Reinforcing the role of the EMA in Crisis Preparedness and Management for Medicinal Products and Medical Devices

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The Constitutional Setup of the EU

The EU is founded on treaties, primarily the Treaty on European Union (TEU) and the Treaty on the Functioning of the European Union (TFEU).

Decision-making institutions: European Parliament, European Council, Council of the European Union, European Commission.

Principle of subsidiarity: EU acts only where results can be better achieved at the EU level.

Competencies of the EU

- Exclusive competences (e.g., customs union, competition rules).
- Shared competences (e.g., internal market, environment).
- Supporting competences (e.g., health, industry).
- Health falls under shared and supporting competences (Article 168 TFEU).

EU Competence in Health

- Article 168 TFEU: High level of human health protection.
- Role in complementing national policies.
- Measures for quality and safety of organs, blood, medicines.
- Cross-border health threats management.

EU Competence in Health

- **Article 168 of the TFEU**

High Level of Human Health Protection

Complementing National Policies

Legislation and Recommendations

- **Article 114 of the TFEU**

Internal Market

- **Article 168(4)(c) of the TFEU**

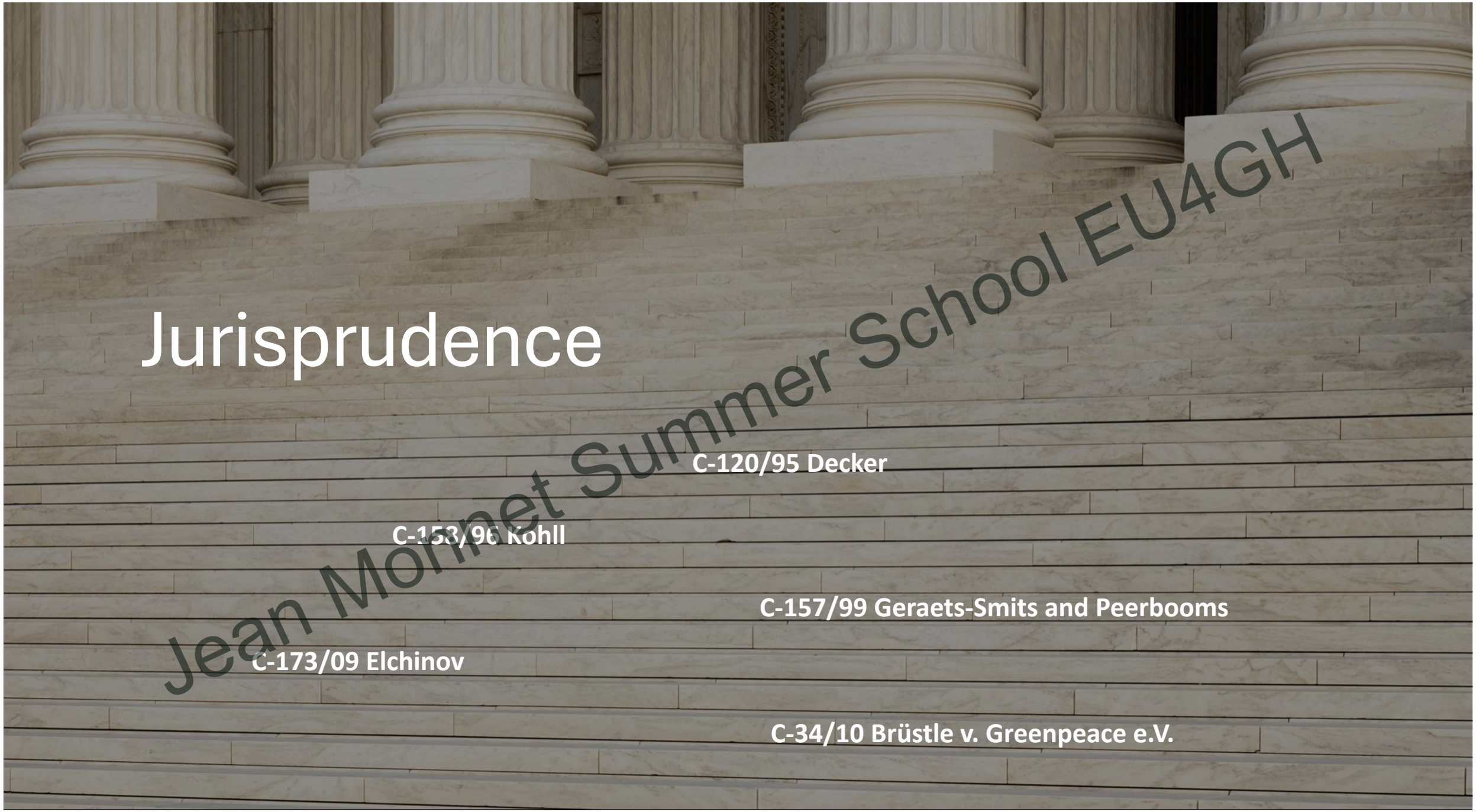
Pharmaceuticals and Medical Devices

- **Article 169 of the TFEU**

Consumer Protection

Practical Implementation: EU Health Policy

- **Examples:**
- **Cross-Border Health Threats**
- The EU has enacted legislation to manage cross-border health threats, such as Regulation (EU) 2022/123, which strengthens the role of the EMA in crisis preparedness and management for medicinal products and medical devices
- **Pharmacovigilance:**
- The EU has established a comprehensive pharmacovigilance system to monitor the safety of medicines across Europe, ensuring a high standard of health protection


Jurisprudence
Jean Monnet Summer School EU4GH
C-120/95 Decker
C-153/96 Kohll
C-157/99 Geraets-Smits and Peerbooms
C-173/09 Elchinov
C-34/10 Brüstle v. Greenpeace e.V.

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the **thalidomide disaster** of the late 1950s

Introduction to the EMA

- Established in 1995.
- Ensures the safety, efficacy, and quality of medicines in the EU.
- Scientific evaluation, monitoring, and advisory roles.
- Coordination of national authorities.

2009
Minor-use-minor-species limited-market policy
First marketing authorisation for an ATMP
2007
First centrally authorised generic medicine
2006
First two biosimilar medicines
Paediatric Medicines Regulation
First conditional approval
2005
SME regulation
SME office established
Herbal Medicines Directive
2004
Review of EU pharmaceutical legislation

2001
Clinical Trials Directive
First two orphan medicines
2000
Orphan Medicines Regulation


First centrally authorised veterinary medicine
1996
Launch of international harmonisation programme for pharmaceuticals
1995
EMA established
First centrally authorised human medicine


2020
Relocation to the Netherlands completed

2019
EMA elected as ICMRA chair
First vaccine against Ebola

2018
First two CAR-T medicines
New Veterinary Medicines Regulation

2017
First public hearing
Mutual recognition agreement on inspections
Amsterdam is announced as EMA's new home

2016
Proactive publication of clinical data
Launch of PRIME (PRIority Medicines) scheme

2015
First joint strategy of EMA and national medicines authorities

2014
First stem-cell medicine

2012
First gene-therapy medicine

2011
First paediatric-use marketing authorisation
Falsified Medicines Directive
First ESVAC report

New pharmacovigilance

EMA’s mandate and role

Evaluation of marketing authorization applications.

Pharmacovigilance: Monitoring adverse effects.

Scientific advice and support for innovation.

Transparency and public information dissemination.

Organization of the EMA

Management Board, Executive Director.

Scientific committees

Working parties and advisory groups.

Collaborations with national competent authorities.

The Pandemic and the European Health Union

- COVID-19 highlighted the need for stronger EU health coordination.
- Acceleration of the European Health Union initiative.
- Enhanced EMA role in crisis management and preparedness.

Regulation (EU) 2022/123

ADOPTED TO STRENGTHEN EMA'S ROLE IN HEALTH CRISIS MANAGEMENT.

AMENDS REGULATION (EC) NO 726/2004 AND REGULATION (EC) NO 1901/2006.

FOCUS ON MONITORING AND MITIGATING MEDICINE AND MEDICAL DEVICE SHORTAGES.

- **Medicinal products**

A substance or combination of substances that is intended to treat, prevent or diagnose a disease, or to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action.

- **Medical device**

A medical device can be any instrument, ap paratus, implement, machine, appliance, i mplant, reagent for in vitro use, software, m aterial or other similar or related article, inte nded by the manufacturer to be used, alone or in combination for a medical purpose.

What we learn from recitals:

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 and Article 168(4), point (c), thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee ([1]),

Having regard to the opinion of the Committee of the Regions ([2]),

Acting in accordance with the ordinary legislative procedure ([3]),

Whereas:

(1) Pursuant to Articles 9 and 168 of the Treaty on the Functioning of the European Union ('TFEU') and Article 35 of the Charter of Fundamental Rights of the European Union (the 'Charter'), the Union is to ensure a high level of human health protection in the definition and implementation of all Union policies and activities.

(2) The COVID-19 pandemic has highlighted the interconnectedness of human, animal, and ecosystem health and the risks posed by the loss of biodiversity on Earth. As recognised by the World Health Organization, many of the same microbes infect animals and humans, so efforts that focus only on human health or only on animal health cannot prevent or eliminate the problem of disease transmission. Diseases may be transmitted from humans to animals or vice versa and therefore need to be tackled in both humans and animals, taking advantage of potential synergies in research and treatments. Approximately 70 % of emerging diseases, and almost all known pandemics, namely influenza, HIV/AIDS and COVID-19, are zoonoses. Those diseases have increased globally over the past 60 years. Changes in land use, deforestation, urbanisation, agricultural expansion and intensification, wildlife trafficking and consumption patterns are factors that have contributed to that increase. Zoonotic pathogens can be bacterial, viral or parasitic, and can include unconventional agents that are able to spread to humans through direct contact or

through food, water or the environment. The COVID-19 pandemic is a clear example of the need to reinforce the application of the One Health approach in the Union to achieve better public health outcomes, since, as stated in Regulation (EU) 2021/522 of the European Parliament and of the Council ([4]), 'human health is connected to animal health and to the environment and … actions to tackle threats to health must take into account those three dimensions'.

(3) The unprecedented experience of the COVID-19 pandemic has also highlighted the difficulties of the Union and the Member States in addressing such a public health emergency. In that regard, it has demonstrated the need to strengthen the Union's role in order to be more effective in managing the availability of medicinal products and the availability of medical devices and *in vitro* diagnostic medical devices and their respective accessories (collectively 'medical devices') and in developing medical countermeasures to address the threats posed to public health at an early stage in a harmonised way that ensures cooperation and coordination between Union, national and regional competent authorities, medicinal products and medical devices industry and other actors in the supply chains for medicinal products and medical devices, including healthcare professionals. While the Union needs to give a higher priority to health, its ability to ensure the continued provision of high quality healthcare services and to be prepared to address pandemics and other health threats has been severely impeded by the absence of a clearly defined legal framework for managing its response to pandemics and by the limited mandates and resources of its health agencies, as well as by the limited degree of Union and Member States preparedness for public health emergencies that impact a majority of the Member States.

(9) The rapid evolution of COVID-19 and the spread of the virus led to a sharp increase in demand for medical devices such as ventilators, surgical masks, and COVID-19 test kits, while disruption of production or limited capacity to rapidly increase production and the complexity and global nature of the supply chain for medical devices led to severe supply difficulties and, at certain times, serious shortages of medical devices. It has also led Member States competing with each other when they respond to the legitimate needs of their citizens, thereby contributing to uncoordinated actions at national level, such as national hoarding and stockpiling. Those issues further resulted in new entities being involved in the expedited production of such medical devices, which subsequently resulted in delays in conformity assessments and the prevalence of medical devices that were over-priced, non-compliant, unsafe, and, in some cases, counterfeits. It is therefore appropriate and a matter of urgency that long-term structures be established within the European Medicines Agency (the 'Agency'), established by Regulation (EC) No 726/2004 of the European Parliament and of the Council (6), to ensure more solid and effective monitoring of shortages of medical devices that can occur during a public health emergency and coordination of the management of those shortages, as well as increased and early dialogue with the medical devices industry and healthcare professionals to prevent and mitigate those shortages.

(10) The COVID-19 pandemic and the subsequent public health emergency revealed the need for a more coordinated Union approach in crisis management. Although the lack of an impact assessment accompanying the Commission proposal for this Regulation was due to the emergency-like nature of the situation, sufficient allocation of resources in terms of staff and funding should be secured, taking into account the specificities of the health sector in the different Member States.

(14) In order to ensure the better functioning of the internal market for safe and efficacious medicinal products for the treatment of COVID-19 or prevention of its spread and to contribute to a high level of human health protection, it is therefore appropriate to approximate and strengthen the rules on monitoring of shortages of medicinal products and medical devices, and to facilitate the research and development of medicinal products which have the potential to treat, prevent or diagnose diseases that cause public health emergencies, with a view to strategically complementing the efforts of the Commission, including the Health Emergency Preparedness and Response Authority ('HERA'), established by Commission Decision of 16 September 2021 ([8]), and Union agencies, to that end.

(15) In order to support the assessment of the crisis-preparedness and crisis-management framework provided for in this Regulation with regard to shortages of medicinal products and medical devices, the Commission should be able to use the outcomes of targeted stress tests performed by the Commission, the Agency, Member States or other relevant actors. Such stress tests entail a simulation of a public health emergency or major event in which some or all segments of the processes and procedures laid down in this Regulation are tested.

(16) This Regulation aims to ensure a high level of protection for human health by ensuring the smooth functioning of the internal market as regards medicinal products and medical devices. Moreover, this Regulation aims to ensure the quality, safety and efficacy of medicinal products that have the potential to address public health emergencies. Both objectives are being pursued simultaneously and are inseparably linked, without one being secondary to the other. As regards Article 114 TFEU, this Regulation establishes a framework for the monitoring and reporting of shortages of medicinal products and medical devices during public health emergencies and major events. As regards Article 168(4), point (c), TFEU, this Regulation should provide for a strengthened Union framework for ensuring the quality and safety of medicinal products and medical devices.

Objectives

1. Enhance crisis preparedness and response.
2. Improve coordination among member states.
3. Ensure the availability of critical medicines and medical devices.
4. Increase transparency and information sharing.

Impact on Member States

BETTER COORDINATION AND MANAGEMENT OF HEALTH CRISES.

REDUCED RISK OF SHORTAGES FOR CRITICAL MEDICINES AND DEVICES.

HARMONIZED RESPONSE STRATEGIES.

STRENGTHENED PUBLIC HEALTH SYSTEMS.

Public perception

- Increased regulatory burden for companies.
- Potential bureaucratic inefficiencies.
- Concerns about data privacy and transparency.
- Implementation challenges across member states.

- Improved crisis preparedness and response.
- Enhanced coordination and data sharing.
- Proactive measures to prevent shortages.
- Support for innovation in public health.

The Future Prospects in EU Health Regulation

- Continued enhancement of the European Health Union.
- Further integration of health data and real-world evidence.
- Strengthening the role of EMA in global health initiatives.
- Ongoing adaptation to emerging health threats.

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