



EU External/global health law EU trade law and health

- EU development law and health
- EU external health security law



Health products

- Medicines: orphan; paediatric; advanced therapy; clinical trials; marketing authorisation; manufacturing and batch control; packaging and labelling; distribution; direct to consumer advertising; pharmacovigilance; pricing (transparency, HTA, parallel trade, IP)
- Medical devices: certification; risk management; obligations of economic operators; novel medical devices
- Joint procurement
- Product liability
- Veterinary medicine



Life-style products

- Tobacco as health threat
- Alcohol as health threat
- Food



Life-style services: gambling as health threat



National health (institutions), affected by EU health law

- Fundamental freedoms (goods, establishment, services)
- Competition law (cartels & anti-competitive, monopolies, state aids, M&A, public procurement)

Substances of human origin (quality, safety, traceability, obligations of relevant organisations)

- Blood
- Human tissue and cells
- Human organ(s) (transplantation)



People/human beings

- Patients (EU and TCN)
- Health care professionals (mutual recognition, access, IMI, etc.)



(Other) public health issues

- Air quality
- Water quality
- Waste, etc.
- Cross border health threats (bioterrorism; communicable diseases; joint procurement)

Health data



- Health data for (non-) health purposes
- European Health Data Space
- EU public health databases



EU health bodies: EMA, ECDC, HERA, EFSA, Drug monitoring

People/human beings



- Patients
 - EU patients: Regulation 883/2004, Art 56 TFEU, Directive 2011/24
 - Cross-border prescriptions
 - Third country nationals
- Health care professionals
 - Mutual recognition of qualification
 - Access to medical education
 - Health professionals qualified outside EU
 - IMI alert system for health professionals

Substances of human origin (quality, safety, traceability, obligations of relevant organisations)



- Blood
- Human tissue and cells
- Human organ(s) (transplantation)

Health data



- Health data for health purposes
- Health data for non-health purposes
- European Health Data Space
- EU public health databases: EudraVigilance, EUDAMED, Clinical Trials database, EudraGMDP

National health (institutions), affected by EU health law: fundamental freedoms and competition law

- Free movement of goods affecting health institutions: product related and selling arrangements
- Freedom of establishment of health institutions: light, medium or strict scrutiny
- Freedom to provide services by health institutions: telemedicine, migrant professionals, health insurance
- Cartels & anti-competitive behaviour of health institutions
- Monopolies in health institutions
- State aids to health institutions
- Mergers & Acquisitions of health institutions
- Public procurement rules as applied to health



Health products

- Medicines
 - Orphan medicines
 - Paediatric medicines
 - Advanced therapy medicinal products
 - Clinical Trials
 - Marketing authorisation for medicinal: centralised, decentralised, generics and biosimilars
 - Manufacturing and batch control of medicines
 - Packaging and labelling of medicines
 - Distribution of medicines
 - (Direct to consumer) advertising of medicines
 - Pharmacovigilance
 - Medicines pricing: transparency of medicines pricing and reimbursement, health technology assessment, parallel trade in medicines, health products and IP
- Medical devices
 - Certification
 - Risk management: pre-market and post-market
 - Obligations of economic operators concerning medical devices
 - Novel medical devices: e.g. software, genetic tests, companion diagnostics, AI
- Joint procurement of health products: medicines & devices
- Product liability for medical harms
- Veterinary medicine



Life-style products

- Tobacco as health threat: composition, packaging and labelling, advertising, pricing
- Alcohol as health threat: production, advertising, pricing, labelling and health claims
- Food: composition, information / labelling, advertising, pricing



Life-style services: gambling as health threat



EU health bodies



- EMA
- ECDC
- HERA
- EFSA
- Drug monitoring

(Other) public health issues



- Air quality
- Water quality
- Waste etc.
- Cross border health threats (bioterrorism, communicable diseases)

EU External/global health law

- EU trade law and health: health conditionality in EU trade agreements, mutual recognition agreements with third countries in health products (essential medicines and other products including devices and equipment, import/export rules for medicines)
- EU development law and health
- EU external health security law



EU Health Law entries in tree form (showing hierarchical relationships)

People	Patients	Reg 883/2004	
		A 56 & Patients' Rights Dir	
		Cross-border prescriptions	
		TCN access to health care	
	Health care professionals	Mutual recognition (auto)	
		Mutual recognition	
		Access to medical education	
		Extra EU qualifications	
		IMI alert	
Substances of human origin	Blood	Traceability	
		Safety and Equality	
	Tissues and cells	Traceability	
		Safety	
	Organs (transplantation)	Traceability	
		Safety	
Data	Health data for health purposes	Health data in scientific research	
	Health data for non-health purposes		
	European Health Data Space		
	Public health databases		
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EU Health Law entries in tree form (showing hierarchical relationships)

Health products	Medicines	Orphan medicines	
		Paediatric medicines	
		Advanced therapy medicinal products	
		Clinical trials	Good clinical practice
			Clinical trial sponsor obligations
			Clinical trial authorisation
			Clinical trial ethical review
			Consent in clinical trials
			Clinical trial transparency
		Marketing authorisation	Centralised authorisation
			Decentralised authorisation
			Authorisation of generics & biosimilars
			Authorisation of herbal medicines
			Authorisation of homeopathic medicines
		Manufacturing & batch control	
		Packaging & labelling	
			Falsified medicines
		Distribution of medicines	
		Medicines advertising	
		Pharmacovigilance	
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EU Health Law entries in tree form (showing hierarchical relationships)

Health products	Medicines (cont)	Medicines pricing	Transparency of pricing
			Health Technology Assessment
			Parallel trade
			Health products & IP
	Medical devices	Medical devices certification	
		Risk management	
		Obligations of economic operators	
		Novel medical devices	
	Joint procurement of health products		
	Liability for harm from health products		
	Veterinary medicine		
Lifestyle products	Tobacco as health threat	Tobacco composition	
		Tobacco packaging & labelling	
		Tobacco advertising	
		Tobacco pricing	
	Diet and nutrition	Food safety	
		Food composition	
		Food labelling	Health claims for food
		Food advertising	
		Food pricing	
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EU Health Law entries in tree form (showing hierarchical relationships)

Lifestyle products (cont)	Alcohol as health threat	Alcohol production	
		Alcohol advertising	
		Alcohol pricing	
		Alcohol labelling & health claims	
Lifestyle services	Gambling as health threat		
National health institutions in EU law	Free movement of goods affecting	Product-related rules	
		Rules related to selling arrangements	
	Freedom of establishment affecting	Light scrutiny institutions	
		Medium scrutiny institutions	
		Strict scrutiny institutions	
	Freedom to provide services	Telemedicine	
		Migrant health professionals	
		Health insurance	
	Cartels & anticompetitive behaviour		
	Monopolies		
	State aids		
	Mergers & acquisitions		
	Public procurement		
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