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# The Values of biomedical innovation

Organised by **Dr Aurelie Mahalatchimy**, Prof  
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# THE VALUES OF BIOMEDICAL INNOVATION: A LEGAL VIEW

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# Introduction

- No general definition of “biomedical innovation” in law
- But potential definitions and regulations
  - Of specific kinds of biomedical innovations
    - Example: Advanced Therapy Medicinal Products in European Union law
  - Of specific steps of development of biomedical innovation
    - Example: laws on funding of R&D, patentability, clinical trials
  - By different laws: mainly European Union law and national laws but it could also come from international law, law issued from Council of Europe, or law from other organisations
- 2 aspects of the value notion for the law

# 1- The legal value of the law on biomedical innovation

- First thought from the legal perspective
- Legal value of the legal texts regulating biomedical innovation
  - Binding texts (“hard law”): compliance is ensured by the Courts
  - Non-binding texts (“soft law”) : compliance is not ensured by the Courts
- Comments
  - Binding texts more on specific steps of development of biomedical innovation
  - Many non-binding texts: e.g. technical guidelines from health agencies
  - Binding texts on what is the most important for the society, linked to the society values to be protected by the law but political and legal contexts of each legislator and regulator.

## 2- The values of the law on biomedical innovation

- The “Values” term is generally avoided by the law specialists as it is globally unknown in law
- The law refers more to
  - Fundamental principles, human rights, General Principles of law, ethical principles
- In Europe, two main binding texts (in addition to national laws) regarding fundamental rights
  - The Charter of Fundamental Rights of the European Union
  - The Convention on Human Rights and Biomedicine (Council of Europe)

# Overview of European fundamental rights potentially affecting biomedical innovation

- Human dignity
- Health (access to healthcare and preventive care, protection of public health, protection of environment)
- Non-discrimination in access to healthcare services and preventive care
- Privacy (physical and physiological integrity including autonomy in the context of medical interventions, protection of personal data, confidentiality of medical files)
- Information and participation (access to health related information, informed consent)
- Right to life
- Prohibition of torture and inhuman and degrading punishment
- Family life (prohibition of compulsory use of contraceptives, non-voluntary sterilisation or abortion, access to fertility treatments)

# Other legal and ethical principles affecting biomedical innovation

- Bioethics
  - Autonomy
  - Justice
  - Beneficence
  - Non-maleficence
- Public health
  - Assessment
  - Precaution
  - Transparency
  - Independence
- Health economics
  - Performance of health systems through efficiency and equity
- EU fundamental freedoms
  - Free movement of goods, persons and services
- Good governance
  - Openness, Participation, Accountability, Effectiveness, Coherence



# A society right to innovation?

- European Charter of Patients rights (2002)
  - “Each individual has **the right of access to innovative procedures**, including diagnostic procedures, according to international standards and independently of economic or financial considerations.”
- International Covenant on Economic, Social and Cultural Rights (1966)
  - **the right of everyone to enjoy the benefits of scientific progress and its applications**

# Conclusion

- Legal value of the law on biomedical innovation
  - What is essential and where compliance has to be ensured
  - But legal and political limits (lack of consensus)
- Values of the law on biomedical innovation
  - Mainly fundamental rights
    - Human dignity, access to healthcare
  - But also other guiding principles by law
    - EU fundamental freedoms for the good functioning of the internal market
  - Balance to be found between principles/objectives
    - Multiple laws, competent authorities, legal traditions
    - Different implementations of these principles
    - Not always a legal answer
- Implementation of a right to enjoy the benefits of scientific progress?

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