

4TH NEWSLETTER HELP PROJECT (2025)

PRESENTATION OF THE PROJECT

The project PRIN 2022 ‘**Health Emergencies and Legal Preparedness: Global, Regional and National Approaches (HELP)**’ - MUR: 2022MYEW4J - examines how Legal Preparedness can enhance policies and activities to prevent and address public health crises. Our goal is to increase awareness of the concept of Legal Preparedness and sensitise the relevant stakeholders tasked with the prevention and response to public health emergencies to the advantages of such an approach. This study is financed by the European Union – NextGeneration EU. The project is carried out by the [Sant’Anna School of Advanced Studies](#) and the [University of Bologna](#). More information at <https://help-prin.it/>.

LEGISLATIVE, POLICY AND POLITICAL DEVELOPMENTS

National level (Italy)

Italy Rejects the 2024 Amendments to the International Health Regulations (IHR). In July 2025, Italy officially notified the World Health Organisation (WHO) of its [rejection](#) of the 2024 [amendments](#) to the International Health Regulations (IHR). The decision was communicated by the Italian Minister of Health, Orazio Schillaci, in a letter to WHO Director-General Tedros Adhanom Ghebreyesus. The letter reaffirms the need to defend national sovereignty against potential interference by the WHO in domestic health policies. In doing so, Italy aligned itself with the [position](#) of the United States.

New National Report on Sales and Use of Antimicrobials in Animals (2023). In September 2025, the Italian Ministry of Health published the [National Report on Sales and Use of Antimicrobials in Animals \(2023\)](#). The report is part of the implementation of Regulation (EU) 2019/6 and its delegated and implementing acts, which require Member States to collect and transmit data on veterinary antimicrobial use. This shared legal framework is a cornerstone of preparedness, ensuring common rules and uniform monitoring to better address the challenge of antimicrobial resistance.

European level

Global Health in the 2025 State of the Union Address by President von der Leyen. On 10th September 2025, European Commission President Ursula von der Leyen gave the annual [State of the Union Address](#) to the European Parliament plenary session. In this year’s speech, von der Leyen said that Europe must “take the lead on global health” and announced a new “Global Health Resilience Initiative”. According to her, “the world is looking to Europe – and Europe is ready to lead”. However, no further [details](#) have been provided on the initiative.

European Medicines Agency (EMA) and the WHO Mark Ten Years of Collaboration. In September 2025, EMA and the WHO signed a [confidentiality agreement](#) to share a wide range of information on safety, quality, and efficacy of medicines already authorised or under review in the European Union (EU) or pre-qualified or under review by the WHO. Since then, EMA and WHO have worked closely together.



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Their [partnership](#) has enabled high-impact cooperation in: a) addressing existing and emerging public health threats; b) accelerating access to essential medicines; and c) supporting research and development of medicines.

International level

Adoption of the Pandemic Treaty. On 20th May 2025, Member States of the WHO formally adopted by consensus the [Pandemic Agreement](#) (PA) during the 78th World Health Assembly (WHA). In the [view of the WHO Director-General](#), the Agreement is “a victory for public health, science and multilateral action”. The treaty has been negotiated for the past three years. However, the PA will be open for signatures and consideration for ratification only once the WHA adopts the [Annex on Pathogen Access and Benefit Sharing](#) (PABS). After sixty ratifications, the agreement will enter into force.

The 2024 Amendments to the IHR Enter into Force. On 19th September 2025, [the 2024 amendments to the IHR](#) entered into force. Among the major changes introduced by the IHR is the establishment of [National IHR Authorities](#) by governments to better coordinate IHR implementation. The amendments also [include](#) provisions on equity and solidarity on strengthening access to medical products and financing; the establishment of the State Parties Committee to facilitate the effective implementation of the amendments and a definition of pandemic emergency. Eleven of the 196 State Parties rejected the 2024 amendments. For these countries, earlier versions of the IHR continue to apply. In any case, they may choose to withdraw their rejections at any time.

ACADEMIC PUBLICATIONS

Reading suggestions:

Meier BM, Inyang NA, Ginsbach K, et al. ‘**Legal Preparedness as a Foundation of Global Health Security**’. Journal of Law, Medicine & Ethics. Vol. 53(2), June 2025. <https://www.cambridge.org/core/journals/journal-of-law-medicine-and-ethics/article/abs/legal-preparedness-as-a-foundation-of-global-health-security/15A9F93F942330291F2D2D32FB85F0BF#access-block>

Giulia Bosi, ‘**The Protection of Mental Health under International Humanitarian Law**’. Journal of International Humanitarian Legal Studies; Advance Articles, August 2025. <https://brill.com/view/journals/ihls/aop/article-10.1163-18781527-bja10121/article-10.1163-18781527-bja10121.xml?ebody=Article%20details>

EVENTS

THE FUTURE OF THE RULE OF LAW IN THE EU IN AN ERA OF GLOBAL DEMOCRATIC DECLINE. On 6th June 2025, Professors Laurent Pech and Giacomo Di Federico engaged in a critical discussion on contemporary challenges to the rule of law in the EU, set against the broader backdrop of global democratic backsliding. The debate highlighted the wider project of strengthening the Union’s legal preparedness: enhancing the capacity of EU and national institutions to anticipate, prevent, and effectively respond to systemic crises threatening European values, through resilient legal frameworks, effective judicial oversight, and a conscious multilevel governance.



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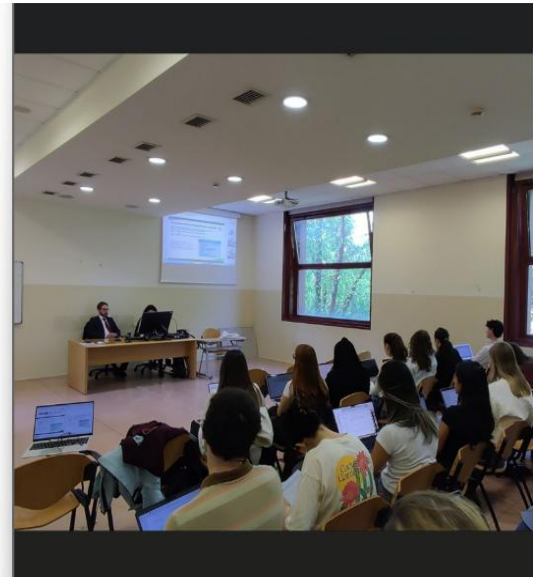
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PREPAREDNESS AND RESPONSE TO SERIOUS CROSS-BORDER THREATS TO HEALTH IN THE EU – THE ECDC ROLE. On 28th April 2025, Stefania De Angelis, an epidemiologist and public health expert and scientific officer at the European Centre for Disease Prevention and Control (ECDC), discussed the new ECDC mandate and the revised EU legislation on serious cross-border health threats with Prof. Giacomo Di Federico at the University of Bologna.



Join us for the **final event of our project** in Pisa at the **Scuola Superiore Sant'Anna** on **20 January 2026!**

Experts will share and discuss our main findings, exploring legal preparedness for health emergencies at the international, regional and national levels.

Follow us for updates and event details soon!

