General Report 2025

on the Activities
of the European Hospital
and Healthcare Federation

hope
European Hospital and Healthcare Federation

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General Report on the Activities of the European Hospital and Healthcare Federation, 2025

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General Report

on the Activities
of the European Hospital

2025

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Executive Summary

The year 2025 was the first full year for the new European Commission and the new European Parliament.

Several pieces of legislation had been adopted before the European Parliament closed, for others the discussion had to be continued, and new ones were presented by the European Commission such as the Critical Medicines Act.

HOPE continued monitoring several pieces of legislation adopted long ago, for example the implementation of the Falsified Medicines Directive or the Regulation on Health Technology Assessment and engaged in the new discussions on the implementation of the Medical Devices and In-vitro Diagnostics Regulations.

During the previous legislation, some past topics had found themselves back on the agenda due to the evaluation of current directives and regulations. This was the case for the Blood, Tissue and Cells Directive, the State Aid Package, the Restriction of Hazardous Substances, the Pharmaceuticals Package. It was also the case for environment-related topics such as Water Pollution and Fluorinated Greenhouse Gases.

Several other initiatives gained momentum on the European political agenda and HOPE closely monitored developments and joined discussions on antimicrobial resistance, vaccination, cancer, mental health and climate to name but a few.

In 2025, HOPE also contributed to the EU non-legislative agenda through several European projects. One project was successfully concluded: RE-SAMPLE (on BPCO). The other projects further developed their activities in 2024 with HOPE as a partner: SAFEST (on quality and patient safety), FLASH (on financing and resilience), DIOPTRA (on colorectal cancer), LUCIA (on lung cancer), KEEPcaring (on stress) and HealthRiskAdapt (on health and environment). One new project kicked off in 2025: EYP (young patients' empowerment). HOPE is also an advisor in several other projects and Joint Actions.

Consistent with HOPE's mission to facilitate cross-border exchange of good practices among its members and beyond, HOPE staff participated as speakers or helped organise several European events.

The HOPE Exchange Programme 2025 was concluded by the HOPE Agora that took place on 13 and 14 June 2025 in Vienna, focusing on the theme ‘Together for Quality!’.

CHAPTER 1

Life and Governance

HOPE gathers 37 national organisations representing hospital and healthcare services – public and/or private – from the 27 EU Member States, the United Kingdom, Switzerland and Serbia.

HOPE is organised around a Board of Governors, a President's Committee, a network of Liaison Officers, a network of National Coordinators of the HOPE Exchange Programme, and a Central Office.

LIFE AND GOVERNANCE

GOVERNANCE

HOPE gathers 37 national organisations representing hospital and healthcare services from 30 countries. It is organised around a Board of Governors, a President's Committee, Liaison Officers, a network of National Coordinators for the HOPE Exchange Programme and a Central Office.

The Board of Governors (BoG) is composed of the President, the Governors, one from each EU Member State and the Head of Delegations from non-EU Member States. It is the forum for all major policy decisions. The BoG met twice in 2025: on 11 June in Vienna and on 4 December in Paris

According to the revised constitution adopted in June 2023, the President's Committee (PsC) consists of five persons: the President, the Vice-President and three governors, who, at the end of 2024 were former presidents Ms Henriette Neumeyer (Vice President and Governor for Germany), Ms Eva M. Weinreich-Jensen (Governor for Denmark) and Mr Urmas Sule (Governor for Estonia), and Professor Carlos Pereira Alves (Governor for Portugal). The PsC oversees the implementation of the decisions taken by the Board of Governors, coordinates the work of the Liaison Officers, acts in the name of HOPE, and authorises legal representation. The PsC met online on 26 May and on 30 October 2025 to discuss the Board of Governors' agendas and the meetings of the Liaison Officers, and to decide on the organisation's priorities.

The role of the network of Liaison Officers is to enhance activities and deliver objectives. In 2025, HOPE Liaison Officers meetings took place on 27 March in Brussels and on 4 December in Paris. At these meetings, Liaison Officers discussed the major EU health topics of the year and the transposition of EU legislation.

The network of National Coordinators of the HOPE Exchange Programme met in Paris on 5 December to prepare the 2026 programme.

Located in Brussels, Belgium, the Central Office is managed by the Chief Executive, Mr. Pascal Garel. Ms. Ana Sofia Carbonell is part-time EU Project Officer. Ms. Marie Nabbe is EU Affairs Officer. Mr. Sascha Marschang is part-time Senior Advisor.

GOVERNANCE AT THE END OF 2025

President	Eamonn Fitzgerald, IRELAND
Vice-President	Henriette Neumeyer, GERMANY

Governors

AUSTRIA	Nikolaus Koller
BELGIUM	Jean Stoefs
BULGARIA	Krasimir Grudev
CROATIA	Željko Plazonic
CYPRUS	Kypros Stavrides
CZECH REPUBLIC	Miloslav Ludvik
DENMARK	Eva Weinreich-Jensen
ESTONIA	Urmas Sule
FINLAND	Tarja Tenkula
FRANCE	Zaynab Riet
GREECE	Yannis Skalkidis
HUNGARY	György Velkey
ITALY	Domenico Mantoan
LATVIA	Jevgenijs Kalejs
LITHUANIA	Dalis Vaiginas
LUXEMBOURG	Sylvain Vitali
MALTA	Clarence Pace
THE NETHERLANDS	Sander Gerritsen
POLAND	Jaroslaw Fedorowski
PORTUGAL	Carlos Pereira Alves
SERBIA	Đorđe Nikodinović
SLOVAKIA	Marian Petco
SLOVENIA	Radivoj Nardin
SPAIN	Pilar Aparicio Azcárraga
SWEDEN	Erik Svanfeldt
SWITZERLAND	Anne Bütikofer
UNITED KINGDOM	Layla McCay

CHAPTER 2

Influence

A major component of HOPE's work is to help shape EU legislation by addressing the realities of healthcare. To achieve this, HOPE follows the development of both hard and soft law.

In 2025, HOPE closely followed and took part in the debate around several key health and social policy issues.

While some pieces of legislation on which HOPE has been active in the past years were back on the European political agenda, 2025 provided an opportunity to engage in several new initiatives.

INFLUENCE

The main role of HOPE is to monitor the European institutions, represent hospitals and healthcare services and liaise with other EU organisations.

REPRESENTATION

HOPE is involved in many ad-hoc events organised by the European Commission. But it is mostly involved in several recurrent meetings part of specific groups.

Medical Device Coordination Group

The Medical Device Coordination Group (MDCG) deals with key issues from the medical devices sector, from Notified Body oversight or standardisation to market surveillance, and from international matters to new technologies and clinical investigation.

The members of the subgroups are appointed by the Member States for three years. Stakeholders (European based associations) and HOPE among them participate in the meetings following applications to dedicated calls for expression of interest.

Its expertise originates from its division into 13 subgroups, which respectively provide advice and draft guidance on their field of expertise. HOPE is following three of them: EUDAMED, Unique devices identification and In vitro diagnostic medical devices

Health technology assessment stakeholder network

The Regulation (EU) 2021/2282 on health technology assessment (HTA) came into force in January 2022 and has applied from January 2025. It sets out a transparent and inclusive framework by establishing a Coordination Group of HTA national or regional authorities, a stakeholder network and by laying down rules on the involvement in joint clinical assessments and joint scientific consultations of patients, clinical experts and other relevant experts. HOPE is part of the HTA stakeholder network.

eHealth Stakeholder Group (EHSG)

Established in 2012, the eHealth Stakeholder Group provides advice and expertise to the Commission, particularly on topics set out in the Communication on enabling the digital transformation of health and care.

Members of the eHealth Stakeholder Group are all umbrella organisations and associations with a European outreach. They represent the following sectors and groups: the health tech industry, patients, healthcare professionals and the research community.

HOPE has been a member since the origin. The group was relaunched in 2020 and held its first meeting on 13 July 2020.

The year 2025 marked the last full year of the EHSG's four-year mandate (ending in January 2026). It was also the final year of the EHSG as such, since this group will be replaced by a new and enlarged European Health Data Space (EHDS) Stakeholder Forum. The latter will be inaugurated by the European Commission in 2027 following a thorough reapplication and selection process scheduled for 2026.

HERA Civil Society Forum

The Civil Society Forum (CSF) is a sub-group of the HERA Advisory Forum of which HOPE has been a member since the origin.

It is intended to help ensure that HERA receives regular input on the views and opinions of the civil society stakeholders. The CSF 2025 was the last year of the first edition, and the launch of the second edition of the CSF. This new edition gathers 28 organisations, including HOPE.

Antimicrobial Resistance One Health Network

This network was created in June 2022 and launched in 2023 to enhance the coordination and dialogue between the human health, veterinary and environmental sectors in the EU institutions, Member States and with stakeholders (and HOPE among them since the origin), in policies to combat antimicrobial resistance.

The network is composed primarily of government experts from the human health, animal health, and environmental sectors, the EU scientific agencies working in the human and animal health sectors (ECDC, EMA, and EFSA) and stakeholders. Its members work towards facilitating mutual learning, sharing innovative ideas, building consensus, comparing progress made in key areas and, where necessary, accelerating national efforts to tackle AMR.

EU Forum for the Protection of Public Spaces

To address terrorist threats and enhance the protection of public spaces, the European Commission adopted in October 2017 an EU Action Plan aimed at supporting EU Member States through funding, the exchange of good practices and lessons learnt, establishing and facilitating networks, enhancing cooperation and providing guidance material.

In December 2017, the Commission launched a public-private Operators Forum bringing together Member States' policy makers and operators from different sectors, such as mass events and entertainment, hospitality, shopping malls, sports and cultural venues, transport hubs and others including hospitals. HOPE is part of the forum.

Working group on resilience measures for critical entities under the CER Directive

The Directive on the resilience of critical entities (EU) 2022/25571 (CER Directive) came into force on 18 October 2024. It seeks to enhance the non-cyber resilience of entities that provide essential services for the maintenance of vital societal functions or economic activities and operate critical infrastructure for that purpose. It applies to certain categories of entities listed in the annex to the CER Directive pertaining to 11 sectors including the healthcare sector.

According to the CER Directive, EU Member States are required to develop national frameworks on the resilience of critical entities and notably identify critical entities by July 2026. Entities that have been identified as critical by Member States will inter alia have to adopt appropriate and proportionate resilience measures within 10 months after having been notified of their identification as critical entities. The CER Directive tasks the European Commission to adopt non-binding guidelines to further specify the technical, security and organisational resilience measures that may be taken by critical entities.

European Medicines Verification Organisation

The European Parliament and Council introduced Directive 2011/62/EU to combat the infiltration of falsified medicines into the legal supply chain. This directive mandates the implementation of the European Medicines Verification System (EMVS) to ensure medication authenticity. Manufacturers are required to upload unique identifiers via the European Hub for verification in National Medicines Verification Systems. Technical and quality standards, including system interoperability and data access, have been established by stakeholders. The EMVS guarantees medicines' authenticity by an end-to-end verification.

The European Medicines Verification Organisation (EMVO) was then created as a joint initiative of EU stakeholders, representing manufacturers (Medicines for Europe, EFPIA, Affordable Medicines Europe), wholesalers (GIRP) and community pharmacists (PGEU). HOPE is participating in the board without voting rights and is also attending the stakeholders' meetings.

General Data Protection Regulation

HOPE is part of the Implementation Dialogue on the application of the General Data Protection Regulation (GDPR). The dialogue allows stakeholders to exchange with the Commissioner and provide their views and ideas on the application of the GDPR. The Implementation Dialogue also explores pathways of improvement that maintain the current high level of data protection in the EU.

Coalition for Vaccination

The Coalition for Vaccination brings together European associations of healthcare professionals and relevant student associations in the field.

HOPE joined the coalition when it was convened by the European Commission in 2019 based on the 2018 Council recommendation on strengthened cooperation against vaccine-preventable diseases. It aims to support delivery of accurate information to the public, combating myths around vaccines and vaccination, and exchanging best practices.

HARD LAW

Hard law refers to legislation that takes precedence over national laws and is binding on national authorities. It consists of EU Regulations, Directives and Decisions.

HOPE intervenes at three different stages in the decision-making process: when the first discussions take place usually with the European Commission, when a proposal is adopted by the Commission and submitted to the European Parliament and Council, and finally when legislation is adopted and enters the implementation phase or the transposition process. This means different types of involvement for HOPE Central Office and HOPE Members.

In 2025, among the major issues regarding EU political activity, the following were of particular importance: the Medical Devices and In Vitro Diagnostic regulations, the European Health Data Space, the revision of the Pharmaceutical Legislation, the Critical Medicines Act. In addition, several other initiatives were on the EU political agenda: the legislative proposal on Artificial Intelligence and the ePrivacy Package.

Other pieces of legislation that had been adopted in previous years were still on HOPE's agenda, as they were in the implementation process or being reviewed by the Commission: the Falsified Medicines Directive; the Health Technology Assessment Regulation; the Cybersecurity Package; the Cross-border Healthcare Directive and the European Reference Networks; the Energy Efficiency Directive; the Energy Performance of Buildings Directive; the Renewable Energy Directive, the Emission Trading Schemes; the Water Directive; the Fluorinated Greenhouse Gases; the State Aid Package; the Restriction of Hazardous Substances.

HOPE closely monitored developments and provided input and participated in key meetings where these issues were debated. It made its voice heard by replying to public consultations organised by the European institutions and agencies.

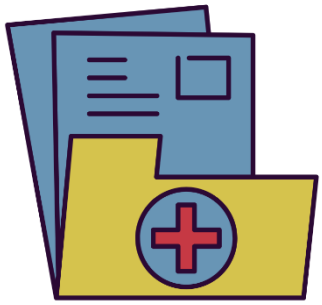
I. DIRECTIVES, REGULATIONS, AND DECISIONS ADOPTED IN 2025

European Health Data Space

The European Health Data Space (EHDS) subject was brought to conclusion at the start of 2025 with a Council re-vote under the Polish EU presidency.

Three years after the initial release of the legislative proposal by the European Commission, this notably shifted the focus of the debate from defining the content of the new regulation (effective beginning on 27 March 2027) to its implementation, at a time when Europe was increasingly under pressure to prove its international competitiveness in the health data realm.

Through meetings of the European Commission's eHealth Stakeholder Group, topical webinars organised by the EU and on- and offline events put on by many other stakeholders, HOPE continued to monitor relevant policy developments and communicated key points contained in its 2023 EHDS Position Paper, further refined by inputs received from HOPE liaison officers. Throughout the year, HOPE also pursued formal and informal exchanges, including with EU policymakers and representatives of organisations representing healthcare professionals, patients, public health, and payers.



Uncertainty remains over the extent to which the Member States will make use of the discretionary powers granted to them in the final EHDS text, especially regarding opt-out mechanisms and the integration of additional data sources. Since multiple Implementing Acts remain to be defined through guidelines and technical specifications, the Joint Action TEHDAS-2 released two comprehensive public consultations (January-February 2025: data discovery and dataset description; October-November 2025: fees, penalties, data access, data protection, secure IT systems and citizens' rights) containing draft technical guidelines for key EHDS components. Overall, 15 documents were brought to consultation.

HOPE commented on those documents relevant to hospitals and healthcare services as data holders and encouraged its members to also participate individually given the complexity of the subject matter and the opportunity to address issues of specific relevance at national and regional level.

HOPE also participated in TEHDAS2 stakeholder meetings, including a workshop on collaboration for data discovery and multi-country applications in November 2025. The objective was to discuss and gain new insights into issues related to the secondary use of data under the EHDS, such as how the principal stakeholders (including Health Data Access Bodies (HDABs), data holders, data users, trusted data holders) will interact and support each other in practice to avoid duplication, overly complex data access requests and unclear responsibilities. Many of the details regarding the secondary use of personal electronic health data will depend on Member State rules.

At the end of 2025, the Commission launched a public consultation on the draft Implementing Act for the establishment and operations of the EHDS Board, which HOPE also replied to, stressing the importance of ensuring that the Board receives advice from the members of the future EHDS Stakeholder Forum.

EU Water Legislation

EU water policy is established by the Water Framework Directive (WFD) and its daughter directives, the Groundwater Directive and the Environment Quality Standards Directive. Dating from the 1970s, the Bathing Water Directive was revised in 2006, while the Drinking Water Directive was recast in 2018. Finally, the Urban Wastewater Treatment Directive (UWWTD) and the Nitrates Directives dealing with pollutants were adopted in the 1990s.

In March 2019, the Commission adopted a Communication outlining a set of actions addressing the multifaceted challenges that the release of pharmaceuticals poses to the environment: the 'Strategic Approach to Pharmaceuticals in the Environment'.

The Commission published on 25 November 2020 an overview of the progress made in implementing the actions of the Strategic Approach to Pharmaceuticals in the Environment. After a public consultation in 2021, the Commission published its proposal on the revision of the Directive on 'Water pollution: EU rules on urban wastewater treatment' on 26 October 2022.

The revised Urban Wastewater Treatment Directive was published on 12 December 2024 in the EU Official Journal. It came into force on 1 January 2025. Member States have until 31 July 2027 to transpose the text into national law. In 2028, the reporting system will move to report under the revised Directive.

HOPE checked for possible impact on hospitals and health care services.

Services Of General Economic Interest

The European Commission adopted on 16 December 2025 a decision on the application of Article 106(2) of the Treaty on the Functioning of the European Union to State aid in the form of public service compensation granted to certain undertakings entrusted with the operation of services of general economic interest and repealing Decision 2012/21/EU.

This decision sets out the conditions under which state aid in the form of public service compensation granted to certain undertakings entrusted with the operation of services of general economic interest ('SGEI') is compatible with the internal market and exempt from the requirement of notification laid down in Article 108(3) of the Treaty.

As requested by HOPE the status quo remains as the scope on article 2 states that:

- "1. The exemption from the requirement of notification laid down in Article 108(3) of the Treaty set out in this Decision applies to State aid in the form of public service compensation, granted to undertakings entrusted with the operation of SGEI as referred to in Article 106(2) of the Treaty, which falls within one of the following categories:
    - (b) compensation for the provision of SGEI by hospitals providing medical care, including, where applicable, emergency services; the pursuit of ancillary activities directly related to the main activities, notably in the field of research, does not, however, prevent the application of this paragraph;

- (c) compensation for the provision of SGEI meeting social needs as regards health and long-term care, childcare, access to and reintegration into the labour market, and the care and social inclusion of vulnerable groups including accessibility and assistive technology services for persons with disabilities."

II. DIRECTIVES AND REGULATIONS ADOPTED IN PREVIOUS YEARS

Blood, Tissues, and Cells

SoHO Coordination Board

Following the adoption of the Regulation (EU) 2024/1938) of Substances of Human Origin (SoHO) in 2024, the main activity turned around the SoHO Coordination Board (SCB) the body that supports a coordinated application of the SoHO Regulation within Member States (MS).

Experts can be invited by the co-chairs to attend one or more agenda items of an SCB or working group meeting; they are selected from the stakeholders' applications that have already been considered eligible by the Commission. HOPE is part of this stakeholder list.

It met five times in 2025; the most important meeting took place on 10 February and 11 February 2025 in Brussels. This was attended by members and alternates from all Member States and observers. The SoHO team provided an update on the progress made and the future responsibilities of the registration and authorization workgroup within the SCB. Guidance documents for hospital entities are currently being developed as part of the Readership Project under the EU4Health initiative. These outcomes will be evaluated by the Registration and Authorisation working group and will eventually require endorsement by the SCB. Furthermore, guidance documents for the registration and authorization of non-hospital entities, as well as for coordinated awareness-building for new SoHO entities must be developed, such as laboratories, registries, human milk banks, and faecal microbiota transplant (FMT) facilities. The Registration and Authorisation working group will need to prepare these documents for endorsement by the SCB.

During the February meeting, the SoHO team outlined an upcoming study on promoting regulatory coherence for SoHO within other cross-sector legal frameworks. This contract service study aims to integrate multiple sector authorities to collaborate and establish common agendas and where possible agreed solutions on specific issues, focusing on the interface of SoHO with medical devices and medicinal products, including advanced therapies. The SoHO Team also noted ongoing EU4H initiatives addressing issues like human breast milk and faecal microbiota transplants, offering new tools and training for professionals and authorities.

To supplement the work being done by EU coordination groups like the SCB, HaDEA published an EU4Health call for tenders to form a Single Framework Contract for Member States in the field of SoHO. The estimated total value is €4,000,000 and the call closed on 23 October 2025. Activities funded under this call will be carried out in accordance with the conditions and procedures set out in the SoHO Regulation, the Commission implementing

and delegated acts to be adopted, as well as the guidance, procedural steps, and the timeframe and templates adopted by the SoHO SCB.

The aim is to support the implementation of new EU rules in the continued provision of SoHO therapies, based on high standards of safety and quality and up-to-date technical rules. The outcomes of this action will be the production of good practices, inspection reports, technical assessments and opinions.

Campaign to increase plasma donation

In line with the EU SoHO Regulation, and articles 62 and 72 in particular, HOPE joined the European Blood Alliance in a campaign launched in 2025 to increase plasma donation: 'Commit to Plasma'.

Hundreds of thousands of Europeans depend on plasma medicines. These can only be made from human plasma. As recently as 2011, enough plasma was collected in the EU to meet the usage of EU patients. Since then, however, despite increases in both public and commercial plasma collections, the increasing demand for plasma has exceeded supply. EU countries do not currently collect enough plasma to meet the needs of EU patients, who have experienced shortages of plasma medicines (plasma-derived medicinal products, or PDMPs).

Europe's insufficient collection and its subsequent reliance on plasma imports, primarily from the US, endanger patient access and thus undermines the health security of EU Member States and Europe as a whole. Experiences during the COVID-19 pandemic and times of increased geopolitical tensions show the dangerous consequences of relying heavily on imports of plasma to manufacture these essential plasma medicines. Europe must address this strategic vulnerability and no longer leave its citizens exposed to this threat.

The campaign, which will continue into the 2026, calls on national authorities to: Publish National Plasma Plans by the end of 2026, with ambitious and clear commitments for national plasma collection goals; earmark the resources required to achieve these goals; establish or intensify their cooperation with the national representatives of all stakeholders supporting this call to work together in reaching these goals; and ensure optimal use of all available plasma.

It also calls on the European Commission, the European Parliament, as well as other relevant institutions such as EDQM, to:

- Work towards equipping Europe with a European Plasma Coordination Plan by 2027, building on the National Plasma plans and to be reviewed regularly;
- Urge national authorities to commit to increasing public plasma collection, as above, through all means at their disposal, be it through the future European Plasma Coordination Plan or more formal instruments at their disposal such as communications, reports or hearings;

- Collect and share national data and practices to accompany plasma-collection progress of Member States and Europe as a whole. Reliable, publicly accessible data is missing today;
- Engage with other regional and global organisations to exchange data, policies and establish a dialogue to address plasma shortages at a global level.

Fluorinated Greenhouse Gases

Fluorinated gases (F-gases) are man-made greenhouse gases used in various products and appliances (e.g., fridges, air-conditioning units). Their emissions contribute to climate warming.

On 5 April 2022, the Commission released the Proposal for a Regulation of the European Parliament and of the Council on fluorinated greenhouse gases, amending Directive (EU) 2019/1937 and repealing Regulation (EU) No 517/2014.

On 7 February 2024, the final act of the F-gases Regulation (EU) 2024/573 and the Ozone Depleting Substances (ODS) (EU) 2024/590 were signed with a publication in the Official Journal of the European Union on 20 February 2024. Both regulations started to apply on 11 March 2024.

The Commission introduced a series of new implementing acts to support the F-gases Directive that HOPE checked for possible impact on hospitals and health care services. The Commission Implementing Regulation (EU) 2024/3122 is on the exemption for using F-gases with a GWP of 150 or more in blood transport boxes and blood plasma contact shock freezers and is applicable from 1 January 2025 to 31 December 2026.

Cross-Border Threats

On 11 November 2020, the Commission published four documents: a Communication called 'Building a European Health Union: preparedness and resilience'; a Proposal for a Regulation on serious cross-border threats to health; a Proposal for a Regulation to extend the mandate of the European Medicines Agency (EMA); a Proposal for a Regulation to extend the mandate of the European Centre for Disease Prevention and Control (ECDC).

With these, the Commission aimed to create an EU-wide pandemic plan; develop a new agency for health emergencies; require countries to submit more health data (for example hospital bed availability, critical care capacity); have the ECDC make policy recommendations; have the EMA manage shortages of medicines and medical devices.

Cross-border threats

The Regulation on Serious Cross-border Threats to Health (EU) 2022/2371 was published in the Official Journal on 6 December 2022. It entered into force 20 days after its publication. The regulation establishes a Health Crisis Board to coordinate and integrate actions related to crisis-relevant medical countermeasures at EU level. The Regulation sets up monitoring mechanisms and enables the procurement and purchase of

countermeasures. It stipulates how to activate EU FAB facilities – a network of ever warm production capacities for vaccines and medicines manufacturing – as well as emergency research.

European Centre of Disease Prevention and Control Mandate

The Regulation (EU) 2022/2370 amending Regulation (EC) No 851/2004 establishing a European Centre for Disease Prevention and Control was published on 6 December 2022. It entered into force 20 days after its publication in the Official Journal of the European Union.

European Medicines Agency Mandate

On 1 March 2022, the new regulation for EMA came into force. This regulation reinforces EMA's role in crisis preparedness and management of medicinal products and medical devices. It puts some of the structures established by EMA during the COVID-19 pandemic on a more permanent footing, while entrusting several new tasks to the agency.

Health Emergency Preparedness and Response Authority (HERA)

The Commission adopted the decision establishing HERA on 16 September 2021. It was established as an internal Commission structure for operational reasons.

The core mission of HERA was defined by the Commission as the following:

- strengthen health security coordination within the Union during preparedness and crisis response times, and bringing together the Member States, the industry and the relevant stakeholders in a common effort;
- address vulnerabilities and strategic dependencies within the Union related to the development, production, procurement, stockpiling and distribution of medical countermeasures;
- contribute to reinforcing the global health emergency preparedness and response architecture.

On 26 March 2025, the Commission published the Review of the Implementation of the Operation of the Health Emergency Preparedness and Response Authority assessing the work of HERA since its creation. The Commission acknowledged the central role of HERA regarding EU's health security, while identifying areas where more work is needed.

Since 2022, HOPE has been a representative stakeholder for the HERA Civil Society Forum (CSF). The forum, as a sub-group of the HERA Advisory Forum, is intended to help to ensure that the HERA receives regular input on the views and opinions of the civil society stakeholders. The last meeting of the CSF took place on 18 March 2025. After an open call for interest, a new edition of the CSF was launched during the year with a first meeting held on 4 December 2025 that HOPE attended.

Health Technology Assessment

Health Technology Assessment (HTA) is a tool for Member States to ensure the accessibility, quality and sustainability of healthcare, as it enables them to allocate national resources to effective health interventions. HOPE has been working on this issue since the first European project 20 years ago.

Regulation 2021/2282 on Health Technology Assessment came into force on 12 January 2025. The text was published in the Official Journal of the EU on 22 December 2021. During this three-year transitional period, the Commission and the Member States prepared by setting up the necessary governance structure and drafting preparatory documents to support an effective application.

From 12 January 2025, these new rules (technology assessment) have applied to applications for marketing authorisation for a new cancer medicine or an advanced therapy medicinal product (ATMP). The rules will be extended to orphan medicines in January 2028 and will cover all new medicinal products as of 2030. Selected high-risk medical devices will also be assessed as of 2026.

The rules apply to companies seeking marketing authorisation for their products, through a new permanent European framework for HTA (single submission dossier at EU level).

HTA rolling implementation plan

The HTA rolling plan contains a list of key activities that the Commission has carried out or intends to carry out in preparation for the implementation of Regulation 2021/2282 on Health Technology Assessment (the HTAR).

The plan is subject to regular review to provide national authorities and stakeholders with the most updated information. It is applicable since 12 January 2025.

Implementing regulation establishing the rules for joint scientific consultations on MD and IvD

On 24 January 2025, the Commission adopted an implementing regulation establishing the rules for joint scientific consultations on medical devices and *in vitro* diagnostic medical devices, under the Health Technology Assessment Regulation.

The implementing act provides detailed procedural rules for the joint scientific consultations, also known as scientific advice, covering:

- the submission of requests from health technology developers;
- the selection and consultation of stakeholder organisations and patients, clinical and other relevant experts;
- cooperation with the European Medicines Agency (EMA) where a medical device developer requests a joint scientific consultation to be undertaken, in parallel with an expert panel consultation.

Joint scientific consultations enable health technology developers to exchange information with HTA bodies on their development plans for a medical device or an *in vitro* diagnostic medical device, within the scope of the HTA Regulation. They allow developers to obtain guidance on the development of clinical evidence likely to be required for subsequent joint clinical assessments of such devices.

The HTA Regulation provides for the adoption of implementing acts, detailing the procedural rules for the different elements in the Regulation. This is the fifth implementing act adopted under the HTA Regulation.

Joint scientific consultations on medical devices

On 3 February 2025, the Commission has launched the first request submission period for joint scientific consultations (JSCs) under the Health Technology Assessment Regulation (EU) 2021/2282.

The JSCs enable health technology developers (HTDs) to exchange information with regulatory authorities on their development plans for a medicinal product or medical device. They also enable HTDs to obtain guidance on the information, data, analyses and other evidence that are likely to be required from clinical studies for the joint clinical assessment of those products. The JSCs are conducted by the JSC subgroup of the Member State Coordination Group for Health Technology Assessment (HTA CG).

Stakeholder meetings

HOPE is part of the HTA stakeholder network. The fifth meeting of the Health Technology Assessment Stakeholder Network (hereafter HTA SN) was held on 1 July 2025 in Brussels. 72 representatives from 50 stakeholder member organisations and 2 observer organisations participated.

The sixth meeting of the HTA SN was held on 24 October 2025 in Brussels. 62 representatives from 48 stakeholder member organisations and one observer organisation participated.

EU Artificial Intelligence Act

Proposed by the Commission in April 2021, the EU Artificial Intelligence Act (AI Act) entered into force on 1 August 2024 as the world's first legal act regulating AI deployment. Most of its rules are meant to be applicable two years after, albeit with some exceptions for specific provisions.

Throughout the political negotiation process and based on its Position Paper, HOPE advocated ethical and fair AI deployment by improving digital health literacy of healthcare professionals and patients, safeguarding fundamental rights, and avoiding an exacerbation of health inequalities resulting from data bias.

The final AI Act stipulates different rules for AI systems based on their risk level (minimal, limited, high-risk and unacceptable) and represents a compromise between the EU's

commitment to human-centric, trustworthy AI and unlocking AI's innovation and commercial potential. The AI Act is also important in the context of AI deployment for the implementation of the European Health Data Space.

In 2025, HOPE continued to keep a close eye on the implementation process as technical work on the EU AI Act continued and important implementing acts remain to be defined. This included the release of Commission guidelines on prohibited AI practices and on AI systems definition (both in February 2025) as well as for providers of General Purpose AI (July 2025), and public consultations to refine details (including copyright-related obligations for General Purpose AI providers, draft implementing act to establish AI regulatory sandboxes). In addition, on 17 December 2025, the Commission published its first draft Code of Practice on marking and labelling of AI-generated content

Despite these developments (following sustained criticism by industry of the original regulatory framework due to its scope and multitude of technical requirements, coupled with a perceived need to ensure Europe's digital competitiveness vis-à-vis international powers which, are taking a lighter approach on AI regulation), the European Commission decided to revisit the AI Act in the autumn as part of wider regulatory simplification measures taken.

NIS-2 Directive

Formally adopted in November 2022 and in force since 2023, the implementation of NIS-2 (Network and Information Security Directive) had not been optimal. In November 2024, the European Commission was forced to open infringement procedures against several Member States because they had not respected the binding transposition deadline. It remained problematic in 2025 although it appears that all EU-27 Member States implemented the law by the end of the year or at least published a draft.

On 26 June 2025, ENISA published a technical guideline for the security measures of the NIS-2 Implementing Regulation to assist digital infrastructures and managed service providers.

To better understand the NIS-2 implementation barriers, HOPE continued to monitor EU and national developments and brought the primary concerns of its 2023 Position on the EU Cybersecurity Framework to representatives of the Commission and the EU Agency for Cybersecurity (ENISA) at stakeholder meetings.

Falsified Medicines

The Falsified Medicines Directive (Directive 2011/62/EU) was published on 1 July 2011 and has been in force since 2 January 2013. It amended Directive 2001/83/EC and it introduced harmonised European measures to fight medicine falsifications and ensure that medicines are safe and that the trade in medicines is rigorously verified. On this basis, the Delegated Regulation 2016/161, laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use, was adopted by the Commission and published in the EU Official Journal on 9 February 2016.

The European Medicines Verification Organisation (EMVO) was created as a joint initiative of EU stakeholders, representing manufacturers (Medicines for Europe, EFPIA, Affordable Medicines Europe), wholesalers (GIRP) and community pharmacists (PGEU). HOPE is member of the Board without voting rights and attends the stakeholder meetings.

In 2025, as in the previous year, HOPE attended the monthly Board meetings as well as the stakeholders' monthly meetings.

Medical Devices and *In-Vitro* Diagnostics

MDR and IVDR

Following the launch in 2010 of a public consultation on the revision of the directive on in vitro diagnostic medical devices to which HOPE responded, the European Commission published in 2012 two proposals of revised regulations: one on medical devices and the other concerning in vitro diagnostics. Following the usual legislative process both texts were finally adopted and published in the Official Journal in May 2017.

The aim of both proposals was to address inconsistencies in how Member States interpret the rules, increase patient safety and transparency, remove obstacles to the internal market and strengthen the rules on traceability.

HOPE closely monitored the legislative process in the European Institutions and advocated that, when done in a safe way, the reuse of medical devices can reduce costs and help protect the environment. Reprocessing medical devices has the following advantages: lower procurement costs, better use of cleaning and sterilisation equipment, less inventory and waste, and lower consumption of raw materials and primary energy.

The new rule on medical devices was supposed to apply from 26 May 2020, but it was first postponed for one year by an extraordinary measure adopted on 23 April 2020, in view of the COVID-19 outbreak. It came into force on 26 May 2021. HOPE published a document summarising the main provisions of the coming legislation, with emphasis on the changes that will extensively influence hospital activities.

Concerning the IVDR, on 15 September 2020, HOPE released a Position on In Vitro Diagnostics Regulation. In this paper, HOPE expressed concern about the date of introduction of the European regulation in the field of in vitro diagnostics (the IVDR), which was scheduled to apply from May 2022. HOPE believed that patient safety and continuity of care could be endangered by this timeframe. Indeed, on 14 October 2021, the Commission proposed a progressive rollout of the new In Vitro Diagnostic Medical Devices Regulation to prevent disruption to the supply of these essential healthcare products. The proposal was adopted by the Parliament and the Council on 15 December 2021. The amending IVDR was published in the Official Journal of the EU on 28 January 2022.

In November 2022, HOPE released a Position Paper to warn about the medical device supply situation facing hospitals today and the risks to patients' health. HOPE highlighted the shortcomings of the MDR, its insufficient implementation as well as the lack of an effective certification infrastructure. HOPE therefore urged the Commission to exercise its

right of initiative and to present a legislative proposal with appropriate solutions as soon as possible.

On 6 January 2023, the Commission adopted a legislative proposal for a regulation amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices. The objective was to give more time to certify medical devices in order to mitigate the risk of shortages. On 16 February 2023 the European Parliament agreed to extend the Medical Devices Regulation (MDR) transition periods. On 7 March 2023, the Council of the EU followed and officially adopted the amendment to the MDR and IVDR. This paved the way for the formal signing of the legislative text on 15 March 2023.

Then on 13 June 2024 the Parliament and the Council adopted Regulation (EU) 2024/1860 amending Regulations (EU) 2017/745 on medical devices (MDR) and (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR) as regards a gradual rollout of the European Database on Medical Devices (Eudamed), the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain *in vitro* diagnostic medical devices.

These measures include granting more time to companies to transition to the new EU rules on IVDs, introducing a new obligation on manufacturers to inform national authorities and the health sector in the event of disruption of supply of certain medical devices and allowing for the gradual rollout of the European Database on Medical Devices (Eudamed).

The Commission decided, however, to open a call for evidence and public consultation at the end of 2024 to assess how the regulations affect the sector's competitiveness and the availability of medical devices in the EU, particularly for orphan and innovative devices. The public consultation was available from 12 December 2024 to 21 March 2025. Responses were obtained from 16 EU Member States, which accounted for 86% of the total responses (332 responses). The majority of replies (42% or 145) were submitted by individuals in Germany and France.

Based on further debates, on 8 September 2025 the Commission launched a consultation on its initiative to simplify EU rules for medical devices and in vitro diagnostics. The feedback to which HOPE replied by a joint letter with Biomed Alliance and the European Patients Forum was open until 6 October 2025.

Finally, on 16 December 2025, the Commission presented its proposal to revise the regulations on medical devices and in vitro diagnostic medical devices.

The proposals aim to simplify EU rules for medical devices, support the digitalisation of procedures, and offer a coherent framework so that companies can respond to changing market conditions and patient needs. To speed up access to medical devices and guarantee a continuous supply, timelines to complete conformity assessments would be introduced.

A stronger role for the European Medicines Agency (EMA) would strengthen coordination at EU level while companies will be offered more scientific, technical, and regulatory expertise. The EMA would also monitor shortages of medical devices, and a list of critical

devices would be created. The reform aims to ensure that patient safety remains the highest priority, while enabling faster access to safe and innovative devices and strengthening the EU's competitiveness in this vital sector. Finally, the proposal would ensure uniform and coherent rules for medical devices incorporating AI applications. Altogether, the Commission considers that these measures would lead to overall cost savings of €3.3 billion per year, including €2.4 billion in annual administrative savings.

The Commission would like to modify how the artificial intelligence regulation applies to medical devices incorporating AI, to limit overlaps and simplify the regulatory framework. Currently, the AI regulation classifies medical devices incorporating AI in Section A of Annex I. The Commission's revision of the regulations moves these devices to Section B of Annex I. As a result, sector-specific legislation, in this case the MDR and IVDR regulations, now takes precedence over the AI regulation regarding medical devices containing AI. The Commission specifies, however, that notified bodies responsible for verifying the compliance of medical devices will continue to work to ensure compliance with the AI regulation, and particularly the obligations concerning high-risk AI, which will continue to apply.

MDCG

Since 2010 HOPE has been a member of the European Commission Expert Group on Medical Devices (MDEG), renamed Medical Devices Coordination Group (MDCG). The group is composed of industry and other stakeholders' representatives and discusses issues related to the implementation of the Medical Devices Directive. Additionally, HOPE is part of its Cybersecurity, EUDAMED and Unique Devices Identification Working Groups as well as the task force on orphan medical devices.

In October 2023, HOPE wrote to the Commission concerning the issue of disappearing medical devices, not limited to devices for children or specific group of patients. In addition, the introduction of new and innovative products in Europe is hampered by the MDR. Quite a lot of innovative new products are developed within (university) hospitals and are brought to the market by startups.

The MDCG met five times in 2025: 18-19 February, 2-3 April, 3-4 June, 24-25 September and on 1 December 2025.

During that last meeting, just two weeks before the publication of the proposed revision, the Commission announced the publication of the notice of functionality for the mandatory use of the first four modules of EUDAMED (Actors, UDI/Devices, NB/Certificates and Market Surveillance modules). The Commission also shared an update on data from the study on monitoring and availability of medical devices. The Commission also confirmed that results from the second survey of economic operators have been published, and a third one will be launched and will remain open until the end of February 2026.

The Commission informed that a conference is scheduled for 16 March 2026 in Brussels with the participation of Commissioner Várhely, high-level representatives from the European Parliament and the Council, stakeholders' representatives and other experts and regulators from the sector. The aim of this conference is to offer an opportunity for reviewing

recent progress and providing an outlook on future developments. Breakout sessions are expected to be co-organised by stakeholders in close collaboration with competent authorities, potentially focusing on key topics such as clinical evidence, optimising conformity assessment process, and breakthrough technologies.

The Commission provided an update on progress on the draft delegated acts for the expansion of the Well-Established Technologies (WET) list, noting that the process is still in the consultation phase with the MDCG, and adoption of the delegated acts should be expected in early 2026. The aim of this measure is to enhance clarity and predictability, expecting to improve the system and offer greater certainty.

The Commission presented the draft guidance developed by the Breakthrough Technologies Task Force, which has undergone several consultations and has been sent for pre-endorsement to the MDCG before final adoption.

Resilience of Critical Entities

On 18 October 2017, the Commission adopted an action plan which proposed new measures to help protect EU citizens against terrorist attacks in public spaces. The Commission set up a High-Risk Security Network in November 2017 to provide a platform for joint training and exercises to improve preparedness against attacks. In December 2017, the Commission launched a public-private Operators Forum bringing together Member States' policy makers and operators from different sectors, such as mass events and entertainment, hospitality, shopping malls, sports and cultural venues, transport hubs and others. HOPE has taken part in several meetings every year since.

A communication from the Commission on the EU Security Union Strategy was published on 24 July 2020, and it mentions critical infrastructure protection and resilience. On 9 December 2020, the Commission adopted a Counter-Terrorism Agenda for the EU.

On 16 December 2020, the Commission then presented a proposal for a directive on the resilience of critical entities (CER Directive) that underpin services fundamental for societal or economic activities in many vital sectors. With this proposal, the Commission intends to create an all-hazards framework to support Member States in ensuring that critical entities are able to prevent, resist, absorb and recover from disruptive incidents, no matter if they are caused by natural hazards, accidents, terrorism, insider threats, or public health emergencies like the one the world faces today. The proposal covers ten sectors: health, energy, transport, banking, financial market infrastructure, drinking water, wastewater, digital infrastructure, public administration and space.

The proposal was presented together with the proposed review of the Network and Information Security Directive (NIS2), which aims to ensure robust cyber resilience on the part of a large number of entities. To ensure alignment between the two instruments, all critical entities identified under the critical entities' resilience directive would be subject to cyber resilience obligations under NIS2.

The Parliament and the Council formally approved the text, and the two institutions signed the final act on 14 December 2022. The text entered into force 20 days after its publication in the Official Journal of the European Union. Member States had to transpose the elements of the directive into national law within 21 months.

On 25 July 2023, the Commission adopted a list of essential services in the eleven sectors covered by the CER. Member States will have to identify the critical entities for the sectors set out in the CER Directive by 17 July 2026.

On 25 June 2024, the Council adopted a recommendation on a blueprint to coordinate a response at EU level to disruptions to critical infrastructure with significant cross border relevance. According to the recommendation, a critical infrastructure incident with significant cross-border relevance takes place is an incident which:

- significantly disrupts the provision of essential services, as assessed by 6 or more affected Member States;
- has a significant disruptive effect on the provision of essential services by a critical entity of European significance;
- significantly disrupts the provision of essential services to or in two more Member States and requires, in agreement with the affected countries, a response at EU level.

The Commission will organise the exercise at EU level not later than 18 months after the adoption of the recommendation.

Safety of Public Places

As part of the implementation of the EU Action Plan for the Protection of Public Spaces, and of the 2020 Counter-Terrorism Agenda for the EU, HOPE joined the EU Forum for the Protection of Public Spaces

HOPE joined the EU Forum for the Protection of Public Spaces that took place in Brussels on 18 June 2025. This was an opportunity to learn more on the report that the Joint Research Centre published on 16 June 2025 presenting an analysis of current and emerging risks in Europe. It highlights the need for a proactive and coordinated approach to risk anticipation, risk assessment and risk governance. In response to the increasingly complex and interconnected risk landscape, the Commission and the High Representative have launched the EU Preparedness Union Strategy. The report aims to support the strategy's objectives by providing a scientific and evidence-based foundation for policy and operational decisions. It examines 47 risks and explores concepts such as cross-border risks, emerging risks, and high-impact low-probability events. The report's methodology involved a wide-ranging review of EU institutions' reports, scientific publications and stakeholder consultations, and provides a multi-faceted perspective on Europe's risk environment.

On 4 December 2025 a second meeting merged in a one-day session with the two branches of the EU Forum that used to meet back-to-back: the Practitioners' Forum and the Operators' Forum. The experience gained throughout the years has highlighted the

significant linkages and common strands of work between the two branches of the EU Forum, considering also the increased role played by the private sector in contributing to the protection of public spaces, alongside and in close coordination with the main responsible state actors.

The meeting also included a tour de table which highlighted the ongoing initiatives at EU level in enhancing the protection of public spaces, presentations of EU-funded projects and the role of the private security sector.

The Commission has published a call for proposals with a budget of 15 million euros to support the implementation of the Critical Entities Resilience (CER) Directive. The call covers the following topics, aiming to support the implementation of the CER Directive: Strengthening the CER framework; Cross-sector and cross-border resilience stress tests of critical infrastructure.

Climate Law

The European Climate Law writes into law the goal set out in the European Green Deal for Europe's economy and society to become climate-neutral by 2050. The regulation entered into force on 29 July 2021. Its objectives are:

- set the long-term direction of travel for meeting the 2050 climate neutrality objective through all policies, in a socially fair and cost-efficient manner;
- set a more ambitious EU 2030 target, to set Europe on a responsible path to becoming climate-neutral by 2050;
- create a system for monitoring progress and for taking further action if needed;
- provide predictability for investors and other economic actors;
- ensure that the transition to climate neutrality is irreversible.

In 2023, for the first time, the Commission assessed progress towards the climate neutrality and adaptation objectives, as required under the European Climate Law. The findings were published as part of the 2023 Climate Action Progress Report and in a separate Staff Working Document on national progress with implementing adaptation.

The EU Climate Law requires the Commission to make a legislative proposal for a 2040 climate target before mid-2024. On 6 February 2024, the Commission published an impact assessment on possible pathways to reach the agreed goal of making the European Union climate neutral by 2050. Based on this impact assessment, the Commission recommends a 90% net greenhouse gas emissions reduction by 2040 compared to 1990 levels, launching a discussion with all stakeholders; a legislative proposal will be made by the next Commission, after the European elections.

On 11 March 2024, the European Climate Risk Assessment (EUCRA) was released, building on and complementing the existing knowledge base on climate impacts and risks for Europe. This assessment aims to help identify policy priorities for climate change adaptation

and for climate-sensitive sectors and shows that Europe's policies and adaptation actions are not keeping pace with the rapidly growing risks.

On 12 March 2024, the Commission published a communication on managing risks in Europe, responding to the EUCRA. This communication sets out how the EU, and its Member States can better anticipate, understand, and address growing climate risks.

In July 2025, the Commission proposed an amendment to the European Climate Law to set an EU climate target for 2040. Following the Commission Political Guidelines for 2024-2029, this amendment proposed to reduce the EU's net greenhouse gas by 90% by 2024. On 5 November 2025, the Council reached an agreement on a new 2040 target of 90% with a domestic target of 85% and up to 5% of international carbon credits. On 10 December 2025, the European Parliament and the Council reached a provisional political agreement.

Energy

In 2020, the Commission presented its 'Renovation Wave' strategy to boost energy renovation of buildings in the EU. This strategy contains an action plan with: (i) regulatory, financing and enabling measures; and (ii) the goal of at least doubling the annual energy renovation rate of buildings by 2030.

The Parliament and the Council reached a provisional agreement on 10 March 2023 regarding the Energy Efficiency Directive. This sets a reduction of primary and final energy consumption by 11.7% at EU level. Annual energy savings by Member States should reach 1.5% on average until 2030, beginning with 1.3% in the period until the end of 2025 and moving progressively towards 1.9% in the period between 2026 and the end of 2030. The Parliament adopted the revised Energy Efficiency Directive on 11 July 2023, as did the Council on 25 July 2023. The act was signed on 13 September 2023 and published in the Official Journal of the European Union. The revised directive entered into force on 10 October 2023. In July 2025, the Commission published a report including an analysis of the data submitted in the 2024 reporting period.

On 7 December 2023, the Council and the Parliament reached a provisional political agreement on the Energy Performance of Buildings Directive (EPBD). The final act was signed on 24 April 2024 and published in the EU Official Journal on 8 May 2024. It entered into force on 28 May 2024. On 30 June 2025, the Commission adopted a support package offering practical guidance to help EU countries implementing and transposing the Energy Performance of Buildings Directive into national law by 29 May 2026. By 31 December 2025, EU countries needed to submit their draft national building renovation plans. On 30 June 2025, the Commission adopted a support package offering practical guidance to help EU countries implementing and transposing the Energy Performance of Buildings Directive into national law by 29 May 2026.

HOPE checked for possible impact on hospitals and health care services.

Workers' Protection from Exposure to Hazardous Medicinal Products

On 18 February 2025 the Commission issued a Communication establishing an indicative list of hazardous medicinal products.

It completes the previous Guidance for the safe management of hazardous medicinal products at work issued by the Commission in 2023. It does not aim to replace HMPs with medicines that are not hazardous or are less hazardous to workers' health.

Through this list, the Commission also aims at improving the quality of the risk assessment according to Directive 89/391/EEC on Carcinogens, Mutagens or Reprotoxic Substances Directive (CMRD) and to provide an EU level approach on this topic.

The Communication follows on Article 18a of Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens, mutagens or reprotoxic substances at work.

It was issued following the request of the co-legislators to develop a definition and establish an indicative list of HMPs or the substances contained therein no later than 5 April 2025.

HMPs are essential in the treatment of patients with a wide range of medical conditions, including cancer and rheumatology. HMPs include notably some antiviral, immunosuppressants and antineoplastics medicines.

Due to their effect on the body, often HMPs fall under the category of carcinogens, mutagens and reprotoxic substances. While they contribute to saving patients' lives, workers who are exposed to them at the workplace may be the subject of unintended effects. Some examples of exposed workers are oncology nurses, oncology pharmacists, radiotherapists and veterinarians in sectors such as healthcare and veterinary care.

On 18 July 2025, the Commission proposed strengthened protections for workers against hazardous chemicals. This represents the sixth revision of the Carcinogens, Mutagens and Reprotoxic Substances Directive (CMRD). In this version, the Commission recommends setting exposure limits for cobalt and inorganic cobalt compounds, polycyclic aromatic hydrocarbons ('PAHs') and 1,4- dioxane. Welding fumes have also been added under the scope of the CMRD.

The Commission's proposal is being discussed by the European Parliament and the Council. Once the directive has been adopted, Member States will have two years to incorporate it into national law.

III. PROPOSED NEW AND REVISED LEGISLATION

Digital Omnibus

On 19 November 2025, following a public consultation launched in September 2025, the European Commission released a so-called "Digital Omnibus package" containing new legislative proposals aiming to simplify EU digital legislation, including modifications to the EU AI Act.

According to the Commission, the public consultation had revealed concerns about the timely implementation of certain key elements of the Act, which were deemed to be complex and costly for companies and public authorities, such as the designation of notifying authorities and the AI literacy obligation. Most importantly, the existence of overlapping rules and timelines for companies emanating from recent EU legislation (including also the Data Act and Cyber Resilience Act) had been flagged as complicating implementation.

Crucially, the AI Omnibus contains a new implementation deadline for certain rules governing high-risk AI systems, now to become applicable only once necessary support tools (including harmonised standards, common specifications, Commission guidelines) are available, as delays are likely to drive up compliance costs. This will be subject to a Commission decision confirming the existence of these supporting measures, effectively pushing back certain provisions to December 2027 and August 2028.

The other sweeping changes proposed around AI include the following measures:

- simplified technical documentation requirements and support for SMEs, and especially also for SMCs (small mid-caps), the latter deemed to be playing a central role in Europe's innovation economy;
- shifting the responsibility for promoting AI literacy from companies to the Commission and Member States;
- issuing Commission guidance on post-market monitoring for providers of high-risk systems to ensure effective compliance;
- relieving providers of AI systems listed in Annex III of the requirement to register them in an EU database (this would also apply to those providers who do not believe their systems pose a significant risk of harm to the health, safety or fundamental rights of natural persons)
- centralising the supervision of many AI systems built on general-purpose AI models or embedded in very large online platforms or search engines within the Commission's AI Office, to avoid diverging national rules and create legal certainty for deployers;
- introducing a new Article to facilitate compliance with data protection law by allowing providers and deployers of AI systems and AI models to exceptionally

process special categories of personal data for the purpose of ensuring bias detection and correction under certain conditions;

- expanding the use of AI regulatory sandboxes and proposing an EU AI regulatory sandbox for certain AI systems that will fall within its supervision. Member States are to be obliged to strengthen cross-border cooperation of their regulatory sandboxes, and the Commission is also proposing changes to the testing of high-risk AI systems in real-world conditions outside regulatory sandboxes.

However, AI is only one of several areas the Digital Omnibus regulatory framework seeks to make lighter. It contains three other elements. The first includes the simplification of cybersecurity reporting via a single-entry interface, allowing companies to meet all their incident-reporting obligations relevant to the NIS2 Directive, the GDPR and the Digital Operational Resilience Act (DORA). It also proposes targeted GDPR amendments to harmonise, clarify and simplify certain rules to boost innovation and support compliance by organisations; the modernisation of cookie rules, and improving access to data by consolidating EU data rules through the Data Act (merging four pieces of legislation for legal clarity); targeted exemptions to some of the Data Act's cloud-switching rules for SMEs (Small and Middle-Size Enterprises) and SMCs; new guidance on compliance with the Data Act through model contractual terms for data access and use, and standard contractual clauses for cloud computing contracts.

The second element is the new Data Union Strategy, which brings additional measures to unlock more high-quality data for AI by expanding access, such as data labs. It also establishes a Legal Helpdesk to support implementation of the Data Act. Europe's data sovereignty is meant to be bolstered through a strategic approach to international data policy including an anti-leakage toolbox, measures to protect sensitive non-personal data and guidelines to assess fair treatment of EU data abroad.

The third element, the European Business Wallets proposal, is meant to enable European companies and public sector bodies to scale up their operations and interactions via a tool allowing for the digital signing, timestamping and sealing of documents; the secure creation, storage and exchange of verified documents; and secure communication with other businesses or public administrations across the EU.

Given the wide-ranging nature of the regulatory simplification amendments proposed in the Digital Omnibus, HOPE began to analyse the content and its potential implications for the hospital and healthcare sector in 2025, with a view to contributing more actively to the evolving discussions in 2026. Indeed, these amendments have been welcomed by centre-right parties in the European Parliament but face strong criticism by digital rights and privacy protection organisations as well as centre-left MEPs.

Pharmaceuticals

On 25 November 2020, the Commission adopted a Pharmaceutical Strategy for Europe with four main objectives: Ensuring access to affordable medicines for patients, and addressing unmet medical needs (e.g. in the areas of antimicrobial resistance, cancer, rare

diseases); Supporting competitiveness, innovation and sustainability of the EU's pharmaceutical industry and the development of high quality, safe, effective and greener medicines; Enhancing crisis preparedness and response mechanisms, and addressing security of supply; Ensuring a strong EU voice in the world, by promoting a high level of quality, efficacy and safety standards.

The Pharmaceutical Strategy for Europe marked the beginning of a process: its implementation included an agenda of legislative and non-legislative actions.

Pharmaceutical legislation

On 30 March 2021, the Commission released a roadmap on the revision of EU Pharmaceuticals legislation, which was open for feedback until 27 April 2021. The Commission then opened a public consultation on the revision on the EU pharmaceutical legislation on 28 September 2021. HOPE contributed to the consultation on 21 December 2021.

The Commission proposed an update of EU pharmaceutical legislation on 26 April 2023. The proposed revision included proposals for a new directive and a new regulation, to revise and replace the existing pharmaceutical legislation, including the legislation on medicines for children and for rare diseases. The key elements of the proposal were the following: Access to medicines; Innovation and competitiveness; Incentives for innovation; Shortages of medicines; Antimicrobial resistance (AMR). The European Parliament adopted its position during the previous legislation which the Council could not.

On 4 June 2025, Member states supported a compromise on the revision of the pharmaceutical legislation proposed by the Polish presidency of the Council of the EU paving the way for inter-institutional talks. This proposal bridged divides between smaller EU countries concerned about access to new medicines and larger, industry-friendly countries pushing more to protect innovation and global competitiveness.

The technical discussions between the Council and the Parliament then began on 17 July 2025 only on the directive.

To prepare for this, the Danish presidency had sought the views of experts from the working group on 'pharmaceutical products and medical devices' regarding the Parliament's mandate during their meeting on 9 July 2025. They asked them about the aspects on which the capitals were 'more flexible' for allowing the Danish presidency to identify its leeway to reach a compromise. Member States were particularly questioned about the issue of shortages and supply security, the duration of regulatory data protection and related incentives, orphan medicines, environmental risk assessment or even digital leaflets.

The presidency had no leeway regarding the duration of regulatory and market data protection, and they considered their proposal to facilitate access to medicines to be more practical and operational than that of the parliamentarians. As expected, the interinstitutional negotiations on the pharmaceutical package held on 7 October 2025 did not lead to major breakthroughs. Only the chapters already approved at the technical level (Chapters 1, 2, 3, and 9 of the Directive, and parts of Chapters 9 and 11 of the Regulation)

received political endorsement. But the meetings allowed each institution to identify the possible room for manoeuvre and flexibility of the others.

The issue of abortive medicines turned out to be the only point of tension among Members of the European Parliament. According to several sources, the rapporteur (EPP) attempted to negotiate an alternative majority with the far right to exclude them from the directive, in line with the Commission's initial proposal but not with the Parliament's position, before being strongly dissuaded by the other political groups.

Finally, the co-legislators reached a political compromise in the early hours of 11 December 2025.

The pharmaceutical package still has some way to go before being adopted. The final technical details of the agreement were refined in interinstitutional meetings at the technical level starting on 12 December 2025 and continuing into the following week.

The Danish Presidency held its debriefing of the trilogue and the agreement with the deputy ambassadors (Coreper 1) on 19 December 2025. However, formal approval of the text was not possible until 2026, first at the deputy ambassadors' level, then in the Council of Ministers.

The timetable was not yet finalised at the end of 2025. Once this step is completed, the European Parliament will have to approve the text at second reading, initially as a recommendation in the Committee on Public Health, before an announcement in plenary session. Only after this can the text be signed and published in the Official Journal of the EU.

Critical Medicines Act

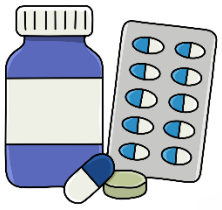
In the EU, most medicine shortages are dealt with at national level. However, the European Medicines Agency (EMA) can be involved in certain situations, for example, when a medicine shortage is linked to a safety concern or affects several Member States. EMA and the Heads of Medicines Agencies (HMA) created an HMA/EMA Task Force on the Availability of Authorised Medicines for Human and Veterinary Use in December 2016 to provide strategic support and advice to tackle disruptions in supply of human and veterinary medicines and to ensure their continued availability.

The COVID-19 pandemic highlighted the EU's long-existing structural problems related to the supply of medicines, and the dependency on third-country imports for certain essential and critical medicines and ingredients. On 15 May 2020, the Parliament released a briefing on the causes of medicine shortage during the novel coronavirus pandemic in the Union, and the responses and solutions at European level. As a direct response to the COVID-19 crisis, the European Health Union Package adopted by the Commission on 11 November 2020, proposed to monitor and mitigate shortages of medicines during a health crisis and to reinforce the EMA capacity.

In the Pharmaceutical Strategy for Europe, the Commission confirmed its willingness to revise the basic pharmaceutical legislation to enhance security of supply and address

shortages and to minimise the impact of medicines shortages on patient care thanks to both preventive and mitigating measure. On 26 February 2021, the Commission launched a "structured dialogue," in which HOPE participated, to address vulnerabilities in the supply of medicines in the EU. The launch of the dialogue followed a request by the Council to reinforce the EU's strategic autonomy in the area of pharmaceutical products. On 9 December 2021, the Commission published a study on medicine shortages in the EU, which had been requested by stakeholders, the Parliament and the Council.

On 17 October 2022, the Commission published a staff working document to present the main findings and proposed solutions during the Structured Dialogue on the Security of Medicines Supply set up as part of the 2020 Pharmaceutical Strategy in which HOPE participated. Following this work, on 24 October 2023, the Commission adopted a set of actions to better prevent and mitigate critical medicine shortages in the EU. The main piece was a communication that built on the work of the "European Health Union", notably the reinforced mandate of the European Medicines Agency and the published pharmaceutical reform.



Following a strong call by Member States at the June 2023 European Council, confirmed in Granada in October 2023, and from the European Parliament, the Commission set up a Critical Medicines Alliance operational in early 2024. It aimed at allowing national authorities, industry, civil society representatives, the Commission and EU agencies to coordinate action at EU level against the shortages of medicines and to address supply chain vulnerabilities. The work of the alliance focused on a targeted number of critical medicines with the highest risk of shortages and impact on healthcare systems and paved the way for the "Critical Medicines Act" that was expected.

On 11 March 2025, the European Commission published its Critical Medicines Act which is set to tackle shortages by addressing supply chain vulnerabilities, including through diversification and international partnerships.

The proposal provides for the following:

- EU funding and State Aid to boost the EU pharmaceutical sector's competitiveness and reduce dependencies on China and India for active substances.
- Promoting that tender winners of public procurement will have to prove their supply chain's strength on top of providing affordable prices.
- It will also facilitate joint procurement beyond cross-border health threats, by allowing Member States to buy other types of medicines together, for example, for rare diseases.

Six months later, on 3 September 2025, the Commission published, its working document intended to explain its policy choices. The Commission fails to explain how it arrived at the measures proposed in the CMA. Normally a routine paper, its absence in the context of the

CMA has been regularly criticized by co-legislators, most recently on 1 September 2025 by MEPs who denounced the speed of the legislative process.

One section of the document does include the list of measures that were considered but not retained in the final proposal, along with an explanation of why they were rejected. What it does not explain, however, is how the Commission arrived at the measures proposed. These are simply said to be expected to have a "positive" impact – without any supporting quantitative data.

The health ministers discussed the Critical Medicines Act in Luxembourg on 20 June 2025 during the Employment, Social Policy, Health and Consumer Affairs Council (Health). For their first technical meeting on the subject, on 3 and 4 July 2025, experts from the 'pharmaceutical products', 'public health', and 'public procurement' groups began with Chapter 4 of the regulation on critical medicines, dedicated to public procurement procedures, collaborative purchasing, and drug storage.

Member States generally supported the Commission's proposals, as was the case at the Health Ministers' Council on 20 June 2025. However, they raised several concerns related to the administrative burden that the introduction of new resilience criteria in public procurement procedures would create. The Commission was supposed to present its working document replacing the impact assessment, but it did not do so – it had until the 11 June 2025 to present this document. The Commission promised the Member States to put it online 'soon'.

In the European Parliament the report on the CMA was presented by rapporteur Tomislav Sokol (EPP Croatia) in the Public Health Committee on 1 September 2025. More than 1300 amendments to the draft report had been tabled. A vote on ENVI opinion took place on 4 November, followed by a vote on ITRE and IMCO opinions on 11 November. The vote in SANT committee on the draft report took place on 15 December 2025.

HOPE submitted in July 2025 its position on the CMA, considering that shortages of medicines have increased in recent years and pose a growing threat to patient care and safety. HOPE then welcomed and joined the Commission's initiative for a Critical Medicines Alliance launched in 2024.

Overall, HOPE welcomes the ambition to strengthen the resilience of the pharmaceutical supply and is positive about the direction of the proposal 'CMA' submitted to consultation. HOPE considers however that:

- the proposed regulation needs a strong impact assessment;
- the proposed regulation needs legal clarity;
- the proposed regulation should stick to a manageable list of critical medicines;
- procurement criteria should be indicative and not mandatory;
- participation in joint procurement should be voluntary;

- the support of public money to industry must be conditional on requirements such as safe deliveries.

The Regulation on critical medicines is now among the top 10 "priority" issues for the Parliament and the Council in 2026.

The two co-legislators and the Commission signed a joint declaration on "EU legislative priorities for 2026" on 18 December 2025. Its annex lists ten issues "to be considered as priorities"—meaning, those on which they must strive to reach an agreement before the end of the year. Most of these texts have already been presented by the Commission in 2025: this is the case for the regulation on critical medicines and the sectoral texts of the next multiannual financial framework for 2028-2034, such as the European Competitiveness Fund. Other Commission initiatives expected in 2026, such as the second regulation on biotechnology, which complements the one specific to the health sector, or the revision of the legislative framework on tobacco, are not included in this top 10.

Antimicrobial resistance

As in previous years, in 2025 HOPE continued to be involved in policy discussions to tackle antimicrobial resistance (AMR), both as an issue covered in the pharmaceutical legislation package and as a non-legislative matter in the context of the ongoing implementation of the Commission's 2017 EU One Health Action Plan against AMR.

A key element of HOPE's policy monitoring remained stakeholder engagement in the second Joint Action on Antimicrobial Resistance and Healthcare Associated Infections (EUJAMRAI2, January 2024 – December 2027), whose first annual meeting HOPE attended on site in Bilbao, Spain, on 12 and 13 March 2025. At the meeting, representatives of the relevant Ministries across the EU-27 Member States reported on their progress made towards a more comprehensive implementation of the Action Plan's One Health vision, notably by including more determinedly the integration of the environmental dimension of AMR. JAMRAI2's goals are to elevate Europe as a model of best practices, supporting the implementation of concrete One Health measures including antimicrobial stewardship and infection prevention and control.

Throughout 2025, JAMRAI2 organised specific workshops as well as monthly 'Tuesday connect' webinars featuring experts, national AMR representatives, and other stakeholders. While the workshops discussed different aspects of tackling AMR (e.g., the environmental dimension, the challenge of matching surveillance targets with IPC implementation, and stepping up the work of JAMRAI2's communicators' network), the webinars shared updates on the Joint Action's work and focused on horizontally relevant topics, such as antimicrobial stewardship programmes.

To gather intelligence and to influence national actions, HOPE also continued to participate in meetings of the European Commission's AMR One Health Network launched in 2023. The two 2025 meetings further notably expanded the range of stakeholders able to contribute to the practical implementation of One Health actions.

The 2025 meetings further underlined the importance of adopting a true One Health approach – the environmental dimension having been notably strengthened over the last year – while reiterating the central roles played by innovation, antimicrobial stewardship, and infection prevention and control. In addition, the meetings stressed the value of multidisciplinary collaboration and ensured that the results of EU-funded projects addressing AMR are communicated widely and effectively.

Due to a technical outage affecting the digital platform hosting the annual European Antibiotic Awareness Day (EAAD) organised by the European Centre for Disease Prevention and Control, the webinar honouring the EAAD took place in early December instead of 18 November. The 2025 theme was 'From Resistance to Resilience: healthcare workers leading the change'.

Late payments

On 12 January 2023, the Commission launched a consultation on late payments that was open until 17 March 2023.

This consultation was even more important for hospitals since HOPE obtained a specific paragraph for hospitals in the Directive 2011/7/EU of the European Parliament and of the Council of 16 February 2011 on combating late payment in commercial transactions. Article 4.4 (Transactions between undertakings and public authorities) states that Member States may extend the time limits of 30 days to a maximum of 60 calendar days for: (b) public entities providing healthcare which are duly recognised for that purpose.

A particular cause for concern in connection with late payment was indeed (and still is) the situation of health services in many Member States. Healthcare systems, as a fundamental part of Europe's social infrastructure, are often obliged to reconcile individual needs with the available finances, as the population of Europe ages, as expectations rise, and as medicine advances. All systems must deal with the challenge of prioritising healthcare in a way that balances the needs of individual patients with the financial resources available. It was considered that Member States should therefore be able to grant public entities providing healthcare a certain amount of flexibility in meeting their commitments. For that purpose, Member States were allowed, under certain conditions, to extend the statutory payment period up to a maximum of 60 calendar days.

The 2015 ex-post evaluation showed that a small number of countries have brought into force provisions that are more favourable to the creditor than those necessary to comply with the minima set out in the directive. Variants include e.g., a higher interest rate, capped payment terms, and the option not to use the exception for public institutions providing healthcare. A limited number of countries have adopted stricter provisions with regards to payment terms.

During its 2,466th meeting on 12 September 2023 the Commission adopted a proposal for a regulation on combating late payment in commercial transactions (europa.eu);

Article 3 (Payment periods) is stricter than the current directive's Articles 3 and 4, by limiting the payment period and the duration of the procedure of acceptance or verification to a maximum of 30 days, and by eliminating any reference to the concept of grossly unfair practices and clauses.

Unsurprisingly, the exceptions for a maximum payment period of 60 days for healthcare and public authorities carrying out economic activities, as set out in Article 4(4)(a) and Article 4(4)(b) of the current directive, are removed.

In the Directive 2011/7/EU of 16 February 2011 on combating late payment in commercial transactions, the article 4 stated that Member States may extend the time limits referred to in point (a) of paragraph 3 up to a maximum of 60 calendar days for: (b) public entities providing healthcare which are duly recognised for that purpose."

On 20 March 2024, the IMCO Committee in the European Parliament adopted its position. The report aimed to improve the payment discipline of all actors (large companies, SMEs, and public authorities) and to boost the competitiveness of companies, in particular SMEs. The draft text puts in place a stricter maximum payment term of 30 in both business- to-business (B2B) and government-to-business (G2B) transactions (where the public authority is the debtor), aiming to standardise timely payments among companies and public authorities.

The request for more flexibility for the healthcare sector was not taken into consideration; however, an amendment proposes that a procedure of acceptance or verification lasting longer than 30 days may be provided for in national law. But such a longer duration is without prejudice to the provisions on the payment period referred to in this article.

The draft report, which was adopted with 33 votes in favour, 10 against and 2 abstentions, was put to a vote at the 23 April 2024 plenary session and will constitute the Parliament's position at first reading. The Parliament adopted by 459 votes to 96, with 54 abstentions, a legislative resolution on the proposal for a regulation of the Parliament and of the Council on combating late payment in commercial transactions.

The Parliament's position adopted at first reading under the ordinary legislative procedure amends the proposal on several aspects. In commercial transactions, the payment period should not exceed 30 calendar days, from the date of the receipt of the invoice or an equivalent request for payment by the debtor. In commercial transactions between undertakings, where expressly agreed in the contract, the payment period may be extended up to 60 calendar days.

Member States should introduce appropriate measures to improve public authorities payment practices towards undertakings by introducing measures to ensure that an undertaking which is a creditor is able to obtain upon request to the public authority, which has not paid the amount due within the maximum payment period, the offsetting of the amount due against any outstanding amount that the creditor has towards the same public authority.

It should not be possible for the creditor to waive its right to obtain interest for late payment when the debtor is a public authority or a large undertaking. Where the conditions are satisfied, interest for late payment should start accruing from the day following the expiry of the contractual or statutory payment period.

Members considered that where interest for late payment becomes payable, a flat fee compensation for recovery costs should be automatically due by the debtor to the creditor and should amount to a fixed sum of €50, per every single commercial transaction of a value between €0 and €1,500, € 100 per every single commercial transaction of a value between €1,501 and €15,000, and €150 per every single commercial transaction above €15,000.

After the European elections, IMCO Committee appointed on 3 October 2024 MEP Ivars Ijabs (Renew, Latvia) as the new rapporteur. In the Council, after discussions, little progress was made on the matter, which is now deemed as blocked.

Public Procurement

The European Commission decided in late 2024 to evaluate Directives 2014/23/EU on concession contracts, and 2014/24/EU on public procurement by entities operating water, energy, transport and postal services. The Commission received 949 contributions on how to assess whether the rules of the directives are working as intended.

On 13 May 2025, the Intergroup on the Social Economy and Services of General Interest hosted a high-level event at the European Parliament to discuss the future of the EU public procurement directive. During the event, key EU and national leaders emphasised the need to align procurement policies with social goals, including SEE President Juan Antonio Pedreño and Director Sarah de Heusch met with Spanish Vice-President Yolanda Díaz and other officials to reinforce collaboration between EU institutions and Member States, aiming to strengthen synergies for a strong European social economy ecosystem. They also highlighted strong political support for using public procurement as a strategic tool to advance the social economy and services of general interest. The proceedings were made in July 2025.

On 7 July 2025 the Internal Market Committee (IMCO) of the European Parliament adopted its own initiative report on the reform of public procurement, which the Commission is set to present by the end of 2026.

According to the press release following the publication of the report, the sole criterion of price should not be sufficient to award a public contract – which is mostly the case for medicines. The quality of the project and its social and environmental impacts must also be considered. Furthermore, there will be a focus on facilitating access for small and medium-sized enterprises (SMEs) to these public contracts – e.g., by simplifying the law – and on prioritising local and European projects. The Commission has already proposed introducing similar criteria for critical medicines.

Thirty-four MEPs voted in favour of the report, from Renew liberals to ultra-conservatives of ECR, including the right of PPE and with the votes of a majority of the Greens/EFA. Thirteen

MEPs voted against, including all social democrats (S&D), who didn't find it ambitious enough.

In the Commission's 2024-2029 political guidelines, a revision of the public procurement directives is mentioned. In its call for contributions, the Commission identified four main issues related to the current rules: the complexity and legal uncertainties of the current framework, particularly concerning tendering procedures and the consistency of the rules with other European legislation; the difficulty in accessing tenders across borders within the internal market; the limited leverage of the current rules to support the EU's new strategic priorities, particularly innovation, European sovereignty, and social and environmental dimensions; and finally, the weakness of the governance and organisation of public procurement: unequal capacities between different authorities, lack of interoperability of portals, etc.

Based on these observations, the Commission outlined three objectives for the revised framework. First, simplify public procurement procedures by developing a more coherent legal framework and creating a digital tendering platform. Next, implement a "Made in Europe" criterion to reinforce the priority of strategic autonomy and European sovereignty. Finally, further align public procurement with EU priorities (social, innovation, environment) by introducing new criteria.

The consultation period on the directives and proposed changes started on 3 November 2025 and concluded on 26 January 2026.

Biotech Act

Following the Draghi report, the Commission considers that EU is lagging behind global competitors in this area, due to "insufficient funding, regulatory bottlenecks and barriers to innovation."

The Biotech Act proposed by the Commission on 16 December 2025 aims to increase Europe's biotechnology potential by supporting the transition of innovative ideas from laboratory to market. It aims to explore new means of funding and investment for biotech companies, through a new health biotech investment pilot to be developed in cooperation with the EIB Group. It aims to boost bio-manufacturing via targeted support.

The Act would incentivise companies to conduct research and production within Europe, accelerate clinical trials authorisations across countries, and fast-track the development of cutting-edge therapies using AI, data and regulatory sandboxes. Furthermore, it would simplify EU regulations to reduce costs and burdens for companies. For complex innovative products, it would establish single regulatory pathways. Ultimately, the Act aims to build a world-leading health biotech industry that delivers for European patients.

The text applies to the entire lifecycle of health biotechnologies. In industrial terms, it draws heavily on the regulation on critical medicines. The Commission plans to implement strategic projects to "strengthen the industrial capacity and value chains" of health

biotechnologies in Europe. This paves the way for accelerated licensing and other support measures.

Regarding access to financing, the European Investment Bank (EIB) and the Commission announced in a press release the earmarking of €10 billion for the 2026-2027 period, under the name 'BioTechEU'.

The biotechnology regulation also provides a twelve-month extension of the Supplementary Protection Certificate (SPC) for medicines developed using biotechnological processes and advanced therapy medicinal products (ATMPs). It also creates a regulatory sandbox for biotechnological health products that are in the early stages of development and introduces targeted amendments to clinical trial regulations to reduce approval times and create sandboxes for clinical trials and simplified procedures for multinational clinical trials.

The extension of intellectual property rights in the biotechnology regulation reignites certain debates surrounding the pharmaceutical package. This is one of the key proposals of the biotechnology regulation.

AI Civil Liability

Published in September 2022 alongside the Product Liability Directive revision in response to a 2020 European Parliament own-initiative resolution, the draft directive on adapting non-contractual civil liability rules to artificial intelligence (AI Liability Directive – AILD) was formally withdrawn by the European Commission in 2025. Henna Virkkunen, the Commission's Executive Vice-President for Technological Sovereignty defended the decision by noting that the AILD would have led to fragmented rules across EU Member States and that new AI liability rules would not be drafted until the AI Act was fully implemented.

As a complement to the AI Act, the draft directive aimed, inter alia, to establish uniform rules for access to information and alleviation of the burden of proof in relation to damage caused by AI systems. It further aimed to give broader protection for victims and harmonise rules for compensation claims outside the scope of the Product Liability Directive, in cases where damage is caused by wrongful conduct.

In the Parliament, the Legal Affairs Committee (JURI) designated MEP Axel Voss (EPP, DE) as rapporteur who undertook an in-depth analysis during the second half of 2024. The withdrawal of the directive occurred despite MEPs voting in favour of continuing to work on the matter and opposition expressed by civil society organisations.

However, Big Tech companies questioned the proposal's adequacy and effectiveness, its coherence with the AI Act, its potential detrimental impact on innovation and the interplay between EU and national rules.

ePrivacy

Following years of dormancy after the European Commission's 2017 proposal for a regulation, the ePrivacy package (which was meant to replace the old ePrivacy Directive 2002/58/EC and specify the GDPR) was also withdrawn in early 2025. Although trilogues had begun as far back as May 2021, the co-legislators failed to agree on questions such as the ePrivacy-GDPR relationship; privacy settings; legal grounds for data processing other than consent; the applicability of rules to service providers assisting national security actions; and the concept of public interest as a basis for justifying restrictive measures.

In the context of rapidly boosting Europe's AI capacities and innovation, the ePrivacy Regulation also did not sit well with the Digital Omnibus simplification measures.

SOFT LAW AND OTHER INITIATIVES

In addition to hard law HOPE also closely monitors soft law in areas such as vaccines, cancer, mental health, climate and European Semester.

Soft law refers to non-binding measures, such as action plans, recommendations and opinions, as well as white and green papers, Commission communications, consultations and programmes.

Apply AI Strategy

On 8 October 2025, the European Commission released its Apply AI Strategy, based on inputs received from a public consultation to which HOPE responded in June 2025.

The Apply AI Strategy is the EU's overarching AI sectoral strategy and is meant to realise the EU's ambitions described in the AI Continent Action Plan of April 2025. Designed to enhance AI competitiveness and strengthen technological sovereignty, the Apply AI Strategy aims to boost AI adoption and innovation, particularly among SMEs. It promotes an "AI first" policy encouraging organisations to consider AI when making strategic or policy decisions, balancing the benefits and risks.

The Apply AI Strategy contains 3 sections:

- Sectoral flagships to boost AI adoption across 10 key industry sectors and the public sector. These sectors include healthcare and pharmaceuticals.
- Support measures and actions to increase EU's technological sovereignty by tackling cross-cutting challenges to AI development and adoption. Several workforce training measures are also planned.
- A new governance system, in which the Apply AI Alliance will be the main coordination forum. It will bring together AI providers, industry leaders, academia and the public sector, to ensure policy actions are grounded in real-world needs. Closely connected, the AI Observatory will track AI trends and assess the impact in specific sectors.

It was accompanied by the AI in Science Strategy, which supports and incentivises the development and use of AI by the European scientific community, and by the Data Union Strategy, which aims to ensure the availability of high-quality, large-scale datasets essential for training AI models. One of the flagship measures of the Apply AI Strategy, COMPASS-AI, establishes a community of experts to advance the safe and effective use of AI in healthcare. It will deliver AI deployment guidelines and work to raise AI literacy of healthcare professionals, hospital managers and patients. Its two priority areas will be cancer care and healthcare in remote areas. Supported by partners with extensive networks across hospitals, professional societies and EU AI healthcare projects, the initiative will also launch an interactive digital platform to map best practices and facilitate knowledge exchange.

HOPE had the chance to communicate key points from its consultation response at webinars hosted by the European Commission in October and November 2025, which discussed critical areas for the future deployment of AI in healthcare, the most relevant research directions for AI in health and training and reskilling initiatives required to prepare the health workforce for AI. The question of how major EU initiatives including Virtual Human Twins, 1+Million Genomes and European Cancer Imaging should adapt to fast-paced changes in AI and other evolving technologies was also addressed. Points raised by HOPE included the need to take accountability for AI's environmental impact, the problem of depending on a small group of (non-EU) companies for computer chips and AI-related services, safeguarding the cybersecurity of AI systems and the need for interdisciplinary evaluation and critical thinking skills.

Cancer

Europe's beating Cancer Plan

The Europe's Beating Cancer Plan was presented on 3 February 2021.

The Stakeholder Contact Group, which discusses, advises and collaborates on implementation, had its first meeting on 28 May 2021. HOPE participates in two thematic groups of the Stakeholder Contact Group on the Europe's Beating Cancer Plan: Early detection and diagnosis and treatment; Research, innovation, and digitalisation.

The Commission announced on 29 September 2023 that the European Cancer Imaging Initiative had taken an important first step towards the creation of a federated European cancer imaging data infrastructure, designed to help healthcare providers and research institutes make the best use of innovative solutions for the treatment and management of cancer. The first version of this digital infrastructure, provided by the EUCAIM (EUropean Federation for CAncer IMages) project, includes a public catalogue of cancer imaging datasets from EU-funded projects related to artificial intelligence for medical imaging, as well as a search tool for understanding the information available on the sites of data providers across the EU. In December 2024, the EUCAIM platform was validated and fully populated with data and a prototype of a federated learning and benchmarking platform was available.

On 18 April 2024, HOPE joined the final workshop concerning the study on mapping and evaluating the implementation of the Europe's Beating Cancer Plan (EBCP).

On 4 February 2025, the Commission released a review of the Europe's Beating Cancer Plan. This document reviews the Cancer Plan from 2021 to 2024, looking at what has been achieved and the state of implementation of its various actions. It concludes that the implementation of the Cancer Plan is well underway with the vast majority of actions having been initiated and being put into practice. There could be, however, some issues with the uptake of the Cancer's Plan actions at national, regional, or local level, and their long-term sustainability.

In December 2025, a new Joint Action was launched under the EBCP. The SHIELD Joint Action (Strategies for Health Interventions to Eliminate Infection related Cancers) will work towards preventing infections that can lead to cancer by making it easier to get vaccinated, tested and treated.

Comprehensive Cancer Centres

The aim of the two joint actions – Joint Action on Networks of Expertise (JANE) and Joint Action on network of Comprehensive Cancer Centres (CraNE) – is the co-creation of an EU Network of (national level) Comprehensive Cancer Infrastructures avoiding potential unnecessary duplication of activities. The two joint actions started in November 2022 and ran for 24 months.

On 25 September 2024, HOPE attended the final meeting of the JA JANE at the European Parliament in Brussels. The key aims of JA JANE have been to prepare for actions, lay the groundwork for the next phase (follow-up EU-funded networks with increased financing), and to perform the conceptual work. The next focus of the cancer networks will focus greatly on stepping up prevention.

On 29 January 2025, the second JA of the Networks of Expertise on Cancer (JANE-2) was launched. The objective of the Joint Action is to establish seven Networks of Expertise on cancer in the EU, implementing the recommendations of the 2021 Europe's Beating Cancer Plan. The Networks bring together the highest expertise with the view of improving EU cooperation in the fight against cancer.

The Joint Action CrANE ended in September 2024 and was followed by the launch of Joint Action "European Network of Comprehensive Cancer Centres" (EUnetCCC) in October 2024. The primary objective of the JA EUnetCCC is to create a cohesive and integrated consortium of CCCs across Europe to ensure that all patients, regardless of their location, have access to high-quality care. This network will also serve as a platform for collaboration, allowing Comprehensive Cancer Centres to share best practices, resources and knowledge.

The first EUnetCCC annual meeting took place on 6 and 7 November 2025. The EUnetCCC Annual Meeting is organised under the Joint Action to present key developments, share progress made by the network, and foster strategic dialogue among all partners and stakeholders. The objective of the network is to support cancer patients in accessing high-

quality prevention, diagnosis, treatment and care with the aim of ensuring that 90% of eligible EU cancer patients have access to such centres by 2030.

Cancer Inequalities Registry

On 2 February 2022, the Cancer Inequalities Registry, a flagship initiative of Europe's Beating Cancer Plan, was released. In February 2024, the first analytical report was published, and it focused on "Beating Cancer Inequalities in the EU. Spotlight on cancer prevention and early detection". This analytical report is the third milestone of the European Cancer Inequalities Registry, prepared in collaboration with the OECD.

After a first edition in 2023, the Commission published the 2025 Country Cancer Profiles for all Member States, Norway and Iceland on 3 February 2025. The profiles are published following a bi-annual cycle.

EU Action Plan on the Cybersecurity of Hospitals and Healthcare Providers

In January 2025, the European Commission released its EU Action Plan on the Cybersecurity of Hospitals and Healthcare Providers. It was originally announced in the Political Guidelines of Commission President Ursula von der Leyen, which was already the subject of preliminary discussions during the second half of the previous year when HOPE was invited by the Commission to share its priorities with a view to shaping the plan's content. Since political agreements were found on the Cyber Resilience and Cyber Solidarity Act in 2024, the action plan thus became the focus of HOPE's cybersecurity work. The action plan is structured around four pillars: prevention, detection, response and recovery, and deterrence. Therefore, it includes actions along the entire threat cycle, from risk management and risk assessment to cybersecurity training for healthcare professionals, an EU-wide early subscription warning service, deployment of the EU Cybersecurity Reserve, incident response services and national exercises, as well as effective punishment of cyber threat actors.

The action plan is designed to be implemented in collaboration with healthcare providers, Member States and the cybersecurity community. A public consultation was launched in May 2025 to gather feedback from stakeholders and refine the plan's most impactful actions, based on which the Commission is planning to release recommendations in 2026. HOPE responded to the public consultation and released its own detailed position paper on the action plan in June 2025, the content of which was brought to the attention of the Commission. Moreover, HOPE's application to join the Health Cybersecurity Board, tasked with providing the Commission and ENISA with advice on the action plan's implementation, was successful (see below).

Increased exchanges with HOPE members on the cybersecurity challenge led to an invitation by the Dutch Hospital Association (NVZ – *Nederlandse Vereniging van Ziekenhuizen*) to join a meeting organised by the European Health-ISAC on the margins of the One Cybersecurity Conference in The Hague. The European Health-ISAC is a collective of European healthcare organisations, national and sectoral CSIRTS (Computer Security

Incident Response Teams) and ENISA, focusing on improving cybersecurity and resilience. The goal is for HOPE to coordinate a small network of member experts on healthcare cybersecurity in 2026.

Feedback on HOPE's contributions to the ongoing debate has been positive, and a note released by the Danish EU Council presidency in December 2025 practically mirrors most concerns voiced in HOPE's position paper.

Emphasising the need for increased synergies between cybersecurity actions in healthcare and the EU's wider cybersecurity policy, HOPE responded to the public consultation on the call for evidence on the revision of the Cybersecurity Act (CSA) in June 2025. The revision is to simplify the regulatory landscape and clarify ENISA's role given the existence of new laws (e.g., Cyber Resilience Act, NIS2), while focusing on harmonising definitions, streamlining reporting, etc. A Commission proposal is expected in early 2026.

Health Cybersecurity Advisory Board of the European Commission

Following a call for selection of members issued in May, HOPE was granted a seat, alongside 14 other individual and organisational members, on the European Commission's new Health Cybersecurity Advisory Board. The latter was set up to advise the EU on matters pertaining to the finalisation and implementation of the European Action Plan on the Cybersecurity of Hospitals and Healthcare Providers launched in January 2025. Among other things, the board members will share their views on impactful actions and best practices for cybersecurity in the healthcare sector, facilitate public-private cooperation, disseminate information to health institutions, promote exchanges between cybersecurity and healthcare professionals, and recommend suitable activities for the European Cybersecurity Support Centre for hospitals and healthcare providers to be established by ENISA, the EU Cybersecurity Agency.

The first meeting of the board took place online on 10 November 2025, and it will continue to meet regularly in 2026, with members appointed for a two-year term.

Climate and Environment

On 2 December 2021, an informal deal was made on the EU Environment Action Programme (EAP) between the Parliament and the Council. This programme is the eighth's EAP and will guide the EU environmental policy until 2030, aligning it with the European Green Deal.

Following the Agora in June 2023 which focused on "Climate and Environment for Hospitals and Healthcare Services", HOPE office prepared a report on "Health in Environment and Climate Adaptation Policies," finalised in October 2023. In October 2024, HOPE finalised the report on the 2024 selection of "Environment and Climate Engagement of HOPE Members".

HOPE co-organised an online event entitled 'Climate Resilience – the role of the healthcare sector' on 13 May 2024. This was an opportunity for HOPE to discuss that climate resilience is adding to several pressure factors such as ageing patients, ageing workforce or austerity

policies. The work of HOPE for the last 15 years on adaptation and mitigation was presented.

On 5 March 2025, the HOPE Office met with the European Climate and Health Observatory to discuss a possible collaboration on adaptation topics in regards of climate change. The meeting was also the occasion to discuss the work of the observatory on relevant topics for hospitals.

In August 2025, HOPE contributed to the Lancet Countdown Consultation for the Refinement of Climate Change and Health Indicators. On 1 December 2025, the Commission opened the public consultation for the European climate resilience and management initiative. This initiative aims to set out an integrated framework to support EU countries in ensuring that the action taken measures up to the scale of the challenges ahead. It is currently a proposal for a regulation.

European Semester

The European Semester is a cycle of economic and fiscal policy coordination between the European institutions and the Member States. It started in 2011 but significantly changed under the Juncker Presidency of the European Commission. The European Semester has indeed gained importance over the years as an instrument to influence national reform programmes in the Member States.

On 24 May 2023, the European Commission released the European Semester Spring Package. The European Semester provides a policy coordination framework for securing competitiveness and long-term prosperity, embedding the implementation of the Recovery and Resilience Facility (RFF). The European Semester cycle also provides updated reporting on progress towards the delivery of the Sustainable Development Goals across Member States. The Commission proposes country-specific recommendations to provide guidance to Member States on how to tackle key economic and social challenges that are only partially or not addressed in their recovery and resilience plans. In the country-specific recommendations, the healthcare thematic area is covered for six countries: Estonia, Greece, Latvia, Lithuania, Austria, and Slovenia.

HOPE closely monitored the 2025 European Semester and reported on it via its monthly newsletter.

Union of Skills

On 5 March 2025, the European Commission presented the 'Union of Skills'. It is a response to trends observed over the years, and a Commission survey found more than 40 occupations with EU wide shortages, particularly in sectors such as construction, trades, transport and some healthcare professions.

While the initiative emphasises digital skills, the need for nurses, medical specialists, and care workers is also highlighted. The 'Union of Skills' aims at adopting an overall framework for EU workers and future workers; it also aims to extending this framework to attract third

country nationals through visa benefits, integration and inclusion plans, and setting up special offices in Member States to provide legal support for incoming skilled workers from non-EU/EEA countries.

HOPE was invited by Executive Vice-President Roxana Mînzatu on 16 September 2025 to the Implementation Dialogue on Fair Labour Mobility.

The high-level dialogue covered the free movement of workers, posting of workers and social security coordination. Since the 1950s, extensive EU acquis has been developed to facilitate the free movement of EU citizens across Member States while ensuring the protection of their social security rights and a level playing field among economic operators. These rules have been regularly modernised. The dialogue was an opportunity to reflect on the challenges and avenues presented by the implementation and enforcement of the existing rules with a view to their possible simplification and reduction of administrative burden while maintaining the current level of protection of citizens' and workers' rights. The dialogue was also an opportunity to identify possible further EU actions to address changing work patterns, increasing labour shortages, digitalisation and the need for legal coherence.

Attention was given to the role digitalisation plays and should further play in facilitating both implementation and enforcement in labour mobility.

The discussion was guided by the following questions: What are the main challenges and opportunities for implementation, simplification and enforcement of the current rules/practices related to labour mobility across the EU? How could digitalisation help to further simplify and improve implementation and enforcement of EU labour mobility rules?

The invitations ensured coverage of all actors involved in labour mobility: Member States' authorities, social partners, businesses, labour inspectorates, social security institutions and public employment services.

Safe Hearts Plan

The Safe Hearts Plan, non-legislative, is the first ever comprehensive EU approach to tackling this immense public health challenge. It presents targeted measures to improve prevention, detection and treatment of cardiovascular diseases.

The plan aims to improve heart health by helping individuals with personalised disease prediction tools and therapies, while addressing risk factors like tobacco, unhealthy diets and alcohol. It seeks to bridge research gaps and integrate data, digital solutions and artificial intelligence to strengthen health systems. With levels of early cardiovascular deaths varying significantly across EU countries, the plan emphasises reducing health inequalities and improving access to healthcare and therapies. For example, the Commission will support Member States in developing national cardiovascular health plans, establish dashboards for monitoring health inequalities, and launch an incubator to speed up the use of AI. Beyond public health benefits, the Safe Hearts Plan also strives to bolster the EU economy and stimulate innovation in cardiovascular care, with clear goals set for 2035.

The Healthy Hearts Plan is cautious on taxing ultra-processed foods. Olivér Várhelyi, the European Commissioner for Health, had indeed emphasised the importance of the polluter-pays principle for cardiovascular health on 12 December 2025. While the initial draft of the plan promised the implementation of new taxes on ultra-processed foods, high in fat, sugar, and salt, by 2026, the final text only provides for a "review of appropriate tools, including possible financial actions that could be deployed to support and finance public health actions in the field of primary prevention."

Regarding tobacco control, the Commission confirms its intention to propose a revision of the legislative framework 'in 2026'. It also reaffirms the target of less than 5% of smokers among its adult population by 2040, an objective of the European plan to defeat cancer.

EU Preparedness Union Strategy

On 26 March 2025, the European Commission launched the Preparedness Union Strategy. Drawing from the conclusions of the Niinistö report, this strategy aims at reinforcing the EU's capability to prevent and respond to emerging threats. This strategy includes 30 key actions and a detailed action plan to be implemented within the next two years.

On 17 July 2025, the European Commission proposed to update the Regulation of the EU Civil Protection Mechanism (UCPM), integrating the financing for health emergency preparedness and response, to ensure a comprehensive and integrated EU response to crises. As one of the first deliverables under the EU Preparedness Union Strategy, the new regulation would enhance EU support and solidarity through the UCPM and health emergency preparedness and response.

The Union prevention, preparedness and response plan was adopted on 28 November 2025 and is part of the EU Preparedness Union Strategy. It addresses all potential health hazards and crises, whether natural, accidental or intentional, caused by various threats. It is planned as a living document that will be updated. It will also be tested through simulation exercises, with the first one scheduled for 2026 and with the involvement of Member States, EU agencies and stakeholders to ensure the plan effectiveness and adaptability to new threats.

CHAPTER 3

Knowledge and exchange

Developing knowledge and helping to share good practices and experiences is what HOPE is all about.

In keeping with this aim, HOPE now regularly participates in projects and joint actions. In 2022, the 39th edition of the HOPE exchange programme and its HOPE Agora took place after two years of postponement. HOPE also organised and co-organised online and on-site events and participated as a speaker or contributed to several international events.

KNOWLEDGE AND EXCHANGE

European programmes and projects

I. HOPE AS A PARTNER - ONGOING PROJECTS

DIOPTRA

Dioptra is a Horizon Europe project, aiming to improve colorectal cancer (CRC) screening. Its mission is to use new technologies to assess CRC risk, improve screening, track patients' progress, and incorporate lifestyle and environmental factors into a single protocol for primary care CRC screening. Dioptra uses network modelling and an artificial intelligence-based decision support system.

The 1st online consortium meeting took place on 20 January 2025 with the presence of the project's advisory board. This was an opportunity to present results. In April, the consortium met face-to-face in Graz during a two-day meeting hosted by Dioptra's clinical partner, the Medical University of Graz. During the different sessions, partners discussed the methodology for identifying biomarkers related to colorectal cancer and conducted a risk assessment of the project. Partners also discussed the new EU Health Data Space Regulation (EHDS), which aims to facilitate the exchange of electronic health data across the EU and may therefore have an impact on various EU-funded research consortia that include partners from various countries, including Dioptra.

Finally, towards the end of 2025, Dioptra held its 6th plenary meeting in Bologna, from 22 to 23 October. It was hosted by i2Grow, a consortium partner based in the Emilia-Romagna Region. The meeting gathered over 50 researchers, clinicians, technologists and policy experts from across Europe to review Dioptra progress and agree on future strategies to implement the project's holistic screening protocol. Partners also discussed the Dioptra app, which was launched over the course of 2025. The app features different modules to support screening and promote healthy lifestyles and it is now available for participants involved in the project's piloting phase via Google Play and the Apple Store.

These meeting have set the stage for continued progress in colorectal cancer research, milestones and data-gathering during 2026.

EYP

HOPE is part of the EYP consortium (Empowering Young Patients). The project kicked off activities in January 2025. For the next two years, five partners (Junior Achievement – Italy, Project School, Action Aid – Italy, Officine Buone and HOPE) will work to benchmark best practices in participative processes involving young patients, develop educational resources (particularly fostering life and civic skills) for children undergoing long-term care, promote policy dialogues and advocacy, and build communities of knowledge.

EYP is funded by the Commission's Citizens, Equality, Rights and Values Programme (CERV) under the call 'Rights of the child and children's participation'. In response to the challenges children and adolescents face in hospital settings, the project seeks to promote their inclusion and participation in civic life within hospitals.

Over the course of 2025, HOPE co-authored the "State of Art Report," specifically the sections related to EU policy and legal frameworks for participative processes for children and adolescents. In addition, the report provides summaries of good practices divided into thematic categories:

- improving access to care and accommodation for young patients and their families;
- promoting inclusion through psychosocial support activities;
- raising awareness about going back to a social and fulfilled life; and
- young patients' right to decide and participate.

During 2026, HOPE will continue to support the communication and dissemination work packages, draft policy recommendations, and prepare to host a policy lab based on project outcomes.

FLASH

FLASH, a 4-year project funded by Horizon Europe, is currently analysing healthcare financing mechanisms in Europe. Using a wide range of methodological approaches, it seeks to provide evidence on the ability of existing financing mechanisms and contracts to address challenges and study potential solutions for more effective, efficient and equitable healthcare systems. As one of 16 consortium partners, HOPE contributes to dissemination- and policy-related tasks.

During 2025, FLASH circulated an online survey as part of an important scientific study on the resilience of European hospital systems. The aim of the questionnaire was to identify the personal views of hospital workers concerning hospital resilience during the COVID-19 pandemic. These results are being processed to help project researchers understand how to improve healthcare systems' responses to future crises and to develop effective strategies.

healthRiskAdapt

healthRiskADAPT (User-driven Health risk Assessment Services and Innovative ADAPTation options against Threats from Heatwaves, Air Pollution, Wildfire Emission and Pollen) is a 4-year project (2024-2028) funded by Horizon Europe.

It is working to address health risks associated with climate change, such as heatwaves, air pollution, wildfire emissions, and pollen. The project's objective is to develop and implement a comprehensive health risk assessment system for Mediterranean, Alpine and Continental regions that will empower local and regional authorities to make informed

decisions in strategic planning, management, and daily operational mitigation of health challenges related to climate change.

KEEPCARING

KEEPCARING (Future Proofing Health- and Care Systems Safeguarding Health Care Workers in Hospital Settings) is a 4-year project (2024-2028) financed by Horizon Europe. The project's objective is to (re-)build the wellbeing and resilience of healthcare workers in European hospitals in the surgical pathways, and to promote onboarding and retention by systematically researching factors and signals of job stress and novel mitigating solutions. HOPE supports tasks related to dissemination, communication and stakeholder engagement, including the establishment of an effective strategy and framework and key messages for different target groups.

During 2025, KEEPCARING hosted a webinar, assembly discussions, and developed a short survey. The purpose of the survey was to ascertain the extent to which hospital-based doctors / specialists, nurses, medical / nursing students and other healthcare professionals in the EU experience burnout, as well as closely related factors of stress and resilience. The survey was available in English, German, Dutch and Danish, and remained open until May 2025. It gathered approximately 1,200 responses and formed the basis of the project's first webinar, which took place on 22 May 2025 and was titled "Understanding Stress, Burnout, and Resilience Among Nursing and Medical Professionals in Europe." The webinar served as an introduction of the project to a wider audience and opened a discussion around the preliminary findings of the survey. It covered topics such as the factors influencing stress, burnout, and resilience among healthcare workers across Europe.

The project's 2025 General Assembly was hosted by the University Clinic Eppendorf (UKE) in Hamburg on 2 and 3 October. Partners discussed the use of robots and digital technologies and their impact on operating room staff (doctors, nurses, technicians, etc.), as well as the creation of a repository of existing stress reduction solutions.

As a follow-up to these discussions, a virtual assembly focusing on the co-created AI-driven Change Management Platform (CMP) to be delivered by the project partners was held on 4 December.

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The consortium is led by NILU, a non-profit research institute based in Norway. The kick-off meeting was held in Oslo in November 2024.

LUCIA

LUCIA is a 4-year Horizon Europe project, launched in 2023. It focuses on identifying risks associated with developing lung cancer and its subtypes, as well as the methods best suited for prompt diagnosis. The LUCIA project is creating a toolbox to discover and understand (new) risk factors contributing to lung cancer development, such as personal risk factors, external factor, and cellular processes. HOPE is responsible for communication and dissemination in the project. Since 2024 and throughout 2025, HOPE has also started to work various policy tasks related to the LUCIA.

The LUCIA project is also part of two cancer clusters under the Cancer Mission: the Prevention and Early Detection (Screening) Cluster and the Understanding Cluster (risk factors & determinants). HOPE participates to the communication and dissemination activities, as well as the policy aspect of the clusters.

To mark World Cancer Day 2025 (4 February), the European Health and Digital Executive Agency (HaDEA) organised an event to showcase EU-funded projects, including LUCIA. The event showcased the impact of various grants and tenders managed by HaDEA in relation to the Europe's Beating Cancer Plan and the Cancer Mission.

Later that same month, the eClinical Medicine Journal, part of Lancet Discovery Science, published an article by LUCIA researchers titled. Indeed, 2025 marked an important year for LUCIA's scientific progress. On 27 May, the consortium organised an event on lung cancer prevention and detection. Following an overview of the project and scientific update, participants discussed two topics: (1) From Prevention to Early Detection, Shaping the Future of Cancer Control and Screening; and (2) Cancer Prevention and Early Detection: A Conversation with the Community.

Finally, on 12 June, LUCIA hosted a 'Social Lab' workshop online, bringing together 26 participants from stakeholder organisations, research projects in cancer prevention and lung cancer, and consortium partners. This event was inspired by the previous 'Social Lab' held in Bilbao in May, where participants worked to refine the mitigation measures list of 10 critical barriers to implementing LUCIA technologies in both population-based and precision screening.

SAFEST

HOPE is part of the SAFEST consortium (Improving quality and patient SAFEty in surgical care through STandardisation and harmonisation of perioperative care in Europe), a four-year project funded under the cycle of the EU framework for research and innovation, Horizon Europe.

During 2024, SAFEST compiled just over 200 patient safety recommendations through iterative research and consensus processes. In turn, these recommendations were

integrated into a guided self-evaluation process, which 10 hospitals across Europe (Spain, Czechia, Estonia, Portugal, and The Netherlands) have implemented. Hospitals conducted feasibility and prioritisation exercises to select the recommendations that best fit their contexts with the support of SAFEST researchers and narrowed the list of recommendations to 101.

During 2025, the project released the SAFEST Compass, a conceptual guide that includes 101 Perioperative Patient Safety Recommendations to improve safety and quality of care in hospitals and other healthcare settings. In addition, SAFEST launched the open phase of the guided self-evaluation to assess and strengthen perioperative safety. To date, 70 hospitals across the world have participated in the initiative, which extends the process the initial 10 SAFEST hospitals undertook.

The project will officially end in 2026, but not before HOPE organises one of two final conferences in the context of the annual Agora, which will be held in Lisbon from 29 to 31 May and will focus on 'Patient Safety, Patient Experience'.

HOPE continues to manage the website and content in accessible language. It contributes to other work packages with surveys, translations, editing and proofreading, and participated in identifying existing perioperative standards as part of a multidisciplinary group. Furthermore, HOPE has supported campaigns to promote the open phase of the guided self-evaluation, as well as showcasing the project's innovation spotlights.

II. HOPE AS ADVISOR

HEROES

HOPE joined the 2nd Stakeholder Forum meeting organised by the joint action HEROES (Joint Action on HEalth woRkfOrce to meet health challEngeS) on 17 March 2025.

The Joint Action on HEalth woRkfOrce to meet health challEngeS (HEROES) provides a common platform for participating Member States to exchange expertise and best practices on health workforce (HWF) planning.

In the Joint Action, 19 European countries (51 partners) are working together to improve their health workforce planning capacities to ensure the sustainability, efficiency and resilience of their healthcare systems. It has a duration of 36 months (01/02/2023 – 31/01/2026) with a possible extension of 6 months.

The HEROES online Stakeholder Forum is organised by the Work Package on Communication and Dissemination and together with the coordinators, the team supports knowledge exchange, workshops and JA networking. The forum is intended to facilitate the exchange of experiences and provide an opportunity for dialogue with EU stakeholder representatives interested in health workforce planning, as well as with stakeholder representatives from the participating countries. Thus, the current status of the country implementations, challenges, but also further ideas and solutions could be discussed. Implementers of participating countries may be invited to the forum to present their main

issues. During the forum, participants were informed about JA HEROES progress and their opinions and positions on specific selected issues were collected. The forum could then provide input to the implementers as well as to HEROES policy dialogues and serve as input for the HEROES Policy Board where the Ministries of Health of the participating countries are represented.

In 2025 all the countries must work in parallel at both the national and international level. In particular at the national and EU levels, each country starts the process of policy dialogues, aimed at raising awareness among policy makers and key national/regional and stakeholders about the need to strengthen health workforce planning. At international level, countries start the process of 'mutual learning', to exchange best practices and experiences among themselves.

On 17 September 2025 HOPE joined the policy dialogue "European health workforce development supporting health system transition and sustainability: strategy discussion and action plan".

This policy dialogue aimed to discuss how results achieved under the Joint Action Heroes can inform policies and further support health workforce development in Europe contributing to health system transition and health system sustainability in times of a health workforce crisis. Achievements of the Joint Action HEROES were used as an opportunity to discuss in detail and concretely what's in it for the EU, the Member States, stakeholders, health workers, patients and citizens.

The HEROES Joint Action (HEalth woRkfOrce to meet health challEnges) focuses on health workforce planning and forecasting in the context of system transformation and emerging models of care. The policy dialogue was the first step towards the development of an EU level Action Plan, which is planned as one of the final deliverables of the Joint Action HEROES.

The policy dialogue addressed three specific thematic objectives: Role of Health Workforce Planning in rethinking the healthcare models and in planning and managing the transformation of health systems; Opportunities for strategic use of health workforce planning in countries; Sustainability of results of the Joint Action HEROES as a core element of work on resilience of health systems.

JAMRAI-2

A core element of HOPE's work on antimicrobial resistance (AMR, see above) in 2025, HOPE continued to be an active stakeholder in the JAMRAI-2 – the second Joint Action against Antimicrobial Resistance.

This included contributing the hospital / healthcare perspective to discussions at the JAMRAI-2 2025 annual meeting in Bilbao as well as subsequent topical webinars organised by the JAMRAI-2 coordinating team. While the scope of stakeholder engagement within the Joint Action is somewhat limited given its focus on driving forward changes at the policy level (notably also ensuring that all Member States develop, update and implement true

One Health National Action Plans against AMR, where the environmental dimension is mostly lacking), there is ample room for contributing best practices and other insights from the hospital / healthcare experience.

TEHDAS-2

HOPE continued to provide stakeholder support to TEHDAS-2, the Second Joint Action Towards the European Health Data Space (May 2024 – December 2026). TEHDAS-2 is being implemented by 29 European countries and coordinated by the Finnish Innovation Fund, Sitra. It is funded by the European Commission's EU4Health Programme and the participating countries.

TEHDAS-2 aims to make it easier to use health data in different countries and support the harmonised implementation of the EHDS legislation. Its results will guide health data authorities, data holders and data users in fulfilling their future legal responsibilities.

The project is developing good practices and outline harmonised means of describing data supporting the discovery of health data and streamlining access to datasets. It also plays a key role in developing technical specifications for secure data processing environments as well as cooperation models and guidelines for data access and licensing fees.

HOPE supported the Joint Action through stakeholder inputs shared during TEHDAS-2 meetings and webinars, providing dissemination support, and contributing expert input into public consultations.

HealthIntelAct

HOPE is an associated partner in HealthIntelAct, a research initiative funded by Horizon Europe through the Marie Skłodowska-Curie Actions – Doctoral Networks. HealthIntelAct comprises 17 fellows pursuing PhD trajectories, each working on groundbreaking research projects focused on critical challenges within three key areas: People, Planet, and Prosperity. These interdisciplinary projects, spanning multiple countries and sectors, aim to develop actionable solutions for inclusive, sustainable, and resilient health systems. Over the course of the first three months of 2025, the recruitment process took place across Europe.

HealthIntelAct unites leading universities, healthcare organisations, and industry partners across Europe and beyond to develop tools, frameworks, and training that will shape the future of health and care. Our interdisciplinary approach ensures that solutions are tailored to the needs of diverse decision-makers, from national policymakers to hospital administrators and community leaders.

Caring Nature

HOPE joined the reference stakeholder group of the Caring Nature project, starting in January 2024. The aim of the project is to develop and validate a set of 10 results to reduce environmental impact of building, waste and patient travel, and to increase governance capability and staff engagement towards this reduction.

Throughout November and December 2025, the Caring Nature project held four different workshops on telemedicine, governance, building and waste, presenting the advancements of the project to the reference stakeholder group.

EU-PROMENS

HOPE is part of the EU-PROMENS Core Contact Group. EU-PROMENS is a capacity-building programme on mental health financed by the EU4Health programme and implemented by the project consortium (GFA Consulting Group GmbH, Trimbos Institute, and Mental Health Europe) between January 2024 and December 2026. It seeks to enhance and improve the capacity of health professionals across Europe in the field of mental health. The programme implements flagship 15 'Initiative for more and better trained professionals in the EU' of the Commission's Communication on a comprehensive approach to mental health.

Orphanet

HOPE is a member of the Orphanet International Advisory Board. This body gives recommendations and advises the Orphanet Management Board on the overall strategy of the project.

Orphanet is a resource gathering and improving knowledge on rare diseases so as to improve diagnosis, care and treatment. It aims to provide high-quality information on rare diseases and ensure equal access to knowledge for all stakeholders. Orphanet also maintains the Orphanet rare disease nomenclature (ORPHAnumber), essential in improving the visibility of rare diseases in health and research information systems.

Orphanet was established in 1997 in France by the INSERM (French National Institute for Health and Medical Research). This initiative became a European endeavour in the year 2000, supported by grants from the European Commission. Orphanet has gradually grown to a consortium of 40 countries, within Europe and across the globe.

Hospital Pharmacy Workforce Expert Panel

HOPE is part of the Hospital Pharmacy Workforce Expert Panel set up by the European Association of Hospital Pharmacists. This workforce project aims to gain a deeper understanding of the current situation and the key factors influencing the availability of the hospital pharmacy workforce. To this end, EAHP has formed an expert panel that would contribute to developing and applying the project's methodology and play a crucial role in formulating the results, conclusions, and recommendations for stakeholders on various levels.

III. PROJECTS THAT ENDED IN 2025

RE-SAMPLE

Since 2021, HOPE has been a partner in the RE-SAMPLE project (REal-time data monitoring for Shared, Adaptive, Multi-domain and Personalised prediction and decision-making for Long-term Pulmonary care Ecosystems). Coordinated by the University of Twente, RE-SAMPLE is a large-scale European project in which real-world data monitoring and artificial intelligence (AI) will be used to improve understanding of chronic obstructive pulmonary diseases (COPD) and comorbidity (two or more chronic conditions).

The project's aim is to ensure that patients with complex chronic conditions receive the right care at the right time faster. This type of care focuses on the individual instead of solely the illness. HOPE was work package leader on dissemination and communication. Towards the end of the project, which was extended 6 months to 31 August, HOPE focused on developing policy recommendations based on the RE-SAMPLE's key findings. The extension allowed the project to rectify earlier timeline disruptions caused by the COVID-19 pandemic and to bring the project closer to its key objective of developing AI-powered personalised care.

Consortium partners worked hard throughout 2025 to gather results, analyse them, and develop scientific and policy recommendations. They had an opportunity to showcase them in Vienna at the annual HOPE Agora. From 11 to 13, the RE-SAMPLE consortium gathered one final time in Vienna ahead of the conference. This meeting marked an important milestone to finalise the project's last steps and quality checks before its conclusion in August. Then on 13 June, the project coordinators Monique Tabak (Project Coordinator), Serge Autexier (Technical Coordinator) and Anke Lenferink (Clinical Coordinator) took the stage to present the project's key results to nearly 150 HOPE Exchange participants.

Finally, on 17 November, RE-SAMPLE held its final event on the EU Health Policy Platform (see 'Conferences' section).

IV. INTERNATIONAL INSTITUTIONS

World Health Organization/Europe region

Over the course of 2025, HOPE participated in a number of World Health Organization (WHO) meetings and initiatives, specifically on social prescribing, healthy ageing, financial sustainability, and quality of care standards.

Social Prescribing

Social prescribing is an innovative approach to systematically address health-related, non-medical concerns. It has its starting point in primary care, where staff are sensitised to these concerns and refer patients to specialists with a link-working function if there is a corresponding need. These specialists work with patients to identify their needs and resources and, where appropriate, refer them to community services.

In a webinar series organised by the WHO Collaborating Centre for Health Promotion in Hospitals and Healthcare at the Austrian National Public Health Institute, in cooperation with the WHO Regional Office for Europe, the National Academy for Social Prescribing, and the International Social Prescribing Collaborative, the question of how social prescribing can also be implemented in hospitals, primary care, or the community was explored. What are the commonalities and differences in implementation in different settings?

HOPE attended the webinar 'Social Prescribing and Network Management: Implementation in Community, Primary Care and Hospital Settings' organised on 27 March 2025. And on 24 April 2025, HOPE was also invited to join part 3. During the webinars international experts shared their experience and lay the foundation for an interactive discussion with the participants. The webinar on network management and implementing social prescribing in community, primary care and hospital settings will provide various practical insights.

Population Ageing and Financial Sustainability

On 28 March 2025 HOPE joined the webinar: 'How does population ageing affect health system financial sustainability and affordable access to health care?' Attended by 500 people, this online event brought together international and country experts to explore the relationship between population ageing, health system financial sustainability and financial protection.

During the webinar, experts shared findings from a simulation exercise using the Population Ageing financial Sustainability gap for Health systems (PASH) Simulator and data on catastrophic and impoverishing health spending to assess the likely impact of population ageing on affordable access to health care.

In addition, HOPE participated in a 2-hour online consultation session on 27 May 2025, organised by WHO/Europe. This consultation was a unique opportunity to shape a regional strategy that aims to ensure all people can age with health, dignity, connection, and purpose. Civil society and non-state actors play a critical role in:

- ensuring that the voices of older persons and underserved communities are heard;
- promoting rights-based approaches and culturally relevant implementation;
- supporting accountability and advocacy for inclusive and equitable healthy ageing policies;
- mobilising intergenerational and community-based action.

The session brought together civil society organisations, NGOs, youth networks, and community-based actors to contribute to the development of the WHO European Strategy on Ageing is Living: Promoting a Lifetime of Health and Well-being (2026 - 2030). The breakout discussions focused on the following key areas: framing the vision for healthy ageing, promoting health and well-being, transforming care ecosystems, creating age-friendly environments, as well as challenging ageism and promoting inclusion.

Regional Committee

Finally, on 9 September 2025, HOPE joined a virtual event linked to the 75th Session of the WHO Regional Committee for Europe devoted to "Improving Quality of Care for Better Patient Outcomes Overview."

Quality of care is recognised as a priority in many WHO strategies, including the Second European Programme of Work for the WHO European Region (2026 – 2030). This session explored ways to improve quality and reduce low-value care to enhance patient-centred outcomes. It also showcased transformative partnerships between policymakers and patients. The event's main objective was to inform Member States on how they can further improve care quality and encourage them to join the community of practice dedicated to this goal.

Member States (Greece, Romania and Slovenia) reflected on the relevance of trend data for policy making and reducing low-value care. A practical example was then presented on co-developing quality standards to measure outcomes that matter for child and youth mental health care, followed by use of CAMH Standards for better patient outcomes in Latvia presented by Karina Beinerte, and finally the Spanish System of notification and learning for safety in primary health care presented by Rocio Montiel Villalonga. HOPE looks forward to our collaboration with the WHO/Europe Region in 2026.

EXCHANGE PROGRAMME

HOPE Exchange Programme and Agora 2025: 'Together for Quality!'

From 19 May to 13 June 2025, around 130 healthcare professionals in management positions in different departments participated in a 4-week hospital exchange across 21 countries in Europe. In line with this year's HOPE Agora theme, 'Together for Quality!', participants were asked to observe how hospitals and health care services are using the principle of collaboration to ensure high-quality healthcare. They identified good practices, shortlisted examples, and on 13 and 14 June shared them at HOPE's Agora in Vienna.

HOPE President Eamonn Fitzgerald, chair of the day, welcomed around 200 participants from across Europe. He was joined by HOPE Secretary-General, Pascal Garel, who moderated the event the following day. The conference started off with a presentation by the coordinators of the RE-SAMPLE project, which HOPE is part of. The presentation explained their model of integrated care in complicated COPD (chronic obstructive pulmonary disease) cases, illustrating the importance of collaboration between clinicians and patients to improve the care of people with multi-morbidities.

The policy and political discussions were led by members of the Head of the Austrian Ministry of Social Affairs, Health, Care and Consumer Protection. These focused on key facets of Austria's new healthcare reforms linked to patient safety and quality, presented by Verena Nikolai, Isabella Weber, Eva Potura, Daniela Rojatz and Lukas Teufl. These introductory presentations laid the ground for the country-by-country best practice presentations led by HOPE exchange participants and informal discussions at the World Café, which took place on day two of the HOPE Agora.

CONFERENCES AND EVENTS (CO-)ORGANISED BY HOPE

RE-SAMPLE: Final webinar

On 17 November 2025, RE-SAMPLE held its final event on the EU Health Policy Platform. In this live webinar, the RE-SAMPLE team presented the project's findings to transfer knowledge about data-driven healthcare tools researched and developed within RE-SAMPLE.

The webinar provided insights into the new parameters RE-SAMPLE developed based on real-world data for monitoring chronic obstructive pulmonary disease (COPD) and complex chronic conditions (CCCs), AI-prediction models for flare-ups of COPD and complex CCCs, the project's privacy-preserving platform, and self-management strategies.

To conclude the event, the RE-SAMPLE team presented its open science strategy and its guidelines on how to integrate personalized digital health tools into pan-European chronic healthcare settings.

European Public Health Conference

The 18th European Public Health Conference (EPH) took place from 12 to 14 November 2025 in Helsinki, Finland. The main theme of this year's EPH Conference was 'Investing for sustainable health and well-being'.

The EPH Conference is an annual scientific conference on public health issues in Europe. Each year the conference takes place in a different country by the EPH Conference Foundation in close cooperation with one or more local partner(s). The conference actively seeks a larger partnership with other European NGOs and institutions.

Future of Health Europe

The Future of Health Europe summit took place in London from 30 September to 1 October 2025. This two-day event was designed to give leaders insight and strategies to tackle these challenges and embrace the opportunities in the future of healthcare, with a focus on digital health, health economics, sustainability and inclusivity. This year, the summit incorporated a new focus on AI with a full day dedicated to AI in Health.

Each year, Future of Health Europe aims to convene public, private and civil sector leaders across health and technology to build towards universally excellent healthcare outcomes.

Policymakers, healthcare providers, academics, and scientists who come together with leaders from industry, technology experts, innovators and entrepreneurs, patient associations, charities, and finance.

25th International Conference on Integrated Care

The 25th International Conference on Integrated Care (ICIC25) was held at the Centro Cultural de Belém in Lisbon on 14-16 May 2025.

With the overarching theme 'Synergising Health and Care: Leveraging Integrated Care for a Sustainable Future', the conference gathered leaders, researchers, clinicians, managers, community representatives, patients and caregivers from around the world who are engaged in the design and delivery of integrated health and care.

CHAPTER 4

Publications

In 2025, HOPE released multiple position papers on important policy developments impacting hospitals. The position papers covered the following topics: cybersecurity, AI, the Critical Medicines Act, as well as the EU's proposed plan to strengthen cardiovascular disease care and prevention.

In addition, HOPE also published its annual HOPE Agora Report and weighed in on the legislative proposals to improve hospital participation in the European Research Area.

HOPE Position on the European Action Plan on the cybersecurity of hospitals and healthcare providers

HOPE greatly welcomes the release of the European Commission's Action Plan on the cybersecurity of hospitals and healthcare providers, the prioritisation of which demonstrates political commitment to this issue at a time of great uncertainty. The Communication sends an unmistakable signal to reinforce and harmonise the European planning and coordination effort in the sector and responds to recurring HOPE calls for increased action to better protect the healthcare ecosystem.

All things considered, the Action Plan is comprehensive (covering the entire cyber threat cycle: prevention, detection, response, recovery, deterrence), addresses key healthcare and cybersecurity actors, and emphasises the urgent need for improved reporting as well as guidelines for easy-to- implement good practices and protocols. The importance placed on awareness-raising and training across different healthcare settings in Europe is also appreciated.

There are nonetheless a few points where HOPE feels clarification is required, the proposed actions could be enhanced or modified, or which could risk compromising its effective realisation. HOPE calls on the Commission to swiftly refine the Action Plan based on the inputs received from the public consultation, and to ensure its solid and committed implementation. These include concerns around funding, gaps in the Cybersecurity Support Centre, training and education, and organising regional and national actions, among others.

HOPE contribution to the European Commission Call for Evidence "The revision of the Cybersecurity Act"

Given the continuously evolving nature of cyber-threats affecting the hospital and healthcare sector, HOPE is generally in favour of targeted European coordination and measures that improve resilience, lend support national, regional, and institutional stakeholders' cybersecurity actions, and enhance the protection of fundamental rights. The "European action plan on the cybersecurity of hospitals and healthcare providers" provides an example of how European and national measures can complement each other. Therefore, it appears sensible to adapt the 2019 Cybersecurity Act (CSA) to reflect legislative developments that have altered the cybersecurity ecosystem over the last six years, and consistent with the changed mandate of the EU Agency for Cybersecurity (ENISA).

However, the Call for Evidence fails to describe in what way(s) the current Cybersecurity Act is inadequate for ENISA to fulfil its broad mandate of achieving a high common level of

cybersecurity across the EU and what specific tasks were added to its portfolio by other EU legislative acts; this should be clarified. An expanded mandate should be accompanied by greater EU funding, both for actions to be carried out by ENISA itself and for EU-initiated measures undertaken at Member State level.

Regarding the CSA revision's focus on streamlining, prioritising and simplification of measures across different cyber legislations, HOPE thinks that the benefits of doing so depend on whether such harmonisation (e.g. in the areas of incident reporting and risk management) improves compliance with existing obligations, such as those stipulated by the NIS2 Directive. From the point of view of hospitals and healthcare, the protection of institutional assets, patient safety and privacy, takes precedence over boosting the competitiveness of technology providers. At the same time, the ability of businesses to effectively meet their obligations and secure their supply chains must not be restrained by overly complex processes or duplicate administrative requirements. Nonetheless, specific attention must be paid to the cybersecurity of critical sectors that harbour especially sensitive data; a revised CSA should not water down the efforts currently underway to strengthen healthcare resilience.

HOPE contribution to the European Commission Call for Evidence "Apply AI Strategy"

In light of the rapid and increasingly opaque artificial intelligence (AI) developments affecting all economic sectors including healthcare, HOPE thinks it is important that the Apply AI Strategy not only stresses Europe's competitiveness and productivity but that its main emphasis is placed on developing human-centric, user-friendly innovation, meeting actual needs and preferences rather than what is technologically conceivable but may hold little applied value. In hospitals and healthcare services, the potential of AI should be seized in areas where automation frees up time (e.g., delegating routine administrative tasks to increase patient contacts) and where it supports professionals by enhancing knowledge, precision, and quality of care (e.g., disease detection, surgical support) as well as patient accessibility.

It is critical to be guided by a distinct, inclusive, and value-based European AI vision: global leadership in this area should mean ensuring solid privacy and data protection measures and safeguards for upholding the fundamental rights of all people. Since the real-world trustworthiness and security of AI systems can only be properly assessed over time, and AI is bound to become a target for cyberattacks, it will be important to closely monitor and evaluate them. All new technologies contain flaws, the impacts of which are not immediately evident.

HOPE Position on the Critical Medicines Act

Shortages of medicines have increased in recent years and pose a growing threat to patient care and safety. HOPE then welcomed and joined the European Commission's initiative for a Critical Medicines Alliance launched in 2024. Overall, HOPE welcomes the ambition to strengthen the resilience of the pharmaceutical supply and is positive about the direction

of the Proposal "Critical Medicines Act" submitted to consultation. HOPE considers however that:

- the proposed regulation needs a strong impact assessment;
- the proposed regulation needs legal clarity;
- the proposed regulation should stick to a manageable list of critical medicines;
- procurement criteria should be indicative and not mandatory;
- participation in joint procurement should be voluntary;
- the support of public money to industry must be conditional on requirements such as safe deliveries.

HOPE Position on the EU Cardiovascular Health Plan

Representing national hospital associations and healthcare organisations across Europe, HOPE welcomes the European Commission's initiative to develop a comprehensive EU Cardiovascular Health Plan. The problem is not only medical but also structural. Cardiovascular diseases account for billions in direct healthcare costs and indirect economic losses, creating sustained pressure on hospital budgets, infrastructure and workforce. Without coordinated action, hospitals will continue to operate in crisis mode, diverting resources to acute interventions rather than long-term health improvement.

HOPE strongly supports the Commission's identification of three actions – prevention, early detection, and management and rehabilitation – as the pillars of the EU Cardiovascular Health Plan. From the hospitals' perspective, each of these areas is vital. Hospitals also call for targeted initiatives addressing vulnerable groups, where cardiovascular risks are more prevalent. Hospitals emphasise that timely identification of cardiovascular risk factors is transformative. EU guidance and protocols for systematic health checks, combined with the deployment of digital tools for monitoring and personalised treatment, will allow hospitals to intervene earlier and with greater precision. This reduces avoidable admissions and improves outcomes for patients, while supporting hospitals in managing resources more efficiently.

Hospitals stress the importance of structured care pathways linking acute, chronic and rehabilitative care. The EU framework should also ensure that AI and digital tools are validated, governed responsibly and accessible to all hospitals, regardless of size or geography. Without such safeguards, digital innovation risks deepening health inequalities rather than reducing them.

HOPE Position on the European Research Area Act

HOPE welcomes the European Commission's initiative to prepare a legislative proposal for an ERA Act. Hospitals, as key actors in Europe's research and innovation ecosystem, are directly concerned by this process.

Hospitals face several structural challenges in advancing research within the ERA. The first is fragmentation. Research efforts remain siloed across Member States, regions and even between hospitals, resulting in duplication, inefficiencies and missed opportunities for collaboration. This fragmentation is compounded by uneven levels of investment in research and innovation, which creates disparities between hospitals in different parts of Europe. A second major challenge is the difficulty in mobilising and retaining talent.

Hospitals believe that the ERA Act must offer robust legislative solutions to these challenges if the ERA is to fulfil its promise in the health sector. The ERA Act should create legal instruments that facilitate the free circulation of researchers and scientific knowledge. Hospitals also call for legislative provisions that guarantee secure, ethical and interoperable access to clinical and research data, aligned with the European Health Data Space. Such a framework would allow hospital-generated evidence to contribute meaningfully to cross-border studies and innovation projects, while ensuring patient trust and data protection.

Finally, hospitals believe the ERA Act must enshrine the principles of scientific freedom, integrity and equality in research. If these solutions are embedded in the ERA Act, hospitals anticipate significant positive impacts. Research within hospitals will become more integrated and collaborative, reducing fragmentation and ensuring more efficient use of resources.

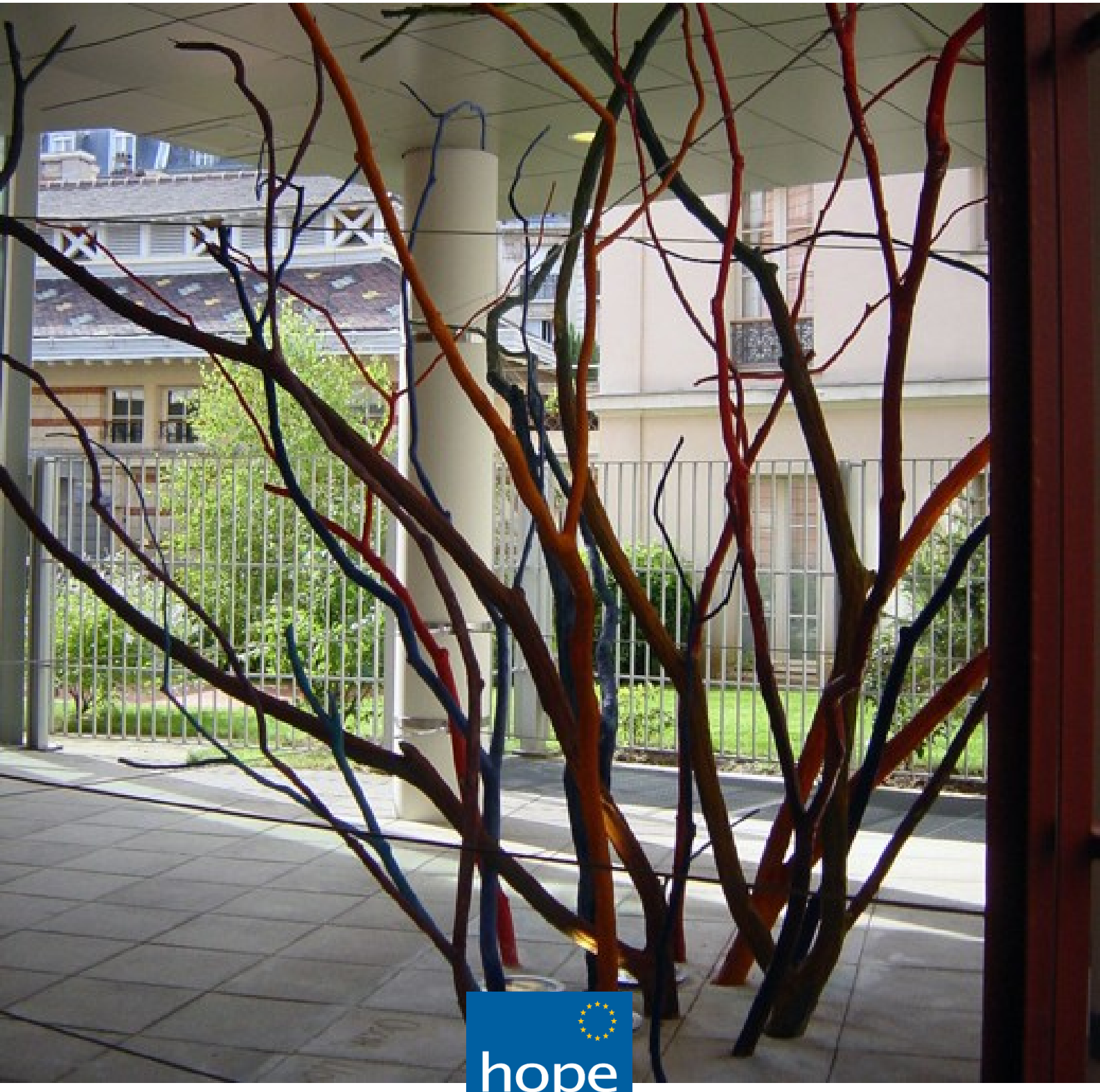
HOPE Agora Report

From 19 May to 13 June 2025, around 130 healthcare professionals in management positions in different departments participated in a 4-week hospital exchange across 21 countries in Europe. In line with this year's HOPE Agora theme, 'Together for Quality!', participants were asked to observe how hospitals and health care services are using principle of collaboration to ensure high-quality healthcare.

The HOPE Agora report covers the presentations and activities that took place during the two-day conference in Vienna, which started off with a presentation by the coordinators of the RE-SAMPLE project, which HOPE is part of. The presentation explained their unique model of integrated care in complicated COPD cases, illustrating the importance of collaboration between clinicians and patients to improve the care of people with multi-morbidities.

The policy and political discussions were led by members of the Head of the Austrian Ministry of Social Affairs, Health, Care and Consumer Protection. These focused on key facets of Austria's new healthcare reforms linked to patient safety and quality, presented by Verena Nikolai, Isabella Weber, Eva Potura, Daniela Rojatz, and Lukas Teufl.

These introductory presentations laid the ground for the country-by-country best practice presentations led by HOPE exchange participants and informal discussions at the World Café, which took place on day two of the HOPE Agora. ◊



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European Hospital and Healthcare Federation

General Report on the Activities of the
European Hospital and Healthcare Federation 2025