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February 24, 2023



Padua, Italy

Museum of Medicine

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International Workshop

The European Health Union

TOWARDS A HEALTHIER AND SAFER UNION

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Promoting Institutions

Department of Political and Social Science, Alma Mater Studiorum, University of Bologna
Department of Political Science, Law and International Studies, University of Padua
Department of Rare Diseases, University Hospital of Padua
Center for Rare Diseases, "Istituto Superiore di Sanità"
International Agency "Motore Sanità"

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School of Medicine and Surgery of the University of Padua
Department of Woman's and Child's Health, University of Padua
Department of Political and Social Science, University of Bologna
Department of Political Science, University of Padua

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Background and rationale

With of budget of €5.3 billion, the EU4 Health program 2021-2027 represents an unparalleled EU financial support in the health area. Releasing such an ambitious program the European Commission has given the clear message that public health is a priority for the EU. Health means welfare, social peace, productivity and progress.

The EU4 Health program has been conceived as one of the main instruments to pave the way to the European Health Union (EHU). Areas of investments are: the urgent health priorities boosted by the COVID-19 crisis, the Europe's Beating Cancer Plan, the Pharmaceutical Strategy for Europe, the digitalization of domestic health systems, the antimicrobial resistance and vaccination strategies, as well as successful initiatives like the European Reference Networks [ERNs] for rare diseases and, in general, the EU-wide cooperation on global health threats and challenges.

Much work still needs to be done in order to realize the EHU: an overarching political and policy strategy, acting as a framework for the Member States, has to be designed; already existing national and international regulations need to be revised; the awareness of EU citizens and other major stakeholders (e.g. political parties, national and regional health authorities, economic players in the health-sector) needs to be raised. Further, the innovative technological solutions that are setting new paradigms for daily clinical practice and caring for individuals and public health must be implemented more extensively throughout the EU. And lastly, "proofs of concepts" need to be developed in order to confirm the working hypotheses underlying the idea of a European Health Union. A Next Generation EU has to be nurtured also in this field.

The EHU could be considered as a fundamental element to consolidate the vision stated in the European Pillar of Social Rights, according to which everyone in the EU should have "the right to timely access to affordable, preventive and curative health care of good quality", this being a necessary step to complete the European project, going beyond economic and monetary integration. The idea of creating the EHU is based on the same fundamental inspiring concept of the European Social Union of sustaining/promoting two types of solidarity: "a pan-European solidarity between countries (...) centred on supranational institutions and the more traditional forms of national solidarity, centred on domestic (...) institutions".

Based on these considerations and on the growing awareness induced by the COVID-19 pandemic that equitable and effective healthcare cannot be left to the individual action of Member States alone, we thought to promote, in conjunction with The Rare Diseases Day 2023 and with the beginning of a new phase of the ERNs, an international multi-professional and multi-disciplinary workshop aimed at promoting a constructive, bottom-up discussion - and, ideally, concrete proposals - to contribute to building the European Health Union.

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8:30 Welcome address & Notes of introduction

9:00 The inspiring principles of the European Union and its future

Objective: To provide an overview of the fundamental principles of the European Union as a possible base for the European Health Union

Moderators: Elena Pariotti & Federico Toth

Discussants: **Piergaetano Marchetti**, Emeritus Professor of Commercial Law, Law Department, Bocconi University, Milan - Past President: Foundation Corriere della Sera

Maurizio Ferrera, Professor of Political Science, Department of Political and Social Science University of Milan, Principal Investigator, European Research Council, project SOLID President of the Network for the Advancement of Social and Political Sciences (NASP), columnist of the magazine "Corriere della Sera"

Eleanor Brooks, Lecturer in Health Policy, UKRI Future Leaders Fellow 2020-2024, University of Edinburgh, Global Health Policy Unit | School of Social and Political Science Edinburgh

Meenakshi Maria Fernandes, Policy analyst, European Parliament Research Service

10:45 Current projects for the construction of the European Union of health

Objective: To report on current European health-related initiatives and projects aiming to open the way for a fully-fledged European Health Union

Moderators: Fabiola Bologna & Mariassunta Piccinni

Discussants: **Jean-Pierre Halkin**, Head of Unit D.2 'Interreg, Cross-Border Cooperation, Internal Borders', European Commission, DG REGIO

Sebastiano Lustig, Representative from the Health Emergency Preparedness and Response Authority (HERA)

Donata Meroni, Head of Unit B.3 'Health monitoring and cooperation, Health networks', European Commission, DG SANTE

Walter Ricciardi, Chair of the Mission Board for Cancer

Luca Sangiorgi, Incaricato del Ministero per la Joint Action sull'integrazione degli ERN in the National Health System

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13:00 Lunch break

14:00 Digitization and new technologies at the service of the journey towards the European Health Union and the great future prospects of individual and public health that they allow us to predict

Objective: To address the role and prospects opened by the digitalized medicine and by the new communication technologies for European public and individual health [with a special reference to the European Health Digital Space]

Moderators: **Barbara Di Camillo**, Professore Ordinario Informatica Università degli Studi di Padova

Roberto Vettor, Professore Ordinario in Medicina Interna, Department of Medical and Surgical Sciences University of Padua and Director of the Medical Clinic 3

Discussants: **Licinio Kustra-Mano**, Strategic Advisor for European Health Data Space at the European Commission

Silvio Brusaferro, President of the Italian National Institute of Health (ISS)

Anita Bressan, PhD - MetabERN's Digital Health Manager

15:15 Feasibility elements of the path towards the European Health Union

Objective: To discuss the role of European economic operators, with a particular focus on the European Pharmaceutical industry, to pave the way to the European Health Union in terms of a fully integrated single market and pharmaceutical supply independence

Moderators: **Lorenzo Rocco & Michele Tessarin**

Discussants: **Antonio Calabrò**, European Economist, Managing Director of Pirelli Foundation and of Museimpresa, the Italian Association of Business Archives and Corporate Museums

Marco Cavaleri, Head of Health Threats and Vaccines Strategy, European Medicines Agency

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16:30 Mini break

16:45 Round table discussion – How to promote a “bottom-up” process to favor the realization of the European Health Union which can encounter the “top-down one” promote by the EU – Ideas for a large common concerted action

Facilitators: Laura Polverari & Rosario Rizzuto

Discussants:

Pietro Fiocchi, Member of the European Parliament, Committee on the Environment, Public Health and Food Safety (ENVI)

Paolo Petralia, Vice-President FIASO – Italian Federation of “Aziende Socio Sanitarie” – CEO ASL4, Liguria

Sabina Nuti, Rector, School of Advanced Studies, Pisa

Maurizio Scarpa, Director National Centre for Rare Diseases, Italian National Institute of Health (ISS)

Simona Bellagambi, representative UNIAMO in EURORDIS

18:00 Concluding remarks and end of the workshop

Giorgio Perilongo, Professor of Paediatrics, Chairman, Department of Rare Diseases; Department of Woman's and Child's Health, University of Padua

Claudio Zanon, Chair Scientific Committee Motore Sanità

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European Institutions Represented

DG¹ SANTE, European Commission – The DG for Health and Food Safety is responsible for EU policy on food safety and health and for monitoring the implementation of related laws. Its responsibility is to make Europe a healthier and safer place. Its mission is to protect the citizens' health and monitor their food making sure it is safe.

DG REGIO, European Commission – The DG for Regional and Urban Policy is responsible for EU policy on regions and cities. Its vision is a European Union where people in all regions and cities can realize their full potential. It aims for lasting improvement in the economy and quality of life for everybody, wherever they live.

HERA, European Health Emergency Preparedness and Response Authority for health emergencies – HERA is new European Commission's Authority. Its mandate is to develop, produce, and procure, medical countermeasures before and during a health crisis. Its aims are: i) to improve EU health security coordination before and during crises; ii) to bring together the EU Member States, industry and relevant stakeholders; iii) to develop, produce, procure, stockpile and equitably distribute medical countermeasures; iv) to reinforce the global health emergency response architecture.

EMA, the European Medicines Agency - Its mission is to foster scientific excellence in the evaluation and supervision of medicines, for the benefit of public and animal health in the European Union. Its aims are: to facilitate development and access to medicines; to evaluate applications for marketing authorisation; to Monitor the safety of medicines across their lifecycle; to provide information to healthcare professionals and patients.

EPRS, the European Parliamentary Research Service is the European Parliament's in-house research service and think tank. Its mission is to provide Members of the European Parliament, and where appropriate parliamentary committees, with independent, objective and authoritative analysis of, and research on, policy issues relating to the European Union, in order to assist them in their parliamentary work.

EURORDIS - Rare Diseases Europe is a unique, non-profit alliance of over 1000 rare disease patient organisations from 74 countries that work together to improve the lives of over 300 million people living with a rare disease globally. By connecting patient, families and patient groups, as well as by bringing together all stakeholders and mobilising the rare disease community, EURORDIS strengthens the patient voice and shapes research, policies and patient services. 'EURORDIS' vision is a world where all people living with a rare disease can have longer and better lives and can achieve their full potential, in a society that values their well-being and leaves no one behind.

¹DG – Directorate-General - The Commission is organised into policy departments, known as Directorates-General (DGs), which are responsible for different policy areas. DGs develop, implement and manage EU policy, law, and funding programmes. In addition, service departments deal with particular administrative issues. Executive agencies manage programmes set up by the Commission.

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European Initiatives/plans launched to foster collaboration among the member states on Health related issues which will be discussed

The European Health Data Space. The European Health Data Space is one of the central building blocks of the European Health Union and a milestone in EU's digital transformation. Its aims are:

- to improve healthcare delivery across the EU, by empowering people to control their health data in their home country or in other EU countries;
- to offer a consistent, secure, trustworthy and efficient framework for the use of health data. Under strict conditions, researchers, innovators, public institutions or industry will have access to large amounts of high-quality health data, crucial to developing life-saving treatments, vaccines or medical devices
- to foster a genuine single market for digital health services and products fulfilling unmet medical needs; supporting a competitive and innovative European pharmaceutical industry; enhancing resilience through diversified supply chains, environmental sustainability, and crisis preparedness; promoting high standards for medical products globally.

Europe's Beating Cancer plan – The Europe's Beating Cancer Plan aims to prevent cancer and ensure that cancer patients, survivors, their families and carers can enjoy a high quality of life. By tapping into a broad array of EU policies, notably digitalisation, research and innovation, the cancer plan helps EU countries turn the tide against cancer. It includes actions and flagship initiatives covering the entire disease pathway: prevention; early detection; diagnosis and treatment; quality of life for cancer patients and survivors. On 20 September 2022, the Commission presented a new approach to support Member States increasing the uptake of cancer screening, which focuses on detecting cancer at the early stage.

European References Networks [ERN] - are virtual networks involving healthcare providers across Europe. They aim to facilitate discussion on complex and rare diseases and conditions that require highly specialised treatment. The ERNs collaborate to review patients' diagnosis and treatment through 'virtual' advisory panels of medical specialists across different disciplines, using a dedicated IT platform. They are also active in the areas of research, setting up registries, developing clinical guidelines, and sharing knowledge and expertise among health professionals and patient organisations.

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Scientific Committee

Anita Bressan, PhD - Digital Health Manager, ERN on Rare Metabolic Diseases (Metab-ERN)

Elena Pariotti, Professor of Legal Philosophy, Chairwoman, Department of Political Science, Law and International Studies, University of Padua, Italy

Giorgio Perilongo, Professor of Paediatrics, Chair, Department of Rare Diseases, University Hospital of Padua & Vice-Chair Department of Woman's and Child's Health, University of Padua, Italy

Laura Polverari, Associate Professor of Political Science, Department of Political Science, Law and International Studies, University of Padua, Italy

Francesca Romanin, Motore Sanità

Maurizio Scarpa, Director Elect, National Center of Rare Diseases, Italian National Institute of Health (ISS)

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Claudio Zanon, Scientific Director, "Motore Sanità", Torino, Italy



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