A considerable number of actions brought before the European Court of Human Rights have concerned health and health care. For example,

- Article 2 ECHR has been used in claims concerning the status of the fetus and abortion, resource allocation in health care systems and the 'right to die'.
- Article 5 ECHR on the right to liberty and security of the person has been used extensively in the context of mental health.
- Article 8 on the right to privacy has been used in claims concerning reproductive rights (and may also have relevance to people with learning disabilities or mental illness),
- Article 12 ECHR on the right to marry and found a family.

European social Charter

The European Social Charter is overseen by the European Committee of Social Rights, which 'makes a legal assessment of the conformity of national situations with the European Social Charter ... and adopts conclusions in the framework of the reporting procedure

European Social Charter

Article 11 of the European Social Charter refers to the right to the protection of health:

With a view to ensuring the effective exercise of the right to protection of health, the Contracting Parties undertake, either directly or in co-operation with public or private organizations, to take appropriate measures designed, inter alia:

1. to remove as far as possible the causes of ill-health;
2. to provide advisory and educational facilities for the promotion of health and the encouragement of individual responsibility in matters of health; and
3. to prevent as far as possible epidemic, endemic and other diseases as well as accidents.



References

- [https://www.coe.int/en/web/european-social-charter?\(EN\);](https://www.coe.int/en/web/european-social-charter?(EN);)
- <https://echr.coe.int/pages/home.aspx?p=home;>
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- International Covenant on Civil and Political Rights, New York, 19;
- Data Protection Directive 95/46/EC “On the protection of individuals with regard to the processing of personal data and on the free movement of such data (the Data Protection Directive)”.

Thank you for your attention !!!

