

3RD 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)

The Italian Decree on Health Data Ecosystem. In March 2025, a [decree](#) of the Italian Minister of Health in agreement with the Minister of the Economy and the Undersecretary to the Presidency of the Council of Ministers with responsibility for technological innovation, establishing the so-called Health Data Ecosystem (HED) was published in the Official Gazette of the Italian Republic. The Health Data Ecosystem aims to centralise, protect and enhance the management of health data. Patient health information will be collected, archived and made accessible to the citizens themselves and the authorised healthcare professionals. It will become fully operational in 2026.

The draft of the Italian Pandemic Plan. In February 2025, the [draft of the new national Pandemic Plan](#) was sent to the State-Regions Conference for its opinion and subsequent approval. The Plan includes the intervention strategy in the event of an emergency caused by a respiratory virus. It considers approved and tested vaccines as effective preventive measures, but it also explains that ‘they cannot be considered the only tools for combating pathogens’ and that they ‘must be used together with the available therapeutic aids’. It also foresees that restrictions on personal freedom can be imposed only in exceptional cases but without recourse to Decreti del Presidente del Consiglio dei Ministri, DPCM (Decrees of the President of the Council of Ministers).

European level

EU Regulation 2025/327 on the European Health Data Space (EHDS). On 5th March 2025, [The EHDS Regulation](#) was officially published in the Official Journal of the EU. This regulation aims to establish the EHDS to improve individuals' access to and control over their personal electronic health data in the context of healthcare, as well as to achieve other purposes that involve the use of electronic health data in the healthcare and welfare sectors more effectively. The Regulation is an important milestone in the EU's efforts to build a secure and efficient digital health ecosystem as part of the European data strategy.

Strategic Report of the Critical Medicines Alliance (CMA). The CMA is a consultative mechanism bringing together relevant stakeholders from EU Member States, key industries, civil society, and the scientific community. In February 2025, they published a report that aims to identify key areas and priorities for action, proposing solutions to strengthen the supply of critical medicines in the EU. Critical medicines are the ones that are considered essential to ensure the provision and the continuity of quality healthcare and to guarantee a high level of public health protection in Europe.

International level

Negotiations of the Pandemic Treaty. In February 2025, the World Health Organization (WHO) held the 13th meeting of the Intergovernmental Negotiating Body (INB), the body in charge of negotiating and drafting the pandemic agreement. The meeting was the first to take place after the United States (US) pulled out of the discussions. The INB missed the deadline of May 2024 to reach a consensus on the pandemic treaty and aims to adopt it this year. At the end of the closing session, Dr Tedros Adhanom Ghebreyesus, WHO Director-General, [said](#) that the 13th INB meeting made progress but ‘maybe not as much as you would have hoped’.

The US’s withdrawal from the WHO. In January 2025, the new US President Donald Trump signed an [executive order](#) withdrawing the US from the WHO. A one-year notice is needed, and as a result, the US will leave the WHO in January 2026. Trump accused the WHO of mishandling the COVID-19 pandemic and other global health crises, of being unable to demonstrate independence from inappropriate political influences of Member States, and of demanding unfairly onerous payments from the US. The US is the top donor country to the WHO and its withdrawal risks [undermining](#) global health security.

ACADEMIC PUBLICATIONS

Find below some interesting reading suggestions:

Zuzanna Zapotoczna, ‘**The European Union influence on the organisation of national healthcare systems. Navigating the trends after the COVID-19 pandemic**’. European Journal of Health Law, Vol. 32, No. 1, January 2025. Available at: https://brill.com/view/journals/ejhl/32/1/article-p1_1.xml?Tab%20Menu=article-metadata

Greta Cranston, ‘**Understanding the expectations, positions and ambitions of LMICs during pandemic treaty negotiations, and the factors contributing to them**’ in PLOS Global Health, Vol. 5, No. 3, March 2025. Available at: <https://journals.plos.org/globalpublichealth/article?id=10.1371/journal.pgph.0003851>.

EVENTS

March 2025 has been a month with several **HELP project events!**

LA (NUOVA) LEGISLAZIONE FARMACEUTICA EUROPEA & LA PROSPETTIVA EUROPEA SUL RUOLO DELLA LEGAL PREPAREDNESS NELLA GESTIONE DELLE EMERGENZE SANITARIE. On 12 March 2024, Emanuele Cesta, a lawyer at the Agenzia Italiana del Farmaco (Italian Medicines Agency), discussed the new EU pharmaceutical legislation with Prof. Giacomo Di Federico at the University of Bologna. On the same day, Miriana Lanotte, a postdoctoral researcher in EU Law at the University of

Bologna, made a presentation on the EU perspective on the role of legal preparedness in the management of health emergencies during a lunch seminar open to the academic community.

EU AND GLOBAL HEALTH GOVERNANCE: POLICIES, INSTITUTIONS AND CHALLENGES. On 17 March 2025, Giulia Bosi, a postdoctoral researcher in International Law at Sant'Anna School of Advanced Studies, discussed the role of the EU in global health governance from a legal preparedness perspective with Prof. Giacomo Di Federico at the University of Bologna. After presenting the current global health law normative developments, she explained how the COVID-19 pandemic has led to the emergence of an EU-leading position in global health policy.

La (nuova) legislazione farmaceutica europea

12 Marzo 2025 - h. 15.00-17.00
[Link per partecipare al seminario online](#)

Coordinato dall'Unione Europea, Le opinioni espresse sono esclusivamente quelle dell'autore/i e non riflettono necessariamente quelle dell'Unione Europea o dell'Agenzia europea per i Farmaci e la salute (EMA/EA), né l'Unione Europea o l'EMA/EA possono essere ritenute responsabili.

Relatore: Emanuele Cesta
 Avvocato presso l'Agenzia Italiana del Farmaco (AIFA)

Moderatore: Giacomo Di Federico
 Professore ordinario presso l'Università Bologna

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LUNCH SEMINAR CRIDS

MARZO - GIUGNO 2025

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| 12 marzo 11.30 - 13 | 4 aprile 15-17 |
| Miriana Lanotte <i>La prospettiva europea sul ruolo della legal preparedness nella gestione delle emergenze sanitarie</i> Aula Pezemo | Ester Gubert <i>Sooner or later: accessing long-term care policies along the care trajectory</i> Aula Farneti |
| 16 aprile 11.30 - 13 | 21 maggio 15 - 17 |
| Francesca Sabatini <i>Le città metropolitane e il PNRR: la sfida della valutazione della qualità urbana</i> Aula Pezemo | Adriana Maria Offredi Rodriguez <i>Care and minimum income policies: when welfare conditionality meets unpaid care work</i> Aula Farneti |
| 6 giugno 11.30 - 13 | |
| Sergio Spatola <i>La salute schiacciata. I bisogni, l'innovazione tecnologica, la cronicità dinanzi ai mezzi finanziari</i> Aula Pezemo | |

Gli incontri sono aperti a tutta la Comunità accademica e intendono costruire un ambiente dialogico e inclusivo in cui condividere temi e percorsi di ricerca.

WWW.CENTRI.UNIBO.IT/CRIDS/IT

DIPARTIMENTO DI SOCIOLOGIA E DIRITTO DELL'ECONOMIA
 PALAZZO HERCOLANI - STRADA MAGGIORE 45, BOLOGNA

Seminar
 17 March 2025, h. 11.00-13.00

EU and Global Health Governance: Policies, Institutions, and Challenges

Room H, Via Beniamino Andreatta 8, Bologna

Speaker: Giulia Bosi
 Research Fellow in International Law at Sant'Anna School of Advanced Studies – Pisa

Discussant: Giacomo Di Federico
 Full Professor at the University of Bologna

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