Quality of care and new technologies – the role of values and ethics

8th European Conference on Health Law | Ghent, Belgium | "Quality of healthcare. Can the law help to guarantee safe and reliable care for the patient?" | 21 April 2022

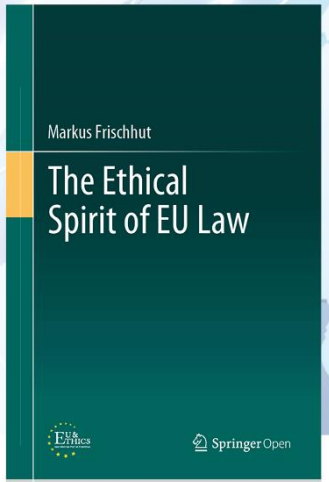
EU VALUES
Jean Monnet Prof. M. Frischhut

EUROPEAN ASSOCIATION of HEALTH LAW
THE EAHL INTEREST GROUP ON SUPRANATIONAL BIOLAW

With the support of the Erasmus+ Programme of the European Union

N.B. Please note that whenever appropriate, screenshots are linked to the relevant website.

JeanMonnet.mci.edu



Previous Chair:
EU & Ethics.
2016 to 2019

EU & ETHICS
Jean Monnet Prof. M. Frischhut

New Chair:
EU Values.
2019 to 2022

EU VALUES
Jean Monnet Prof. M. Frischhut

With the support of the Erasmus+ Programme of the European Union

Cf. Frischhut, M. (2019). *The Ethical Spirit of EU Law*. Cham: Springer International Publishing.

Health, AI & robotics

- **Possible fields of application** (on health see also pts. 70-83); cf. also AI Reg prop [*see below*], recital 3
  - "whereas, in industry and services associated with high technology, AI is key to turning Europe into a 'start-up continent' by exploiting the latest technologies to generate growth in Europe, in particular **in the areas of health technology, healthcare services and programmes, drug discovery, robotic and robot-assisted surgery, treatment of chronic diseases, and medical imaging and records**, as well as securing a sustainable environment and safe food production; whereas Europe is currently lagging behind North America and Asia in terms of research and patents in the field of artificial intelligence" (recital AF)
  - "whereas there is a **broad catalogue of possible applications** of AI and robotics **in medical care**, such as managing medical **records and data**, performing **repetitive jobs** (analysing tests, X-rays, CT scans, data entry), **treatment design**, **digital consultation** (such as medical consultation based on personal medical history and common medical knowledge), **virtual nurses**, **medication management**, **drug creation**, **precision medicine** (as genetics and genomics look for mutations and links to disease from the information in DNA), **health monitoring** and healthcare system **analysis**, among other applications" (recital AH)

> **12 February 2019** | EP A comprehensive European industrial policy on **artificial intelligence and robotics** | (2018/2088(INI))

Quality | definition

Definition of ‘quality’ | (only) a relative concept

- Oxford Dictionary: “the standard of something as **measured against other things** of a similar kind” (Stevenson, 2010, 1451)
- Quality as a **value-neutral** term, i.e. the “degree to which a set of inherent characteristics meets requirements” (Kraft, 2021, 562-563, translation; referring to DIN EN ISO 9000:2015-11)
- "Today there is however still **no agreement** on how to define the concepts of access and quality of care.“ (Health Ministers, 2015, 1)

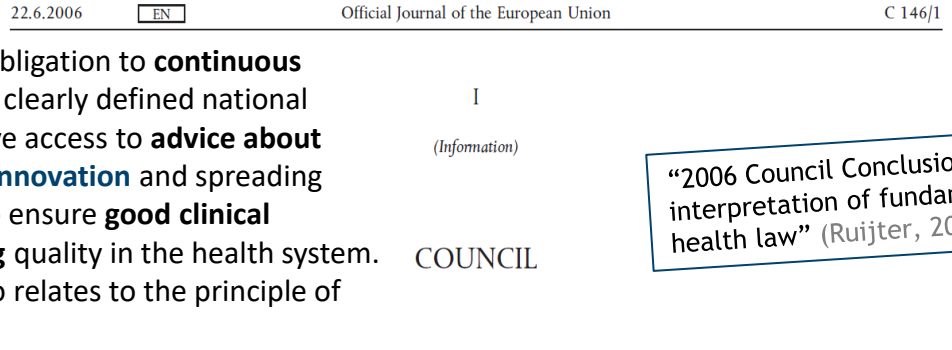
Quality in health: “The Institute of Medicine (IOM) 2001 report ‘Crossing the Quality Chasm: A New Health System for the 21st Century’ outlines **six core values** for defining and evaluating the quality of healthcare: healthcare should be **safe, effective, efficient, patient-centred, timely and equitable**.” (Roscam Abbing, 2012, 415)

Safety | narrower concept than quality: “Patient safety is **narrower** in its definition than quality of healthcare. The World Health Organisation (WHO) sees patient safety as a critical component of quality management. The WHO defines patient **safety as freedom for a patient from unnecessary or potential harm** associated with healthcare.” (Roscam Abbing, 2012, 415)

Sources: (N.B. throughout this presentation, emphases added in terms of printing in blue colour and in bold)

- Kraft, M. (2021). A. Medizintechnik - Eine ingenieurwissenschaftliche Einführung. In K. J. Chibanguza, C. Kuß, & H. Steege (Eds.), *Künstliche Intelligenz: Recht und Praxis automatisierter und autonomer Systeme* (1st ed., pp. 557-570). Nomos Verlag.
- Health Ministers. (24-25th September 2015). *The role of Health in the European semester: Informal meeting of Health Ministers* [Session II. Discussion paper].
- Stevenson, A. (Ed.). (2010). *Oxford dictionary of English: First edition edited by Judy Pearsall, Patrick Hanks* (Third edition). Oxford University Press.
- Roscam Abbing, Henriette D.C. (2012). Patients' right to quality of healthcare: How satisfactory are the European Union's regulatory policies? *European Journal of Health Law, 19*(5), 415-422. https://doi.org/10.1163/15718093-12341247

Health values and principles



22.6.2006 EN Official Journal of the European Union C 146/1

I

(Information)

COUNCIL

Council Conclusions on Common values and principles in European Union Health Systems

(2006/C 146/01)

"achieved in particular through the obligation to **continuous training** of healthcare **staff** based on clearly defined national standards and ensuring that staff have access to **advice about best practice** in quality, **stimulating innovation** and spreading good practice, developing systems to ensure **good clinical governance**, and through **monitoring** quality in the health system. An important part of this agenda also relates to the principle of **safety**"

"2006 Council Conclusions may help shape the interpretation of fundamental rights in the context of EU health law" (Ruijter, 2017, p. 486; cf. also 2019, p. 188)

- **Overreaching values**:
  universality, access to good **quality** care, equity, and solidarity

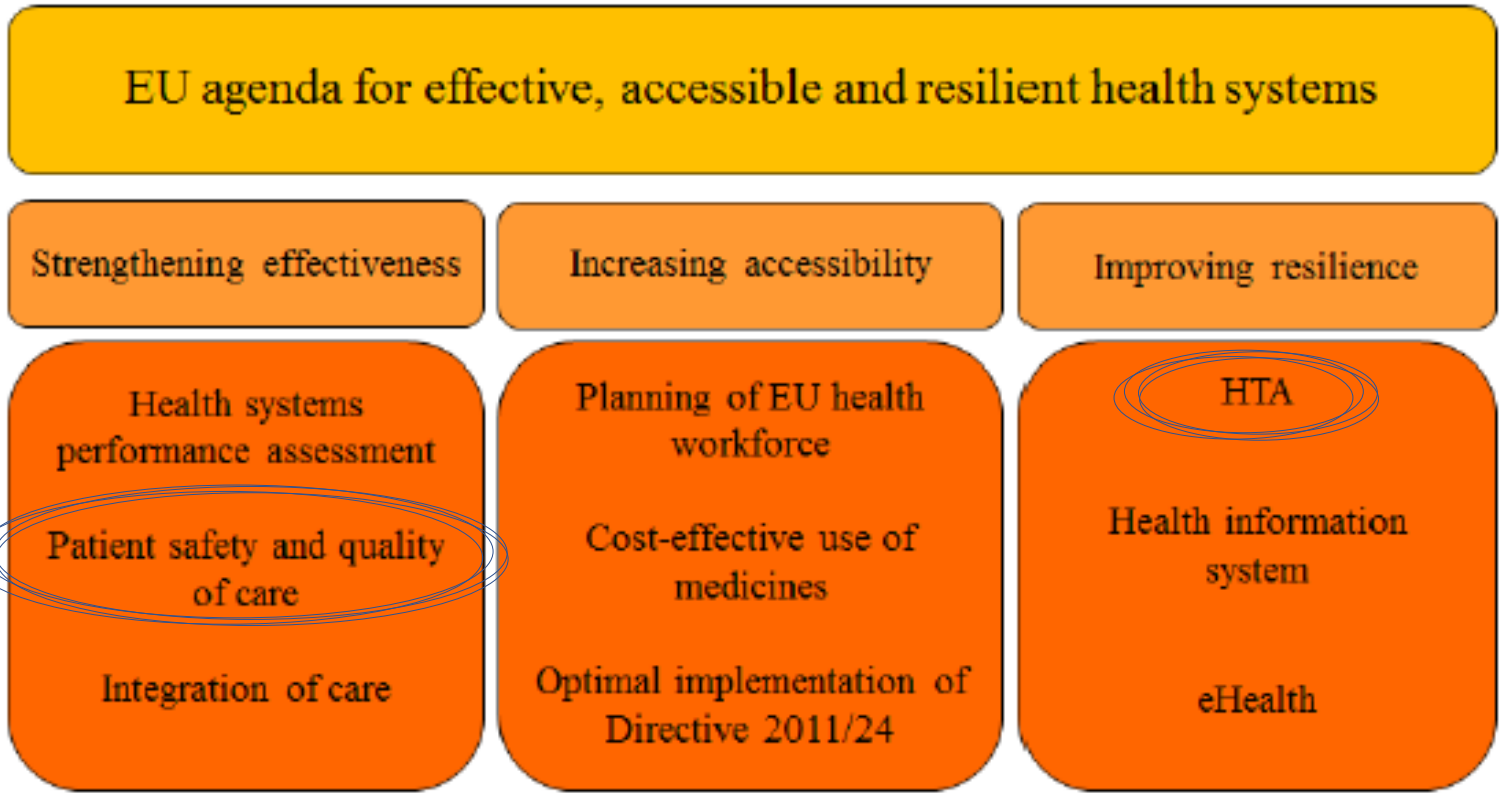
  specific | general

- **Operating principles**:
  quality, **safety**, care that is based on evidence and ethics, **patient involvement**, redress, privacy and confidentiality

Cf. Ruijter, A. de. (2017). The impediment of health laws' values in the constitutional setting of the EU. In T. K. Hervey, C. Young, & L. E. Bishop (Eds.), *Research Handbook on EU Health Law and Policy* (pp. 479–495). Edward Elgar Publishing. | Ruijter, A. de. (2019). *EU Health Law & Policy: The Expansion of EU Power in Public Health and Health Care*. OUP.

Source: Council Conclusions on Common values and principles in European Union Health Systems, OJ 2006 C 146/1.

Systems | effective, accessible, resilient



Source: European Commission, On effective, accessible and resilient health systems, COM(2014) 215 final 4.4.2014, p. 17.

Right to healthcare | GC14 | AAAQ

World Health Organization

Quality, amongst others, as one element of the right to health

- CESCR General Comment No. 14: The Right to the **Highest Attainable** Standard of Health (Art. 12)
  - Essential elements (para 12)
    - **Availability**: "Functioning public health and health-care facilities, goods and services, as well as programmes, have to be **available in sufficient quantity** within the State party. The precise nature of the facilities, goods and services **will vary depending on numerous factors**, including the State party's developmental level."
    - **Accessibility**: including four dimensions of non-discrimination, physical accessibility, economic accessibility (affordability), information accessibility
    - **Acceptability**: "be respectful of medical ethics and culturally appropriate, i.e. respectful of the culture of individuals, minorities, peoples and communities"
    - **Quality**: "be **scientifically and medically appropriate** and of good quality. This requires, inter alia, skilled medical personnel, scientifically approved and unexpired drugs and hospital equipment, safe and potable water, and adequate sanitation"

Source: Covenant on Economic, Social and Cultural Rights, General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12), Committee on Economic, Social and Cultural Rights, 11 August 2000. | Cf. also Council Conclusions on Access to medicines and medical devices for a Stronger and Resilient EU, OJ 2021 CI 269/3, on the "trinity of **Accessibility, Availability, Affordability** of medicines and medical devices"

High level of health | EU

High level of health protection

- "high level of **human health**" (Art 9 TFEU; Art 114 para 3 TFEU; Art 168 para 1 TFEU; Dec No 32; Art 35 CFR)
- "high level of protection, taking account in particular of any **new development based on scientific facts**" (Art 114 para 3 TFEU), since Amsterdam Treaty (Frischhut, 2017, 70)
- High, although **not highest** level (Frischhut, 2017, 66-66); Secondary law to be interpreted in this light (Frischhut, 2017, 64)

High level of health and precedence over economic considerations

- "In accordance with settled case-law, the objective of the protection of **health takes precedence over economic considerations**, the importance of that objective being such as to **justify even substantial negative economic consequences** […]" (ECJ, C-452/20, para 50)

High level approach elsewhere

- Harmonisation of national law | environment | employment | education and training | Area of Freedom Security and Justice | consumer protection | services of general interest

Sources:

- Frischhut, M. (2017). Standards on quality and safety in cross-border healthcare. In A. d. Exter (Ed.), *Cross-border health care and European Union law* (pp. 59-86). Erasmus University Press.
- ECJ judgment of 24 February 2022, *Agenzia delle dogane e dei monopoli und Ministero dell'Economia e delle Finanze*, C-452/20, EU:C:2022:111

Right to healthcare | Council of Europe

- **Oviedo Convention (Link)**
  - Article 3 – Equitable access to health care
    "Parties, taking into account health needs and available resources, shall take appropriate measures with a view to providing, within their jurisdiction, equitable access to **health care of appropriate quality**."

  - Explanatory Report to the Oviedo Convention (Link)
    - "This care must be of a fitting standard **in the light of scientific progress** and be subject to a **continuous quality assessment**." (pt. 24)
    - "The Parties to the Convention are required to take appropriate steps to achieve this aim as far **as the available resources permit**. The purpose of this provision is **not** to create an **individual right** on which each person may rely in legal proceedings against the State, but rather to prompt the latter to adopt the requisite measures as part of its social policy in order to ensure equitable access to health care." (pt. 26)
  - Oviedo convention as **living instrument** (Lwoff, 2020, 336)

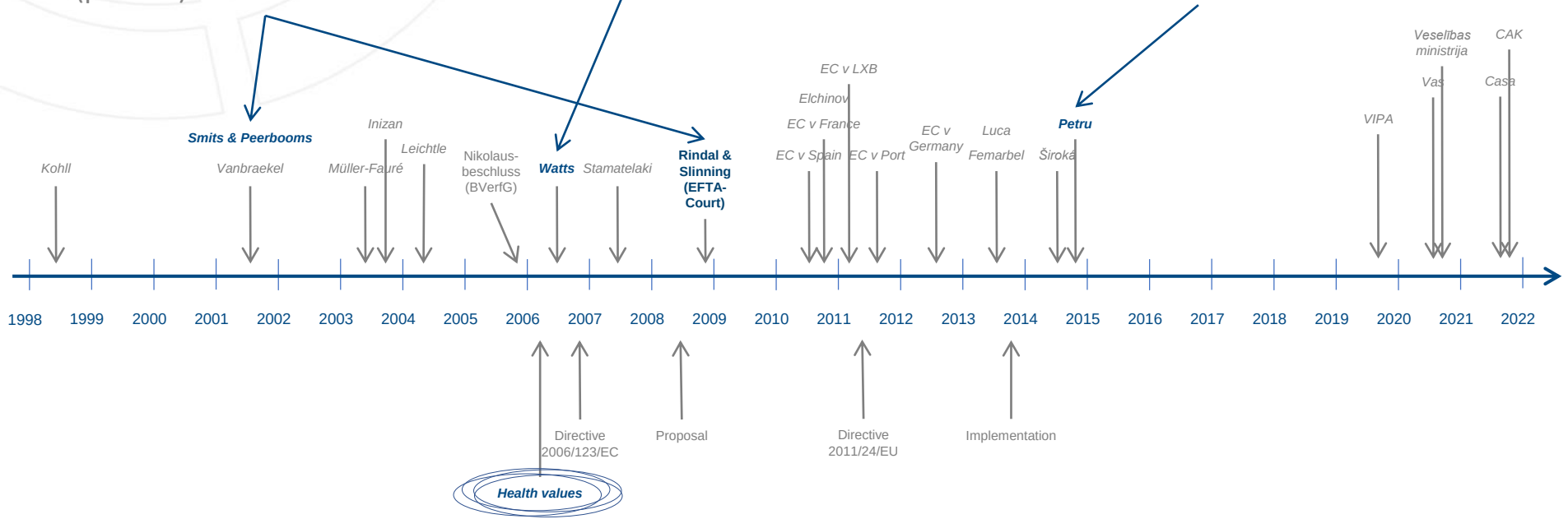
Cf. Lwoff, L. (2020). New Technologies, New Challenges for Human Rights? The Work of the Council of Europe. *European Journal of Health Law*, *27*(3), 335–344. https://doi.org/10.1163/15718093-BJA10007

Quality in ECJ case-law

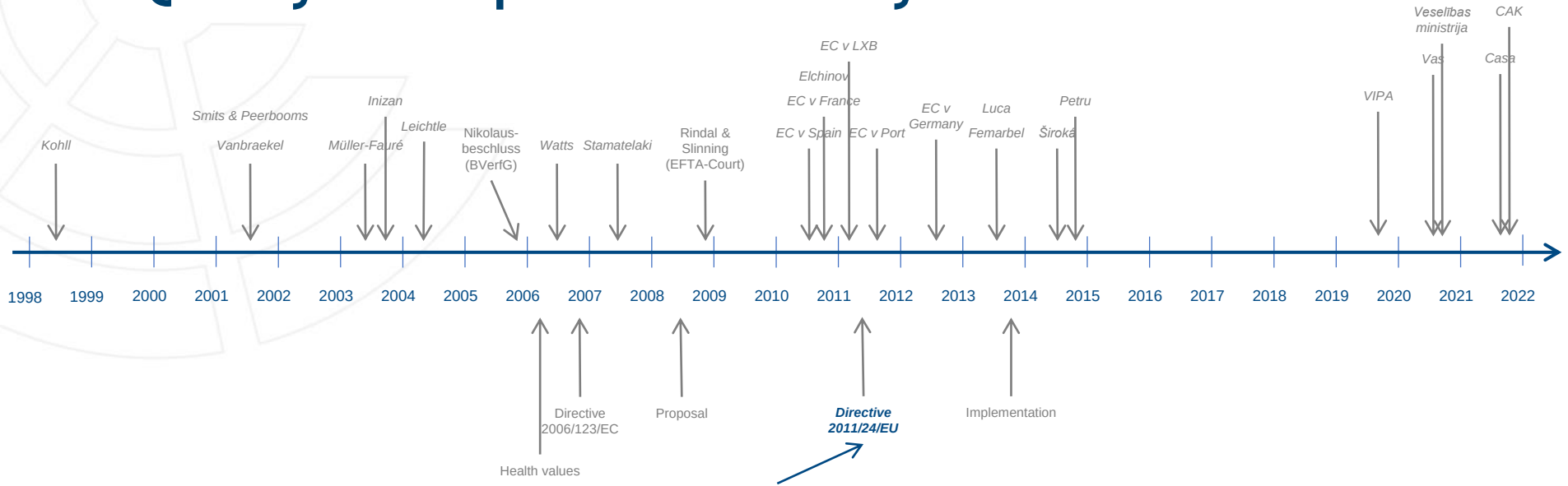
- "the state of **international medical science** and **medical standards**" (para 92)
- "sufficiently tried and tested" (para 94)

Waiting lists: **individual** patient's situation maters (para 119)

- **rejecting the idea** of the Advocate General that in case of "structural and prolonged **deficiencies** [**of resources**, the Reg. would not require] Member States to authorise a service" (paras 28-33)
- Prior authorisation "cannot be refused where it is because of a lack of medication and basic medical supplies and infrastructure" (para 36)



Quality in EU patient mobility directive

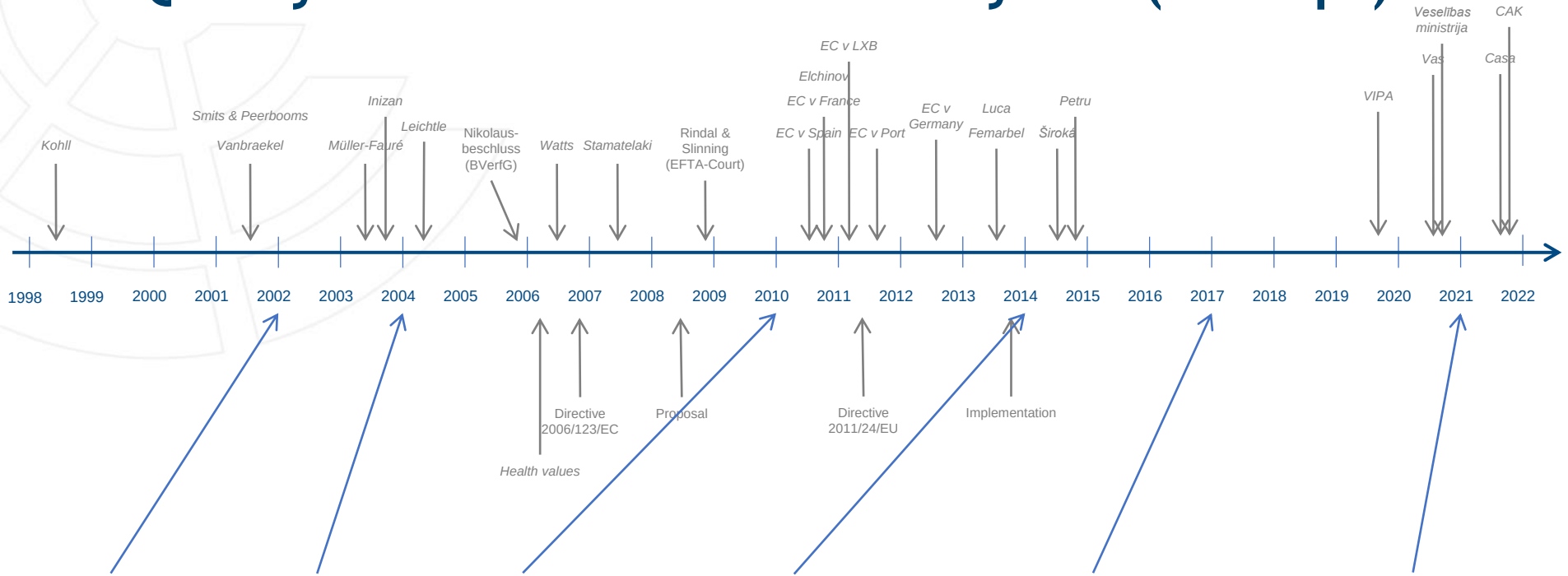


- The **aim** of this Directive is "to establish rules for facilitating access to **safe and high-quality** cross-border healthcare in the Union" (recital 10; see also recital 64 and Art 1 para 1)
- Reference to **health values**; although (only) addressed as 'principles' (Art 4 para 1)
- **Member State of treatment** in charge of quality of care (Art 4)
- Quality concerns with regard to **patient, general public and provider** (Frischhut, 2017, 78)
- Art 10 'Mutual assistance and **cooperation**', incl. "on standards and guidelines on quality and safety" | Art 15 **HTA**

Regulation (EU) 2021/2282 on **health technology assessment [HTA]** and amending Directive 2011/24/EU

Source: Frischhut, M. (2017). Standards on quality and safety in cross-border healthcare. In A. d. Exter (Ed.), *Cross-border health care and European Union law* (pp. 59-86). Erasmus University Press.

Quality in EU other EU secondary law (excerpt)



Directive 2002/98/EC quality and safety **blood** etc.

Directive 2004/23/EC quality and safety **tissues and cells** etc.

Directive 2010/53/EU quality and safety **human organs**

Council conclusions **patient safety and quality of care** etc.

Regulation (EU) 2017/745 on **medical devices** etc.

Regulation (EU) 2021/2282 on **health technology assessment [HTA]** and amending Directive 2011/24/EU

Quality in EU | blood, tissues, organs

- **Similarities of three directives**
  - Only **minimum harmonization**: Organs Art 31 para 2; T&C Art 4 para 2; Blood Art 4 para 2
  - **Quality and safety related rules**: competent authorities; designation, authorization, accreditation or licensing of an establishment, etc.; qualification and training of responsible persons and personnel; inspections and controls; quality management: documentation, record keeping, framework for quality and safety, reporting systems; traceability (cf. Frischhut, 2017, 83)
- **High vs highest level**
  - Basically all three Directives refer to **high** standards of quality and safety
  - The T&C Directive tasks the EU to "promote the **highest possible** level of protection" (recital 5) and also the Organs Directive refers to the "**highest possible** protection of living donors" when requiring Member States to take all necessary measures in order to fully guarantee the quality and safety of organs for transplantation (Art 15 para 1; cf. also Frischhut, 2017, 82)

Cf. Frischhut, M. (2017). Standards on quality and safety in cross-border healthcare. In A. d. Exter (Ed.), *Cross-border health care and European Union law* (pp. 59-86). Erasmus University Press.

Quality in EU | medical devices

- **Objective:** “**high level of protection** of health for patients and users” (recital 2)
- **Manufacturers etc.**
  - ‘**Quality management** system’ as ‘**general obligations** of manufacturers’ (Art 10), also for ‘post-market surveillance system of the manufacturer’ (Art 83)
  - Requirements for ‘**person responsible** for regulatory compliance’ (Art 15)
  - Cf. Annex IX ‘Conformity assessment based on **quality management system** & assessment of technical documentation’; Annex XI ‘Conformity assessment based on **product conformity verification**’
- **Notified bodies** (assess the conformity of medium- and high-risk medical devices; Art 35ff) **& risk based approach**
  - Have to fulfil high-quality standards and must have the required competences, resources and staff for their tasks
  - Cf. Annex VII ‘Requirements to be met by **notified bodies**’: pt. 2: quality management requirements; pt. 4.5.2. ‘Quality management system auditing’
- **Other**: traceability, cf. UDI (Art 25ff), incident reporting (Art 87ff), Eudamed (Art 33), etc.

Directive 2002/98/EC quality and safety blood etc.

Directive 2004/23/EC quality and safety tissues and cells etc.

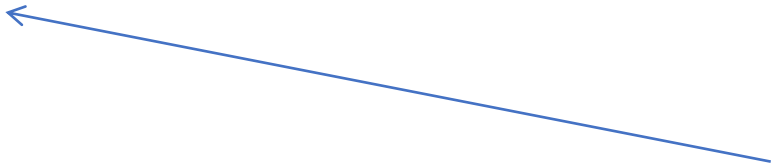
Directive 2010/53/EU quality and safety human organs

Regulation (EU) 2017/745 on **medical devices** etc. Delayed date(s) of application due to Corona, Regulation (EU) 2020/561 (Link)

Regulation (EU) 2021/2282 on health technology assessment [HTA] and amending Directive 2011/24/EU

Quality in EU | HTA

- **High quality**
  - "Joint work […] should aim to achieve the **highest level of quality, transparency and independence**." (recital 12)
  - Objective to guarantee the "**highest quality** of joint clinical assessments" (recital 16); "the joint work carried out under this Regulation, in particular the joint clinical assessments, should aim to produce **high-quality and timely results** […]" (recital 38)
  - Joint clinical assessments: "of **high quality and based on the best scientific evidence available** at any given time" (recital 19)
  - "ensure that joint work is of the highest **scientific quality** and reflects the **state of the art**" (recital 45; cf. also Art 4)
  - "The Coordination Group should develop methodological guidance on the joint work provided for in this Regulation, following international standards of evidence-based medicine. The assessment process should rely on relevant, up-to-date and high quality clinical evidence." (recital 48)



Directive 2002/98/EC quality and safety blood etc.

Directive 2004/23/EC quality and safety tissues and cells etc.

Directive 2010/53/EU quality and safety human organs

Regulation (EU) 2017/745 on medical devices etc.

Regulation (EU) 2021/2282 on **health technology assessment [HTA]** and amending Directive 2011/24/EU

Quality in EU | HTA

- **HTA**
  - Objective: “high level of health protection” (recital 11)
  - Definition: “Health technology assessment (HTA) is a **scientific evidence-based** process that allows competent authorities to determine the **relative effectiveness** of **new or [!] existing** health technologies. HTA focuses specifically on the **added value** of a health technology in comparison with other new or existing health technologies” (recital 2)
- **Quality assurance (Art 4)**
  - The “Coordination Group shall ensure that the joint work […] is of the **highest quality**, follows **international standards of evidence-based medicine**, and is delivered in a timely manner” (para 1)
  - Obligation to “regularly review, and where necessary update, methodological and procedural guidance” (para 3)
- **Identification of emerging health technologies (Art 22)**
  - “emerging health technologies expected to have a major impact on **patients**, **public health** or healthcare **systems**”; “address the estimated clinical impact and the potential **organisational and financial consequences** of emerging health technologies for national healthcare **systems**” (para 1)

Directive 2002/98/EC quality and safety blood etc.

Directive 2004/23/EC quality and safety tissues and cells etc.

Directive 2010/53/EU quality and safety human organs

Regulation (EU) 2017/745 on medical devices etc.

Regulation (EU) 2021/2282 on **health technology assessment [HTA]** and amending Directive 2011/24/EU
“shall apply from 12 January 2025” (Art 36[2])

Interim summary | overview

1. Health systems: effective (incl. quality), accessible, resilient (EC 2014)
2. Health providers: addressed mainly in terms of training for quality
3. **Patients**

Right to health: high level (EU), highest attainable (GC14)

… also available, accessible, acceptable (GC 14)

Quality in health

- Individual patient's perspective and international state of the art (ECJ), MST (Dir)
- Health care of appropriate quality (Art 3 OC)
- Safe, effective, efficient, patient-centred, timely and equitable (Henriette)
- Indirect approach: via rule on competent authorities (blood, tissues, organs)
- QM system as manufacturers' obligation; notified bodies (MedDev Reg)
- Quality assurance (HTA Reg)

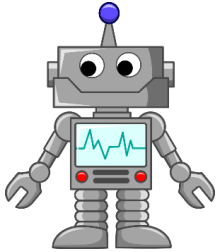
Safety

- Quality as a health value and also operating principle (2006)

Reliable care:

- "**human decisions** should be reliable and accurate" (AI Reg prop [*see below*], recital 28)
- "**provision of medicinal products** to the public is reliable and of good quality" (C-570/07, Blanco Pérez, para 64)

Digitalization | excerpt



Picture source: Link

Picture source: Link

> **16 February 2017** | European Parliament resolution of 16 February 2017 with recommendations to the Commission on **Civil Law Rules on Robotics** (2015/2103(INL)) | Link

> **9 March 2018** | European Group on Ethics in Science and New Technologies (**EGE**) "Statement on Artificial Intelligence, Robotics and 'Autonomous' Systems"| Link

> **25 April 2018** | European Commission (EC) AI **strategy** | COM(2018) 237 final; plus SWD(2018) 137 final on liability

> **11 February 2019** | Council Conclusions on the **coordinated plan** on artificial intelligence | Doc. 6177/19

> **12 February 2019** | EP A comprehensive European industrial policy on **artificial intelligence and robotics** (2018/2088(INI)) | Link

> **8 April 2019** | AI HLEG publishes "**Ethics guidelines** for trustworthy AI", **including** "Trustworthy AI Assessment **List**" (pp. 26-31), as well as glossary (pp. 36-38) | Link, and definition (Link)

> **19 February 2020** | **EC** White paper on AI, report on safety, strategy for data, Europe's digital future, etc.

> **15 December 2020** | EC **Proposal** on a Single Market For Digital Services (**Digital Services Act**) and amending Directive 2000/31/EC, COM(2020) 825 final | Link

> **21 April 2021** | EC **Proposal** for a **Regulation** on a European approach for **Artificial Intelligence**, COM(2021) 206 final | Link (see also COM(2021) 205 final, Link)

> **21 April 2021** | EC **Proposal** for a **Regulation** on **machinery products**, COM(2021) 202 final | Link

> **26 January 2022** | EC European **Declaration on Digital Rights** and Principles for the Digital Decade, COM(2022) 27 final (Link) & COM(2022) 28 final (Link)

> **2 February 2022** | EC Communication An EU **Strategy on Standardisation**. Setting global standards in support of a resilient, green and digital EU single market, COM(2022) 31 final (Link)

Digitalization | EP res civil liability

- **Medical robots**
  - **Likewise importance of training, also minimum level approach**:
    "Underlines the importance of appropriate **education, training and preparation** for health professionals, such as doctors and care assistants, in order to secure the **highest degree** of professional competence possible, as well as to **safeguard and protect patients' health**; underlines the need to define the **minimum** professional requirements that a surgeon must meet in order to operate and be allowed to use surgical robots; considers it vital to respect the principle of the supervised autonomy of robots, whereby the initial planning of treatment and the **final decision** regarding its execution will always remain **with a human** surgeon;" (pt. 33)
  - **Reference to bioethical principles ('principlism'), values and human rights**:
    "the guiding ethical framework should be based on the **principles of beneficence, non-maleficence, autonomy and justice**, on the principles and **values** [cf. Art 2 TEU and CFR], **such as** human dignity, equality, justice and equity, non-discrimination, **informed consent**, private and family life and **data protection**, as well as on other underlying principles and values of the Union law, such as **non-stigmatisation**, **transparency**, **autonomy**, **individual responsibility** and **social responsibility**, and on existing ethical practices and codes" (pt. 13)

> **16 February 2017** | European Parliament resolution of 16 February 2017 with recommendations to the Commission on **Civil Law Rules on Robotics** (2015/2103(INL)) | Link

Digitalization | safety and liability

- **Quite some legislation already in place (status quo); however, also necessity of constant re-evaluation**
  - Overview: horizontal and sectoral approach
    - Directive 85/374/EEC on **product liability** (Link)
    - Directive 2001/95/EC on **general product safety** (Link)
    - Directive 2006/42/EC on **machinery** [etc.] (Link) | N.B. To be amended by COM(2021) 202 final 21.4.2021 (Link)
    - Regulation (EC) No 765/2008 on accreditation and **market surveillance** of products (Link) [CE labelling]; see also: Decision No 768/2008/EC on a **common framework** for the marketing of products (Link); Regulation (EU) 2019/1020 on market surveillance **& compliance** of products (Link)
    - Directive 2014/32/EU on **measuring instruments** (Link)
    - Directive 2014/53/EU on **radio equipment** (Link)
  - Existing product safety framework is **technology neutral**, hence also applies to products incorporating these technologies; other provisions such as on medical devices have already considered these new issues (p. 4)
  - **Necessity of adaptation of EU legislation**
    - e.g. "to consider requirements for transparency of **algorithms**, as well as for robustness, accountability and when relevant, human oversight and unbiased outcomes, particularly important for the ex-post mechanism of enforcement and to build trust in the use of those technologies" (p. 9)
    - "While in principle the existing Union and national **liability** laws are able to cope with emerging technologies, the dimension and combined effect of the challenges of AI could make it more difficult to offer victims **compensation** in all cases where this would be justified" (p. 17)

> **19 February 2020** | **EC** Report on the **safety and liability** implications of Artificial Intelligence, the Internet of Things and robotics, COM(2020) 64 final (Link)

Digitalization | safety and liability

- **Various (technical) challenges, but also emphasising vulnerability and principles**
  - Physical and mental wellbeing: necessity to take into account situation especially of **vulnerable people** (p. 8)
  - **Connectivity** (as such, also in case of a loss of); **cybersecurity**; bad data; **opacity** ('black box-effect')
  - **Complexity** (especially in case of interconnection with other devices): covered in Regulation medical devices and (to some extent) in Directive general product safety
  - **Software**:
    - **Safety**: more necessity of adaption in case of **stand-alone** software (less for software integrated in a product)
    - **Liability**: despite broad definition of product, necessity to **clarify scope** so that compensation is always available for damage caused by products that are defective because of software or other digital features
  - Complex **value chains** (mainly producer, but also imposing obligations to several economic operators; principle of "shared responsibility")
- **Principles**
  - transparency, robustness, accountability, human oversight and unbiased outcomes (p. 9)

> **19 February 2020** | **EC** Report on the **safety and liability** implications of Artificial Intelligence, the Internet of Things and robotics, COM(2020) 64 final (Link)

Digitalization | proposal Reg AI | summary

- **In a nutshell**
  - Emphasising **health, safety and fundamental rights** as main objectives; high level of health (recital 1, etc.)
  - **Risk** based approach
    - Prohibited: Art 5 (manipulation; vulnerable; rating of humans; biometrical real-time distance tracking)
    - High-risk (Annex III): Art 6 ff (Art 9: risk management system; Art 10: data and data governance; Art 11: technical documentation)
    - **Relation to other EU Secondary law**: classification of high-risk in AI does not necessarily lead to classification as high risk in other fields, such as medical devices and in vitro diagnostic medical devices (recital 31)
- **Quality**
  - Mainly refers to 'high quality **data**' (recitals 38, 42-45; for more details, see Art 10 'Data and data governance')
  - In relation to '**intended purpose**': "Training, validation and testing data sets should be sufficiently relevant, representative and free of errors and complete in view of the **intended purpose** of the system." (recital 44, etc.)
  - **Provider** has to establish "a sound **quality management system**"; plus "required conformity assessment procedure", relevant documentation and "robust post-market monitoring system" (recital 54; see also Art 16 lit a i.c.w. Art 17 [details] and Annex VI [and conformity assessment procedure])

> **21 April 2021** | EC **Proposal** for a **Regulation** on a European approach for **Artificial Intelligence**, COM(2021) 206 final | Link (see also COM(2021) 205 final, Link)

Digitalization | proposal Reg AI | health

- **Health related issues: health of humans and humans first | access to innovation**
  - **Health and safety of persons**: safety in case of products including AI; also with regard to **autonomous robots**, whether in the context of manufacturing or personal assistance and care; “in the **health sector** where the stakes for life and health are particularly high, increasingly sophisticated **diagnostics** systems and systems supporting human decisions should be **reliable and accurate**” (recital 28)
  - **Health as an argument the other way round**: if rapid **availability of innovative technologies** necessary, authorisation of placing on the market **without conformity assessment** can be possible (recital 68; cf. Art 43 and Art 47[1])
  - **Human oversight**: “Human oversight shall aim at **preventing or minimising the risks to health**, safety or fundamental rights that may emerge when a **high-risk AI system** is used in accordance with its **intended purpose** or under conditions of reasonably foreseeable misuse […]” (Art 14[2])
  - **AI regulatory sandboxes**: “Any significant **risks to health and safety and fundamental rights** identified during the **development** and **testing** of such systems shall result in **immediate mitigation** and, failing that, in the **suspension** of the development and testing process until such mitigation takes place.” (Art 53[3])

> **21 April 2021** | EC **Proposal** for a **Regulation** on a European approach for **Artificial Intelligence**, COM(2021) 206 final | Link (see also COM(2021) 205 final, Link)

Digitalization | proposal Reg AI | values etc.

- **Values matter | trustworthy AI | again, protection of vulnerable persons**
  - "[…] Regulation supports the **objective** of the Union of being a **global leader** in the development of **secure, trustworthy and ethical artificial intelligence**, as stated by the European Council[33] , and it ensures the protection of **ethical principles**, as specifically requested by the European Parliament [34]." (recital 5)
  - "artificial intelligence in conformity with Union values" (recital 1)
  - "AI systems providing social **scoring** of natural persons for general purpose by public authorities or on their behalf may lead to **discriminatory** outcomes and the exclusion of certain groups. They may **violate the right to dignity** and **non-discrimination** and the **values of equality and justice**." (recital 17)
  - **Vulnerable persons**: **children** (recitals 16 and 28); natural persons applying for or receiving **public assistance benefits** and services from public authorities (recital 37); **migration** (recital 39); **AI systems themselves** in context of cybersecurity (recital 51, Art 15[4]); "group of persons due to their **age, physical or mental disability**" (Art 5 [1] lit b); "potentially harmed or adversely impacted persons are in a vulnerable position in relation to the user of an AI system, in particular due to an **imbalance of power, knowledge, economic or social circumstances, or age**" (Art 7[2] lit f)

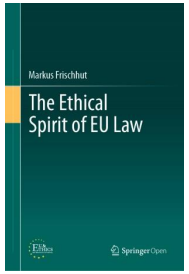
> **21 April 2021** | EC **Proposal** for a **Regulation** on a European approach for **Artificial Intelligence**, COM(2021) 206 final | Link (see also COM(2021) 205 final, Link)

Digitalization | machinery products

- **Quality, similar approach for machinery products | i.e. not focussing directly on humans' health**
  - **Quality and conformity assessment** (Art 21 and Annex IX, 'module H')
    - Declaration based on the **sole responsibility** of the manufacturer (pt. 1); has to operate an approved **quality system** (pt. 2)
    - **Quality system**: "application for assessment of his or her quality system with the notified body of his or her choice" (pt. 3.1)
    - **Surveillance**: "purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system" (pt. 4.1); "notified body may pay **unexpected visits** to the manufacturer" (pt. 4.4)
    - **Conformity marking and declaration of conformity** (pt. 5)
    - Relation to (proposed) AI Regulation: combined, then machinery regulation only for safe integration into the overall machinery (Art 9)
    - Annex III, health and safety requirements: manufacturer (etc.) has to "ensure that a risk assessment is carried out in order to determine the **health and safety requirement**" (pt. 1)
- **Risk based approach**
  - **Emphasising health and safety requirements** (132 hits); Regulation instead of Directive (recital 4)
  - High risk according to Annex I: software and machines in the field of AI (pts. 24-25)
  - List of high risk machinery, cf. also Annex I Directive 2006/42 (recital 45; Art 5 and Annex I)
  - **Presumption of conformity** (Art 17), cf. Regulation 1025/2012 (Link) | N.B. mentioned in strategy standardisation (Link) and in ECJ case C-613/14, *James Elliott Construction*, para 40; mentioned there in Chapter III

> **21 April 2021** | EC **Proposal** for a **Regulation** on **machinery products**, COM(2021) 202 final | Link

EU values, principles & ethics (excerpt)



Trust (as an overreaching goal)

General field | *Health field (additionally)*

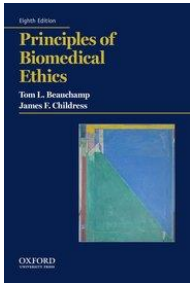
more abstract

Common values (Art 2 TEU):

- human dignity, freedom, democracy, equality, the rule of law and respect for human rights, including minority rights
- pluralism, non-discrimination, tolerance, justice, solidarity and equality between women and men

Health values (2006): universality, access to good quality care, equity, and solidarity

more concrete



Beauchamp, T. L., & Childress, J. F. (2019). *Principles of biomedical ethics* (Eighth edition). Oxford University Press.

principles of biomedical ethics':

- respect for autonomy
- nonmaleficence
- beneficence
- justice

legal principles:

- non-discrimination
- privacy
- traceability
- transparency
- responsibility
- proportionality & balance
- precaution
- solidarity

Operating principles (2006): quality, safety, care that is based on evidence and ethics, patient involvement, redress, privacy and confidentiality

(other) **law as minimum standard** (e.g. above-mentioned EU Secondary Law)

Cf. Frischhut, M. (2020). EU Values and Ethical Principles for AI and Robotics with Special Consideration of the Health Sector. In M. Hengstschläger & Austrian Council for Research and Technology Development (Eds.), *Digital Transformation and Ethics* (pp. 244-274). Ecowin. | Frischhut, M. (2019). *The Ethical Spirit of EU Law*. Cham: Springer International Publishing. On principles and fast-paced technological change, see also Sethi, N. (2021). Rules, Principles and the Added Value of Best Practice in Health Research Regulation. In G. Laurie, E. Dove, A. Ganguli-Mitra, C. McMillan, E. Postan, N. Sethi, & A. Sorbie (Eds.), *The Cambridge Handbook of Health Research Regulation* (pp. 167-176). Cambridge University Press. https://doi.org/10.1017/9781108620024.021

From animal welfare to health as a value

- Judgment of 17.12.2020, C-336/19, *Centraal Israëlitisch Consistorie van België and Others* (GC) | **no animal slaughter without stunning (and reversible stunning)** | Belgium
  - 1. EU values **outside Art 2 TEU** (i.e. Art 13 TFEU) | mentioned in Regulation, accepted by Court (in this 3rd case)
  - 2. Values **entitling** not humans, but **animals**
  - 3. Balancing between various values at **national** level
  - 4. Charter as **living instrument**, changes in "values and ideas", concerning society and legislation
- Evolution:
  - In Jippes "the Court declined the invitation to recognize animal welfare as a general principle of law" (Tridimas, 2006, p. 27, with further references)
- 'One health' & 'planetary health':
  - "In its most comprehensive form, [the **One Health** approach] extends to fostering the health of **humans**, **animals** and their shared **environments**" | "The OH approach to disease is grounded in a well-established scientific fact: that the health of humans, animals and the environment are **interdependent**." (c.f. Johnson & Degeling, 2019, p. 239)
  - E.g. in the field of AMR: "maximise coordinated efforts between the human health sector and the veterinary sector in the fight against AMR" (OJ 2012 C 211/2, pt. 13; see also OJ 2016 C 269/26)
  - "**Planetary health** is grounded in the understanding that the achievement of the highest attainable standard of health is dependent on the flourishing of the natural environment, recognizing that many impacts on human health directly arise from human-caused disruptions to the Earth's natural systems" (Phelan, 2020, p. 433)

Sources: Johnson, J., & Degeling, C. (2019). Does One Health require a novel ethical framework? *Journal of Medical Ethics*, *45*(4), 239-243. https://doi.org/10.1136/medethics-2018-105043. | Phelan, A. (2020). The Environment, a Changing Climate, and Planetary Health. In L. O. Gostin & B. M. Meier (Eds.), Foundations of Global Health & Human Rights (417-438). Oxford University Press. | Tridimas, T. (2006). *The General Principles of EU Law* (2nd edition). Oxford University Press.

Vulnerable persons and inclusivity

- Vulnerability: "the human capability of being wounded, either physically or mentally" (Andorno, 2016, p. 258)
  - "In human rights discourse, for instance, the term vulnerability is used to indicate a **heightened susceptibility** of certain individuals or groups **to being harmed or wronged** by others or by the state. Populations which are particularly prone to being harmed, exploited or discriminated include, **among others**, children, women, older people, people with disabilities, and members of ethnic or religious minority groups." (Andorno, 2016, p. 258)
- Inclusivity according to the **Oxford Dictionary**
  - Inclusive: "**no excluding** any section or society or any party involved in something" (Stevenson, 2010, p. 884)
  - Inclusivism: "the practice of **trying to incorporate diverse** or unreconciled elements into a single system" (Stevenson, 2010, p. 885)
- Solidarity and inclusivity
  - "**Solidarity** however becomes a very thin concept if we only apply it to those who are very much like us and if it comes with conditions and negotiations. It is most potent and meaningful when it extends unreservedly also to those who are different. It is more important than ever in this difficult time to uphold a **form of solidarity that is inclusive** of everyone, which recognises that respect is due to everyone, and not exclusive to those that live in our own town, region, or country." (EGE, 2020)

Source:

- European Group on Ethics in Science and New Technologies. (2020, April 2). *EGE Statement on European solidarity and the protection of fundamental rights in the COVID-19 pandemic.*
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Leave no one behind

- In the EU, this concept (also known from the UN 2030 Agenda) can be found in the Green Deal, in the field of **digitalisation**, health, development policy, and migration, to name but a few.
  - EC 'The European **Green Deal**', COM(2019) 640 final 11.12.2019, p. 4 ("guide action in ensuring that no one is left behind"); EC 'A Farm to Fork Strategy: for a fair, healthy and environmentally-friendly food system', COM(2020) 381 final 20.5.2020.
  - EC '**Artificial Intelligence** for Europe', COM(2018) 237 final 25.4.2018, p. 2 ("No one is left behind in the digital transformation"); EC '2030 Digital Compass: the European way for the Digital Decade', COM(2021) 118 final 9.3.2021, p. 2 ("The European vision for 2030 is a digital society where no-one is left behind").
  - EP resolution of 24 November 2021 on a **pharmaceutical strategy** for Europe (2021/2013(INI)), https://www.europarl.europa.eu/doceo/document/TA-9-2021-0470_EN.html, pt. 4 ("ensure that no patient is left behind").
  - EP resolution of 14 February 2017 on the revision of the European Consensus on **Development** (2016/2094(INI)), OJ 2018 C 252/62, pt. 24 ("the principle of leaving no-one behind").
  - EP resolution of 25 October 2016 on **human rights and migration** in third countries (2015/2316(INI)), OJ 2018 C 215/111, pt. 70 ("the 'leave no one behind' principle").
  - EC European **Declaration on Digital Rights** and Principles for the Digital Decade, COM(2022) 27 final 26 January 2022 (Link), promote inclusion and leave no one behind | see also COM(2022) 28 final (Link)

Cf. Frischhut, M. (2022, forthcoming). *The ethical spirit of EU values*. Cham: Springer International Publishing.

Summary (status quo ...)

- While the topic of AI and other **new technologies** is broader (both in terms of technology and law), it also affects **healthcare**.
- Quality of care relates to health **systems** (effective, resilient, etc.), **providers** (quality management), and **patients** (GC14 right to health).
- In the latter field, ECJ case-law emphasises the necessity to take into account the '**international state-of-the-art**' and the EU patient-mobility directive assigns the competence in this respect to the Member **State of treatment**.
- Existing rules (e.g., blood, tissues, organs) follow a **minimum harmonization** approach, focusing on **quality management** systems (e.g., medical devices, proposed AI and machinery Reg.) and **high quality** (e.g., HTA).
- These existing rules on safety and liability apply to new technologies, although in some fields need to be **adapted** (e.g., in case of algorithms).
- As mentioned by Brownsword, "new technologies should not present unacceptable risks to the legitimate interests of humans" (2021, 274).

Source: Brownsword, R. (2021). Regulating Automated Healthcare and Research Technologies. In G. Laurie, E. Dove, A. Ganguli-Mitra, C. McMillan, E. Postan, N. Sethi, & A. Sorbie (Eds.), *The Cambridge Handbook of Health Research Regulation* (pp. 266–274). Cambridge University Press. https://doi.org/10.1017/9781108620024.033.

Summary (… and outlook)

- The proposed AI Regulation, like the existing one on medical devices, take(s) a **risk-based approach** (cf. Giovanni & Dunn, 2022; Palmieri, Walraet, & Goffin, 2021), and in terms of quality mainly focuses on **quality of data**.
- Although the concept of '**quality**' in itself is only a **relative** concept (meeting certain requirements), I argue that against the concept of a 'high level' of healthcare, **values and (ethical) principles** have to be taken into account to strive for safe, reliable and trustworthy healthcare. In this context, **health** can also be seen **as a value**, protecting the vulnerable and leaving no one behind (**equity and inclusivity**; see also EAHL Interest Group on Supranational Biolaw, Joint Statement). The same holds true for the narrower concept of '**safety**'.
- Consequently, in this context EU law focuses on **safe and reliable** products (and services), but **not** (so much) **directly** on patients (see also Kolfschooten, 2022, 102).

Source: Giovanni, D. G., & Dunn, P. (2022). The European risk-based approaches: Connecting constitutional dots in the digital age. *Common Market Law Review, 59*(2), 473–500.

Source: Palmieri, S., Walraet, P., & Goffin, T. (2021). Inevitable Influences: AI-Based Medical Devices at the Intersection of Medical Devices Regulation and the Proposal for AI Regulation. *European Journal of Health Law, 28*(4), 341–358. https://doi.org/10.1163/15718093-bja10053.

Source: EAHL Interest Group on Supranational Biolaw. (2022). *Joint Statement 'Health as a fundamental value. Towards an inclusive and equitable pharmaceutical strategy for the European Union'*. https://eahl.eu/eahl-interest-group-supranational-biolaw. See also: Gennet, É. (2020). Introducing 'Health Vulnerability': Towards a Human Right Claim for Innovative Orphan Drugs? *European Journal of Health Law, 27*(3), 290–307. https://doi.org/10.1163/15718093-BJA10005

Source: van Kolfschooten, H. (2022). EU regulation of artificial intelligence: Challenges for patients' rights. *Common Market Law Review, 59*(1), 81–112.

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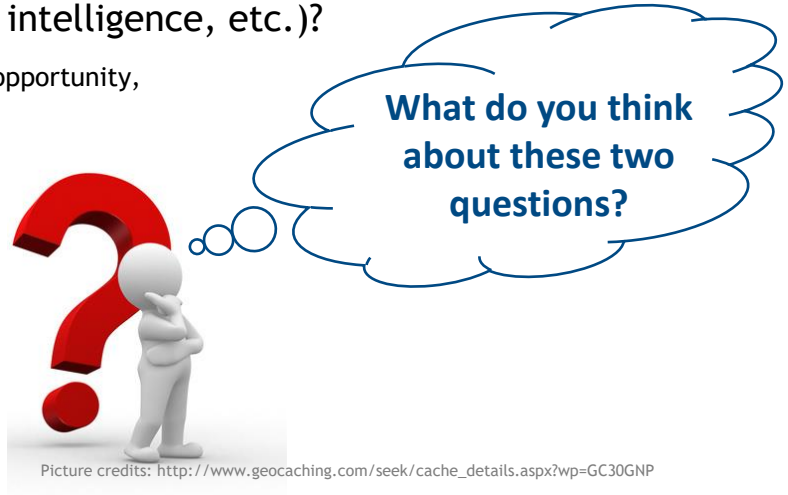
Q&A

- Based on similar discussions in EU patient mobility, should quality in case of ‘new health technologies’ be measured rather in terms of **resources or outcome**?
- Are similar quality-related standards as in **offline** situations (continuous training, best practice, monitoring, etc.) also enough for **online** situations (artificial intelligence, etc.)?
  - Cf. avoiding bias in AI systems: unclear “whether the benchmark will be equality in opportunity, or equality in outcomes” (EG IG Supranational Biolaw, 2022)
  - Resources or outcome (Frischhut, 2017, 74; Frischhut & Fahy, 2016, 52-53)
  - Patient’s perspective (Watts, waiting lists) vs. resources (*Petru*) (Frischhut, 2017,85)



Picture credits: http://www.geocaching.com/seek/cache_details.aspx?wp=GC30GNP

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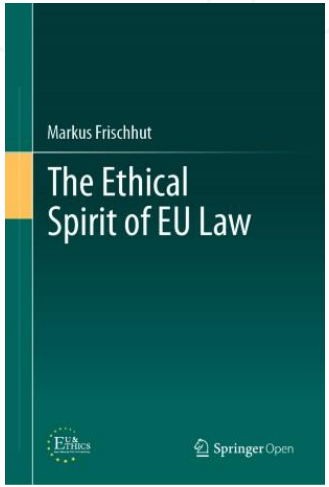

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