# General Report 2024

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, 2024**

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# General Report

On the Activities
of the European Hospital

2024

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# Executive Summary

The year 2024 was marked by many elections, including the European Parliament election.

This impacted the EU legislative activity, with several pieces adopted before the European Parliament closed. Negotiations between the European Parliament and the European Council succeeded on the legislative proposal on Artificial Intelligence and the European Health Data Space.

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

Some past topics 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 legislation. It was also the case for environment-related topics: the Energy Efficiency Directive; the Energy Performance of Buildings Directive; the Renewable Energy Directive; Emission Trading Schemes, 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 2024, HOPE also contributed to the EU non-legislative agenda through several European projects. Three projects were successfully concluded, HosmartAI, InnoFacilitator Project and XpanDH. The other projects further developed their activities in 2024 with HOPE as a partner: RE-SAMPLE, SAFEST (quality and patient safety), FLASH (financing), DIOPTRA (colorectal cancer), and LUCIA (lung cancer). Two new projects kicked off in 2024: KEEPcaring (stress) and HealthRiskAdapt. HOPE is also an advisor in several projects and Joint Actions including a new project on persons with intellectual disability.

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 2024 was concluded by the HOPE Agora that took place on 7 and 8 June 2024 in Brussels, focusing on the theme 'Keeping our health workforce!'.

# 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 (public and/or private) from 30 countries.

It is organised around a Board of Governors, a President's Committee, Liaison Officers, a network of National Coordinators of 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 2024: on 7 June and 5 December in Dublin.

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. Eva M. Weinreich-Jensen (Governor for Denmark) and Mr Urmas Sule (Governor for Estonia), as well as Ms. Henriette Neumeyer (Governor for Germany). 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 2 May and on 21 October 2024 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 2024, HOPE Liaison Officers meetings took place: on 13 March and on 6 June in Brussels, and in Dublin on 5 December. 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 Dublin on 6 December to prepare the 2025 programme.

Located in Brussels, Belgium, the Central Office is managed by the Chief Executive, Mr. Pascal Garel. Ms. Ana Sofía 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 2024

| | |
|---|---|
| **President** | Eamonn Fitzgerald, IRELAND |
| **Vice-President** | Francis De Drée, Belgium |

**Governors**

| | |
|---|---|
| Austria | Nikolaus Koller |
| Bulgaria | Krasimir Grudev |
| Croatia | Željko Plazonic |
| Cyprus | Kypros Stavrides |
| Czech Republic | Miloslav Ludvik |
| Denmark | Eva Weinreich-Jensen |
| Estonia | Urmas Sule |
| Finland | Kirsi Varhila |
| France | Zaynab Riet |
| Germany | Henriette Neumeyer |
| Greece | Yannis Skalkidis |
| Hungary | György Velkey |
| Italy | Domenico Mantoan |
| Latvia | Jevgenijs Kalejs |
| Lithuania | Dalis Vaiginas |
| Luxembourg | Marc Hastert |
| Malta | Walter Busuttil |
| The Netherlands | Sander Gerritsen |
| Poland | Jaroslaw Fedorowski |
| Portugal | Carlos Pereira Alves |
| Serbia | Georgios Konstantinidis |
| Slovakia | Marian Bencat |
| 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 2024, 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, 2024 provided an opportunity to engage in several new initiatives.

# INFLUENCE

## 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 2024, 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 legislation on Substances of Human Origin, the revision of the Pharmaceutical Legislation and the revision of the Late Payments directive. 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 AND REGULATIONS ADOPTED IN 2024

### Blood, tissues, and cells

On 11 October 2019, the Commission published its Evaluation on the EU Blood, Tissues and Cells Legislation. This was the first evaluation since the adoption of the basic Acts in 2002 (blood) and 2004 (tissues and cells).

Following the publication of the evaluation, the Commission organised on 28 October 2019 a conference to present the findings and give stakeholders, including HOPE, an opportunity to discuss them.

Then on 17 November 2020, the Commission launched the initiative for the revision of the EU legislation on blood, tissues and cells (BTC), with the objective of addressing the gaps and shortcomings identified in the evaluation. The initiative aimed to update the current legislation to allow for more flexible alignment to scientific and technological developments. It aimed to address the (re-) emergence of communicable diseases, including lessons learnt from the COVID-19 pandemic. It also wanted to address increasing commercialisation and globalisation in the sector. HOPE was contacted as representative of stakeholder organisations that were approved for invitation to ad hoc meetings with Competent Authorities for Substances of Human Origin (SoHO) and the Commission during the evaluation of the EU legislation on blood, tissues and cells.

Finally, on 14 July 2022, the Commission adopted the proposal for a regulation on standards of quality and safety for substances of human origin for human application, which repeals the 2002/98/EC Blood Directive and the 2004/23/EC Tissues and Cells Directive. In a nutshell, the proposal aimed to:

- support the continued provision of substances of human origin (SoHO) therapies based on high safety and quality standards and up-to-date technical rules;
- extend protective measures to new groups of patients, to donors and to offspring born from medically assisted reproduction;
- improve harmonisation across Member States, facilitating cross-border exchange of SoHO and improving patient access to the therapies they need;
- create conditions for safe, effective, and accessible innovation in a unique sector driven by public health services and voluntary and unpaid donations;
- improve crisis preparedness and resilience to safeguard access to therapies;
- implement digital-ready policies;
- contribute to the European Health Union by pooling of technical expertise and achieving economies of scale.

More specifically, the proposal implied a broader scope to cover all substances of human origin, apart from solid organs, including human breast milk. It envisaged updating the technical guidelines based on the expertise of the EU technical bodies and introducing proportionate and risk-based measures to strengthen national monitoring and EU support measures for national authorities. Furthermore, regarding innovation, the proposal aimed to implement a common procedure for assessing and authorising SoHO preparations, to register all entities involved in SoHO activities and to establish a SoHO Coordination Board (SCB) to support the implementation of the Regulation. In the digital field, the creation of a SoHO IT platform is planned.

HOPE worked on its position at all stages of the process and was invited on 15 November 2023 to the stakeholders' kick-off meeting of the project ReaderSHip (Recommendations and Guidance for the Management of SoHO in hospitals). This is a two-year project that commenced in July 2023. Its primary goals were to create a coordination model for administrative and legal support in the form of recommendations and guidance for the management of SoHO in hospitals (focusing on blood, cells, and tissues) and to ensure that the measures introduced in the proposed regulation (published in March 2021) improve

the quality and safety of SoHO applications in hospitals, while limiting the burden of professionals.

In a fast process lasting less than a year and a half, the Council reached a provisional agreement with Parliament in December 2023. The agreed text broadened the scope of SoHO to include human breast milk and intestinal microbiota. It also aimed to future-proof EU legislation by covering other SoHO that may be applied to humans in the future and allowing more flexibility for updates. In addition to improving quality and safety, the provisional agreement aimed to facilitate cross-border exchanges and access to SoHO, including by:

- setting up an EU-level SoHO coordination board supporting Member States in the implementation of the regulation.
- introducing common EU-wide procedures for the authorisation and assessment of SoHO preparations.
- requiring Member States to designate a SoHO national authority and other competent authorities to authorise SoHO preparations and ensure independent and transparent oversight of SoHO-related activities.
- setting out additional authorisation and inspection requirements for establishments that both process and store, release, import or export substances of human origin.
- establishing a new common IT platform, the EU SoHO platform, to register and exchange information on related activities.

Furthermore, the provisional agreement emphasised that donations of SoHO should be voluntary and unpaid as a matter of principle, and donors must not be provided with financial incentives to donate. Living donors may receive compensation or reimbursement as appropriate in line with national legislation. The draft regulation also provided for a rapid alerts system to cope with serious incidents or reactions that are likely to pose a risk for recipients or donors. Member States should also make reasonable efforts to ensure the sufficient, adequate, and resilient supply of critical SoHO in their countries, including by drawing up national emergency plans, including measures to respond to critical shortages.

The Parliament adopted on 24 April 2024 those new rules to increase the safety and quality of SoHO. The Council quickly followed in formally adopting the new revised legislation to increase the safety and quality of SoHO, which will become applicable in 2027.

## European Health Data Space

In 2024 HOPE continued to monitor relevant policy developments, attend stakeholder meetings, and participate in regular informal exchanges (including with representatives of organisations defending the interests of healthcare professionals, patients, public health, and payers) regarding the last stages of the Commission's proposal for a Regulation on a European Health Data Space (EHDS). Following its initial release in May 2022 as the first of nine sector-specific European data spaces, and intense political negotiations of the previous year, the EHDS matter attained near-conclusion under the Belgian

presidency when a political agreement was reached between the Parliament and the Council of the EU on 15 March 2024.

Specifically, HOPE advocated key points from its 2023 Position Paper, which stressed the high level of fragmentation of digitalisation in health across the Member States and regions; the resulting need to take into account specific preferences including primary (i.e., recording certain priority data categories in Electronic Health Record Systems) and secondary (research, policy, regulatory) uses of personal electronic health data within the EHDS; the importance of including hospitals and healthcare services in the EHDS governance structure; the need to address economic concerns regarding the set-up and maintenance costs involved; ensuring the responsibilities of hospitals and healthcare providers in their role as data holders, as well as those of national / regional authorities, can be assumed; and establishing proper alignment with other digital health-relevant EU legislation. These exchanges took place primarily during webinars and meetings of the Commission's eHealth Stakeholder Group. In May 2024, HOPE had the privilege to exchange views on the pros and cons of the EHDS and the data protection implications with a visiting delegation of the Japanese government's Health Data Policy Committee.

As a partner in the Horizon Europe-funded XpanDH project ("Expanding Digital Health through a pan-European EHRxF-based Ecosystem", 2023-2024), HOPE contributed to the establishment of an ecosystem, including via the involvement of a member in an "X-Net" of healthcare providers, to explore the potential advantages of the European Electronic Health Record Exchange Format as the basis for specifications for the registration and exchange of electronic health data (expected to become mandatory under the EHDS for priority data categories). This activity culminated in the 2nd European EHR Exchange Format Expert Summit held on 13 November 2024 in Brussels.

Due to the need for a thorough legal-linguistic review, the EHDS could not yet get fully adopted by the end of 2024. This is because a so-called corrigendum procedure had been launched by the Parliament in the autumn, reflecting the fact that the review process resulted in extensive changes to the wording and sequence of the Regulation, albeit without altering the core content of the agreement. The process only formally concluded with Parliament and Council re-votes taking place in December 2024 and January 2025.

The final EHDS text agreed between the Parliament and the Council grants the Member States slightly more powers to implement it in line with national laws and rules. It notably includes the possibility for Member States to legislate a reversible opt-out also for primary uses of health data (which relevance for certain countries had always been downplayed by the lead rapporteur). It also strengthens the power of market surveillance authorities, which may enforce corrective actions on manufacturers of EHR systems if they discover non-compliance with regulatory requirements. The timelines were extended compared to the Commission's original proposal, the law being applicable two years following entry into force but leaving four to six years for the more complex provisions. A great number of Implementing Acts remain to be defined through guidelines and technical specifications, which will provide HOPE with opportunities to provide stakeholder inputs into public consultations coordinated by the Joint Action TEHDAS-2 starting in 2025.

With a view to contributing to EHDS implementation consultations in 2025 and 2026, HOPE prepared in 2024 a comprehensive analysis of key EHDS provisions as the basis for targeted internal discussions with members.

## EU Artificial Intelligence Act

The EU Artificial Intelligence Act (AI Act) was adopted by the Parliament on 13 March 2024, (with 523 votes in favour, 46 against and 49 abstentions), followed by formal endorsement of the Council of the EU on 21 May and publication in the Official Journal on 12 July 2024. Most of it will apply two years after entry into force, with some exceptions for specific provisions.

In the run-up to the votes, but also during the ongoing implementation process initiated after the summer, HOPE continued at EU stakeholder meetings to build up knowledge and voice key concerns, outlined in the 2021 Position Paper and 2023 Joint Statement led by Health Action International and Brunel University London Centre for AI. Among others, this included making the case for ethical and fair AI deployment by improving digital health literacy of healthcare professionals and patients, respecting fundamental rights, and avoiding an exacerbation of health inequalities resulting from data bias.

Proposed by the Commission in April 2021, the AI Act stipulates different rules for AI systems taking a risk-based approach (minimal, limited, high-risk and unacceptable). A provisional agreement between the co-legislators was reached in December 2023. The final text of the agreement attempted to strike the right balance between the distinctly European vision of a human-centric and trustworthy AI respectful of Union values and rights, on the one hand, and being able to unlock AI's vast innovation potential on the other. This was an extremely challenging task given that the trilogues held over the previous year involved lengthy discussions about the definition of prohibited practices (e.g., emotion recognition, predictive policing software, biometric recognition except for exceptional cases); the access, reporting and impact assessment obligations for high-risk use cases including in hospitals; information and compliance requirements for general-purpose AI systems like ChatGPT; and the setting of administrative fines applicable in cases of AI Act violations.

Prior to the co-legislators' votes, increasingly heated discussions over AI focused on the feasibility to properly oversee or "control" AI in the face of rapidly evolving and highly complex developments like generative AI, but also growing concerns about succumbing to the temptation to deploy AI for harmful purposes including mis- and disinformation, warfare, surveillance and tracking of individuals in an increasingly crisis-ridden, polarised world. The EU views the AI Act's value-based human-centricity as a blueprint for global export, but it remains to be seen whether AI behemoths in the United States and China share this vision and wish to regulate similar aspects.

Technical work will continue in 2025, with Commission guidelines expected to be released early in the year alongside public consultations aiming to refine important details (definitions and exceptions, scope of certain provisions) of the Act. In preparation for this process, HOPE analysed the final AI Act text from the hospital / healthcare services perspective, looking in particular at the interplay with the EHDS (see above), which also

includes the "training, testing and evaluating of algorithms, including in medical devices, in vitro diagnostic medical devices, AI systems and digital health applications" among the authorised secondary uses of electronic personal health data.

## Cyber Resilience Act

HOPE continued to monitor the progress of the Commission's proposal for a Cyber Resilience Act (CRA) and communicated points from its 2023 Position Paper at stakeholder meetings. Originally released on 15 September 2022, a political agreement on the proposal was established between the Council and Parliament in December 2023. It was formally approved by the Parliament on 12 March and by the Council on 10 October prior to publication in the EU Official Journal on 20 November 2024.

The purpose of the Cyber Resilience Act is to impose horizontal cybersecurity requirements on manufacturers and vendors of products with digital elements. In doing so, it complements the NIS2 Directive, and its requirements closely interact with those enshrined in the EU Medical Devices / In Vitro Diagnostics Devices Regulations, the Radio Equipment Directive, the EU Artificial Intelligence (AI) Act and European Health Data Space Regulation.

Crucially, the Cyber Resilience Act applies to various digital networks, IT systems and Internet of Things (IoT) solutions commonly deployed in hospitals and healthcare settings (professional and domestic) not covered by other EU legislation. It sets harmonised rules for placing connected hard- and software products on the market and for vulnerability handling during the entire product life cycle. Manufacturers and supply chain actors have to comply with strict conformity requirements, considering cybersecurity risks during all phases, i.e. design, development, production and placing on the market. This includes Electronic Health Record (EHR) systems deployed under the EHDS. Soft- and hardware products will bear the CE marking to indicate regulatory compliance.

## Cyber Solidarity Act

Another piece of the Commission's cybersecurity framework is the Cyber Solidarity Act (CSA). First proposed in April 2023, it is meant to strengthen solidarity at EU level to better detect, prepare and respond to cyber threats and incidents. A political agreement was reached on 5 March 2024 under lead rapporteur Lina Gálvez Muñoz (S&D, ES) followed by votes in the Parliament in April and November (approval of a corrigendum), and formal endorsement on 2 December 2024 in the Council of the EU.

The Cyber Solidarity Act includes three actions: building a European Cybersecurity Alert System, consisting of a network of National and Cross-border Cyber Hubs, which will leverage state-of-the-art tools and infrastructures, such as AI and advanced data analytics, to detect cyber threats and incidents; creating a Cybersecurity Emergency Mechanism to support preparedness testing of entities in critical sectors for potential vulnerabilities, build an EU Cybersecurity Reserve, and enable mutual financial assistance; and establishing a European Cybersecurity Incident Review Mechanism to review and assess significant or large-scale incidents.

In addition, Parliament and Council also agreed on an amendment to the Cybersecurity Act regarding the adoption of European certification schemes for managed security services. This will help provide a framework for establishing trusted providers in the EU Cybersecurity Reserve. Managed security services play an important role in preventing and responding to cyber incidents, yet they are also themselves a target. The certification of such services will further strengthen cybersecurity in the EU.

## Product Liability

Political agreement over the directive on liability for defective products ("Product Liability Directive" – PLD) was reached in December 2023. Subsequently, the Parliament adopted it on 12 March 2024 and the Council on 10 October 2024. Member states will have two years to transpose the directive into national law.

HOPE continued to monitor the PLD in parallel to other EU legislation of relevance in the health digital sphere. The PLD is designed to help adapt liability rules to the digital age, the circular economy and the impact of global value chains. It aims to modernise and reinforce manufacturers' obligations regarding the compensation of personal injury, damage to property or data loss caused by unsafe products, from smart technology to pharmaceuticals. The PLD revision was the first in forty years and the consequences for industry are significant. Under the new regime, manufacturers will be liable for defectiveness resulting from a component under its control, which might be tangible, intangible, or a related service, like the traffic data of a navigation system. A product is deemed defective when it does not provide the safety a person is entitled to expect based on the foreseeable use, legal requirements, and the specific needs of the group of users for whom the product is intended. One of the elements considered is the capacity of the product to learn and acquire new features or knowledge; this means it also covers AI based on machine learning techniques.

Under the PLD, material damage includes death, personal injury, psychological harm and destruction of property. At the same time, national liability regimes may still regulate compensation for non-material damages, such as those resulting from discrimination. The concept of damage also includes the loss or corruption of data that is not used exclusively for professional purposes. Claimants must prove the product's defectiveness, the damage suffered, and the causal link between the two. However, under certain conditions, the defectiveness of the product will be assumed, and it will be on the defendant to disprove it.

The directive will not apply to free and open-source software developed or supplied outside a commercial activity. The liability rules apply when the software is supplied in exchange for a payment or personal data used for anything other than improving the software's security or compatibility.

The Parliament included the possibility of EU countries using existing or new national sectorial compensation schemes for victims of defective products who fail to obtain compensation because the economic operator is insolvent or no longer exists.

## 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.

In the Parliament, the Urban Wastewater Treatment Directive file was adopted on 5 October 2023. The matter was referred to ENVI for interinstitutional negotiations. The Council adopted its general approach on the subject on 16 October 2023.

On 29 January 2024, a provisional deal between the parliament and the Council was reached on the Urban Wastewater Treatment Directive. The agreed text was formally approved by the Parliament on 10 April 2024. The text was approved by the Council on 5 November 2024. It will now be signed and published in the Official Journal of the EU. The text will enter into force on the 20th day after its publication. Member States will then have up to 31 months to transpose the directive into their national legislations.

Following formal approval by the co-legislators, the final act, signed on 27 November, was published on 12 December 2024 in the EU Official Journal. Member States have until 31 July 2027 to transpose the text into national law.

## 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 5 October 2023, the Council and the Parliament reached a provisional agreement on strengthened rules to massively reduce GHG emissions from F-gases and ozone-depleting substances (ODS).

On 16 January 2024, the European Parliament adopted those new rules to minimise emissions from powerful greenhouse gases. The text was endorsed with 457 votes in favour, 92 against and 32 abstentions. Then on 29 January 2024, the Council followed. Both regulations were published in the Official Journal after being signed and they entered into force 20 days later.

## II. DIRECTIVES AND REGULATIONS ADOPTED PREVIOUS YEARS

### 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.

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. But HOPE invested much more time in the Critical Medicines Alliance.

## 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.

On 31 January 2018 the Commission put forward a proposal for a Regulation on Health Technology Assessment (HTA), a topic already in the Directive 2011/24/EU on Patients' Rights in Cross-Border Healthcare. HOPE released a position in June 2018. Following a rather short process, on 13 December 2021, the Regulation on Health Technology Assessment (HTA) was adopted by the Parliament and the Council. The regulation provided for a delayed application of three years, during which the Commission had to: set up the Member State Coordination Group; establish the Stakeholder Network; adopt the necessary implementing and delegated acts; and facilitate the development of methodology for joint HTA work by the Coordination Group as required by the regulation.

On 12 December 2022 the Commission launched a call for applications to join a stakeholder network on HTA. The call was addressed to patient associations, consumer organisations, non-governmental organisations in the field of health, associations of health technology developers and health professionals' organisations. HOPE applied and was selected together with 43 other organisations as members of the HTA Stakeholder Network.

And since the first meeting on 14 June 2023 HOPE attends meetings of this formal stakeholder body created under the Health Technology Assessment Regulation.

In 2024, HOPE attended on 11 June the 3rd meeting during which an update on the implementation of the HTA Regulation was provided with individual presentations of each guidance:

- guidance on direct and indirect comparisons,
- guidance on outcomes for joint clinical assessments,
- guidance on reporting requirements for multiplicity issues and subgroup, sensitivity and post hoc analyses in joint clinical assessments,
- guidance documents by the subgroup for methodological and procedural guidance,
- guidance on joint scientific consultations (JSC) for medicinal products and results of the survey of HTDs on intentions to apply for JSC in 2025.

On 29 November 2024 the 4th meeting of the HTA stakeholder network was organised in Brussels. An update was provided by the Commission and the Chair of the HTACG. A report on the survey of the cooperation with stakeholders on the identification of emerging health technologies followed. Then breakout sessions were held on: Update on the work in the JSC subgroup; Update on the work in the JCA subgroup; Protection of commercially sensitive data and personal data in joint work; Identification of patient and clinical experts and other experts for the joint work; Joint work on medical devices. Finally, a session was devoted to feedback from 38th Workshop of the EURORDIS Round Table of Companies (ERTC): Bridging Perspectives: Preparing for Success in Joint Clinical Assessments in EU HTA and to present on the EUCAPA patient training project by EURORDIS. A presentation of HTA plain language summaries by Cancer Patients Europe followed.

## NIS-2 Directive

The EU's cybersecurity policy framework continues to evolve, and the fact that health is an especially volatile sector due to its enormous fragmentation across Europe is increasingly turning European policymakers' attention to the sector. Earlier elements are the 2029 Cybersecurity Act (which gave the European Cybersecurity Agency – ENISA a permanent and expanded mandate) and the 2020 Cybersecurity Strategy for the Decade as the centre piece of a second cybersecurity package following that of 2013. In addition, cybersecurity-relevant actions and investments are contained in the EU Digital Strategy, the Recovery Plan for Europe and the Security Union Strategy 2020-2025.

Particularly important in the health context is Directive 2022/2555 on measures for a high common level of cybersecurity across the Union (the so-called NIS-2 Directive), which repeals the previous cybersecurity law. Adopted alongside the directive on the resilience of critical entities (CER Directive), NIS-2 thus applies to the hospital and healthcare sector and confers strict responsibilities on senior management including training and awareness-raising, coupled with extending cyber security practices to supply chain actors and stricter enforcement requirements. Overall, the directive aims to take a strategic, comprehensive and collaborative approach to cyber protection, inter alia stipulating the establishment of national competent authorities and of computer security incident response teams (CSIRTs) tasked with monitoring and analysing threats and incidents. In addition, the supranational EU-CyCLONe (EU Cyber Crisis Liaison Organisation Network) helps national cyber crisis management authorities prepare for large-scale incidents.

However, although formally adopted by the Parliament and Council in November 2022 and in force since 2023, the implementation of NIS-2 remained problematic: the deadline for transposing relevant provisions into national law passed on 17 October 2024 with most of the Member States lagging behind. Therefore, on 28 November 2024, the Commission decided to open infringement procedures by sending a letter of formal notice to 23 Member States.

To better understand the NIS-2 implementation barriers faced at national level, including those affecting healthcare entities, HOPE closely monitored relevant EU and national developments and brought the primary concerns of its 2023 Position on the EU Cybersecurity Framework to representatives of the Commission and ENISA during stakeholder meetings (see also below). The year 2024 witnessed further cyber-attacks on hospitals across Europe, many of which were ransomware attacks, prompting HOPE to stress the need for a thorough analysis of why this is happening and whether the healthcare sector is unique in this regard, as well as ensuring complementarity of the different cybersecurity legislative and non-legislative initiatives (see below).

## 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.

In 2024, as in the previous year, HOPE attended the monthly Board meetings as well as the stakeholders monthly meetings. HOPE informs liaison officers and experts identified by liaison officers on a monthly basis. Since the creation of EMVO, meetings take place on a regular basis (usually monthly): Board of EMVO, stakeholders' meetings, project managers' meetings and EFPIA-Medicines for Europe project managers' meeting.

## 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 on medical devices and in vitro diagnostic medical devices.

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. The new Medical Device Regulations also introduced the Unique Device Identification system to facilitate

traceability of medical devices, to allow for better monitoring by relevant authorities, and to help reduce medical errors and fight against falsified devices.

HOPE closely monitored the legislative process in the European Institutions and advocated in particular 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. Following the agreement on the draft regulations, 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.

The Commission presented the likely elements of a legislative proposal for a targeted amendment of the MDR and IVDR during the EPSCO Health Council on 9 December 2022. Then 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. The proposal introduced a longer transition period to adapt to new rules, as set out under the Medical Devices Regulation. The length of the proposed extension of the transition periods depended on the type of device: higher risk devices such as pacemakers and hip implants will benefit from a shorter transition period (until December 2027) than medium and lower-risk ones, such as syringes or reusable surgical instruments (until December 2028).

On 16 February 2023 the Parliament agreed to extend the Medical Devices Regulation (MDR) transition periods to avoid a shortage of life-saving products in the economic region. The vote also put a veto on the sell-off date provision for existing products specified in the MDR and In Vitro Diagnostic Medical Devices Regulation (IVDR). 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 measures give more time to consider possible actions to safeguard patient care in instances where certain devices are discontinued and increase transparency regarding medical devices on the market.

The availability of IVDs, such as HIV or hepatitis tests, is crucial for patients. A considerable number of IVDs currently on the market do not yet comply with the EU rules which have been applicable since May 2022. Subject to certain conditions, the new rules give more time for manufacturers to transition to the new requirements without compromising safety and to mitigate the risk of shortages.

The additional time granted to companies depends on the type of device:

- highly individual and public health risk devices such as HIV or hepatitis tests (class D) have a transition period until December 2027;
- high individual and/or moderate public health risk devices such as cancer tests (class C) have a transition period until December 2028;
- lower risk devices (class B) such as pregnancy tests and (class A) sterile devices such as blood collection tubes have a transition period until December 2029.

Manufacturers are also required to give prior notice if they anticipate a disruption in the supply of certain IVDs or medical devices. They must provide this information 6 months in advance to the competent authorities, as well as to distributors and healthcare providers. This will allow them enough time to take action to guarantee patient care.

The agreement by the Parliament will also facilitate the launch of parts of the European database on medical devices, Eudamed. From the beginning of 2026, the use of several

parts of Eudamed will become mandatory. This will increase transparency in the EU and provide an overview of medical devices available on the European market.

On 30 May 2024, the Council adopted those new rules updating the law on medical devices to help prevent shortages as well as ease the transition to greater transparency and access to information.

In July 2024, the Commission published a Q & A document on the extension of the IVDR transitional periods and updated its Q & A document on the extension of the MDR transitional periods. All the related texts, guidance and supporting information are available on the Commission's webpage under the title, 'Extension of the transition periods provided for in the Regulations'.

On 9 October 2024, political groups debated over a possible revision of the medical devices regulation after the European Commissioner for Values and Transparency, Věra Jourová, standing in for Health Commissioner Stella Kyriakides, opened the door to a revision.

On 23 October 2024, MEPs adopted the joint resolution of the EPP, S&D, ECR, Renew Europe, and Greens/EFA groups regarding the revision of the regulation on medical devices and the regulation on in-vitro diagnostic medical devices. While the resolution was broadly supported, political groups in Parliament showed divisions regarding the timeline.

Finally, the Commission opened 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.

### 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.

The Medical Devices Coordination Group proposed a new work item in 2023: guidance for manufacturers and notified bodies on the application of clinical evaluation requirements to orphan devices in view of their certification in accordance with the Medical Devices Regulation. On 7 September 2023H OPE attended 'open session' that followed the 6 September 2023 'closed session' with only competent authorities. The first topic for discussion was the definition of an 'orphan device' following on from discussions based on current working definition which is: 'Orphan device' means a medical device specifically intended to benefit patients in the treatment or diagnosis [or prevention] of a disease or condition that has an annual incidence of not more than 1 in 37,000 per year in the EU. A second topic was Orphan IVDs with the report from meeting of 'small group' on orphan IVDs on 30 August 2023. There were also reports by healthcare professionals about discontinued or 'threatened' legacy orphan devices. In its position paper MDCG 2022-14,

the MDCG stated that the Orphan Devices Task Force confirmed that generating sufficient clinical data for orphan devices is challenging due to the epidemiology of the disease or condition to be treated (small patient populations). Meeting the clinical evidence requirements set out in the MDR within an appropriate time will be too burdensome or not even feasible for orphan 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.

On 15 December 2023 HOPE participated in the meeting of the Medical Devices Coordination Group orphan device task force and in a first draft of the guidance on Clinical evaluation of orphan medical devices, further refined and amended during the next phase of the drafting in January/February 2024, taking into consideration comments. The invitation was extended to representatives of several European Reference Networks (ERN) for rare diseases, which manage registries that could be useful to gather clinical data on orphan devices.

In June 2024, the Medical Device Coordination Group (MDCG) endorsed the new document MDCG 2024-10 to provide guidance to manufacturers and notified bodies on clinical evaluation of orphan medical devices. Following publication of MDCG 2024-10, in September 2024, the European Medicines Agency (EMA), in cooperation with the Commission, organised an online information session on the pilot for expert panels' advice for orphan medical devices. Manufacturers of high-risk medical devices and notified bodies were invited to apply for the pilot programme for free scientific advice by the expert panels on possible orphan device status and on the clinical evaluation of orphan medical devices.

## Safety of public places

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 also mentions critical infrastructure protection and resilience. On 9 December 2020, the European 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. In order 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 particular 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.

## 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 2025, the EU Climate Law is expected to be amended to introduce an intermediate 2040 target.

## 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.

On 7 December 2023, the Council and the Parliament reached a provisional political agreement on the Energy Performance of Buildings Directive (EPBD). The Parliament endorsed the provisional agreement on 12 March 2024, as did the Council on 12 April 2024. 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.

## Workers' protection from exposure to hazardous medicinal products

On 16 December 2021, the Council and the Parliament reached a provisional agreement on the fourth revision of the carcinogens and mutagens directive, a legislation that HOPE has been following since the beginning of this discussion.

Following the agreement on the inclusion of reprotoxic substances in the revision, the directive was renamed the carcinogens, mutagens and reprotoxic substances directive (CMRD). On 17 February 2022, the Parliament gave the final green light for an update to EU rules on limiting workers' exposure to carcinogens, mutagens or reprotoxic substances. On 3 March 2022, the Council did the same. The directive was signed on 9 March 2022 and published on 16 March 2022. It entered into force on the twentieth day after its publication in the EU Official Journal, on 5 April 2022. Member States had until 5 April 2024 to transpose the directive in their national laws.

Following a two-stage consultation process with social partners, scientists, worker representatives, employers, and Member States, a political agreement was reached on 14 November 2023 between the Parliament and the Council on the Commission's proposal to amend two directives:

- for lead – the Directive on the protection of workers from the risks related to exposure to carcinogens, mutagens and reprotoxic substances at work; and
- for lead and diisocyanates – the Directive on the protection of workers from the risks related to chemical agents at work.

The update seeks to improve workers' protection from the health risks linked to the exposure to dangerous chemicals: lead and diisocyanates, which can affect reproductive functions (in the case of the former) and the respiratory system (in the case of the latter), among other health issues.

The agreement is part of the work towards fulfilling the aims of the European Pillar of Social Rights Action Plan in terms occupational safety and health, as well as the EU Strategic Framework on Health and Safety at Work for 2021-2027. Furthermore, the agreement contains guidelines to support Member State implementation, as well as data collection clarifications to support SMEs and microenterprises.

After the formal approval of the agreement by the Parliament and the Council, Member States will have two years to incorporate the EU Directive into national law.

On 27 November 2023 the legislative proposal of the codification for the protection of workers from the risks to exposure to carcinogens, mutagens or reprotoxic substances at work was adopted by the Commission. The text was referred to the Parliament on 14 December 2023.

The Council voted in favour on 26 February 2024. The final act of the Directive (EU) 2024/869 was signed on 13 March 2024 and was published in the EU Official Journal on 19 March 2024, entering into force 20 days thereafter.

In parallel, eleven Member States are failing to fully transpose EU rules regarding the exposure to carcinogens, mutagens and reprotoxic substances at work. The Commission has sent a letter of formal notice to the eleven Member States that have yet to fully transpose Directive (EU) 2022/431 into national law.

Three Member States are failing to transpose EU rules regarding the use of hazardous substances in electrical and electronic equipment. The Commission has sent a letter of formal notice to Belgium, Malta, and Slovakia for failing to transpose Directives (EU) 2023/1526 and (EU) 2023/1437 into their national legislation:

- Commission Delegated Directive (EU) 2023/1526 of 16 May 2023 amending Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead as a thermal stabiliser in polyvinyl chloride used as base material in sensors used in in-vitro diagnostic medical devices.

Commission Delegated Directive (EU) 2023/1437 of 4 May 2023 amending, for the purposes of adapting to scientific and technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for mercury in melt pressure transducers for capillary rheometers under certain conditions.

## III. PROPOSED NEW AND REVISED LEGISLATION

### AI civil liability

In 2024 HOPE continued to monitor policy developments pertaining to the draft directive on adapting non-contractual civil liability rules to artificial intelligence ("AI Liability Directive" – AILD). The AILD aims to establish uniform rules for access to information and alleviation of the burden of proof in relation to damage caused by AI systems, establishing broader protection for victims, and it aims to encourage the AI industry by increasing guarantees. It would harmonise certain rules for compensation claims outside the scope of the Product Liability Directive, in cases where damage is caused by wrongful conduct.

The Commission published the AILD proposal on 28 September 2022 alongside the Product Liability Directive revision and in response to a 2020 European Parliament own-initiative resolution.

In the Parliament, the Legal Affairs Committee (JURI) is leading the AILD dossier, with MEP Axel Voss (EPP, DE) as rapporteur.

In 2024, AILD discussions were on hold pending the AI Act adoption and JURI request for a complementary impact assessment, released on 19 September 2024. The study critique identifies key shortcomings in the Commission's original impact assessment, such as an incomplete exploration of regulatory policy options and an abridged cost-benefit analysis of the liability regime. It proposes the AILD should extend its scope to include general-purpose and other 'high-impact AI systems', as well as software. Notably, it recommends transitioning from an AI-focused directive to a software liability regulation, to prevent market fragmentation and enhance clarity across the EU.

As a complement to the AI Act, the proposed rules are intended to ensure that persons harmed by AI systems enjoy the same level of protection as those harmed by other technologies in the EU. The AILD would create a rebuttable 'presumption of causality' to ease the burden of proof for victims to establish damage caused by an AI system. It would, furthermore, give national courts the power to order disclosure of evidence about high-risk AI systems suspected of having caused damage.

Initial discussions revealed that stakeholders are questioning 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.

Following an in-depth analysis undertaken by the lead rapporteur, AILD negotiations are expected to resume in February 2025.

## ePrivacy

HOPE continued to keep an eye on relevant ePrivacy developments in 2024, but the negotiations remained dormant as in previous years. A notable exception was the Hungarian Presidency's Council conclusions on mastering Europe's digital needs (December 2024), which noted that "questions related to the privacy of electronic communications should be reassessed to reflect technological developments and with a view to effectively ensuring the confidentiality of electronic communications". This invokes a potential revival of the ePrivacy review.

The first attempt failed despite a drawn-out process. On 10 January 2017, the Commission published a proposal for a regulation on the respect for private life and the protection of personal data in electronic communications ('ePrivacy package') that was meant to replace Directive 2002/58/EC and specify the General Data Protection Regulation (GDPR). The proposed measures aimed to update the rules and extend their scope to all electronic communication providers. They also aimed to create new possibilities for processing communication data, reinforcing trust and security in the Digital Single Market, and aligning the rules for electronic communications with the GDPR. Among other things, the ePrivacy Regulation is meant to enhance security and confidentiality of communications and the rules on tracking technologies and spam.

Following multiple revisions submitted by EU Presidencies (2018-2020), trilogues finally commenced in May 2021. However, there was much disagreement on central issues including the ePrivacy-GDPR relationship; privacy settings; the legal grounds for data

processing other than consent; the applicability of the new rules to service providers assisting competent authorities for national security purposes; and the concept of public interests as a basis for justifying restrictive measures.

Since then, the subject has been lying in limbo as no common ground has yet to be found.

## Pharmaceuticals

### Pharmaceutical strategy

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.

Although the strategy was much more than a crisis-response instrument, it drew lessons from the initial response to the COVID-19 pandemic and aimed to make Europe's pharmaceutical sector better prepared and more resilient. The strategy supported diversified and secure supply chains, ensuring the EU's open strategic autonomy in the world, and it promotes environmentally sustainable pharmaceuticals.

The Pharmaceutical Strategy for Europe marked the beginning of a process: its implementation includes 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 was expected to propose an update of EU pharmaceutical legislation towards the end of 2022. It was finally made public 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: new incentives to encourage companies to make their medicines available to patients in all EU countries and develop products that address unmet medical needs. Furthermore, earlier availability of generic and biosimilar medicines would be facilitated, and market authorisation procedures

simplified. Measures for greater transparency of public funding of medicines development would be introduced, and the generation of comparative clinical data will be incentivised.

- Innovation and competitiveness: The scientific evaluation and authorisation of medicines would be sped up (e.g., EMA authorisation procedures will take 180 days, helping reduce the current average of around 400 days), thanks to simplified procedures (e.g., by abolishing in most cases marketing authorisation renewal and introducing simpler procedures for generic medicines) and digitisation (e.g., electronic submissions of applications and electronic product information).
- Incentives for innovation: minimum period of regulatory protection of 8 years that could be extended in the following cases: if medicines would be launched in all Member States, if they address unmet medical needs, if comparative clinical trials would be conducted, or if a new therapeutic indication would be developed, up to a maximum of 12 years.
- Shortages of medicines: new requirements for the monitoring of shortages of medicines by national authorities and EMA, and a stronger coordination role for EMA. Obligations on companies would be strengthened, including earlier reporting of shortages and withdrawals of medicines and the development and maintenance of shortage prevention plans. An EU-wide list of critical medicines would be established, and supply chain vulnerabilities of these medicines would be assessed, with specific recommendations on measures to be taken by companies and other supply chain stakeholders. In addition, the Commission can adopt legally binding measures to strengthen security of supply of specific critical medicines.
- Antimicrobial resistance (AMR): incentives through transferable vouchers to companies that invest in novel antimicrobials that can treat resistant pathogens. Measures and targets for prudent use of antimicrobials, including adapted packaging and prescription requirements, would also be introduced.

At the Employment, Social Policy, Health and Consumer Affairs Council (EPSCO) on 13 June 2023 in Luxembourg, the Health Ministers of the EU countries discussed the proposals but had to wait until the pharmaceutical package had been translated into several languages before it could formally begin negotiations at a technical level. This was done on 13 September 2023.

The ministers for the internal market and industry scrutinised the pharmaceutical package on 25 September 2023 in a session of the Competitiveness Council. A position paper drafted by industry ministries in Germany and Austria expressed worries for business with the package proposed by the Commission. Some Member States, in particular smaller ones, made comments pointing out their support to the current proposal (Malta, Estonia, Cyprus, Hungary, Ireland and Bulgaria) except Denmark supporting the Austrian/German initiative.

On 14 September 2023 the Parliament decided to refer the proposals to the committees responsible. On 3 October 2023, MEP Pernille Weiss (EPP, Danish) submitted her draft report amending the proposed directive on pharmaceutical products. It will shortly be discussed by the European Parliament's Environment Committee. On 3 October 2023, the European Parliament's rapporteur on the proposed regulation on medicinal products (link

to the draft report), Tiemo Wölken (S&D, German), suggested several amendments to the initial proposal. These include the introduction of a 'European Medicines Facility' to replace the controversial 'transferable data exclusivity vouchers'. The two draught reports (by Tiemo Wölken and Pernille Weiss) on the 'pharmaceuticals package' were discussed by the European Parliament's Environment Committee on 7 November 2023.

After receiving the Commission's proposal on 26 April 2023, the Council started to work mostly on shortages of medicines.

During the Employment, Social Policy, Health and Consumer Affairs Council (Social policy) that took place on 21 June 2024, the main item of discussion was the regulatory incentives set out in the revision of the EU's pharmaceutical legislation. The Belgian Presidency presented its pharmaceutical package progress report and asked Ministers to reply to three questions on the basis of a pharmaceutical package policy report.

The Belgian Presidency has suggested four options. The first three involve a progressively less rigorous definition of the efforts that the company should make in order to benefit from the incentive under the modulation system. The fourth option dissociates the issue of access from the incentive-based structure and formulates a proposed solution based on an obligation. Some support has been expressed for option 1 (Slovenia), while other countries, such as Denmark, Luxembourg and Germany, prefer option 4.

The Belgian Presidency suggested that the modulation of data protection and the market should be seen as an important tool for encouraging companies to achieve essential public health objectives. It proposes to keep this modulation as a guiding principle for the negotiations but considers that it is too early to set the duration of the reduction in basic data protection (which is reduced from eight to six years in the Commission's proposal and from eight to seven and a half years in the Parliament's position).

Denmark, Sweden and Italy had presented a document in which they oppose the incentives proposed by the Commission in its proposals on the reform of pharmaceutical products. Denmark took the view that access to medicines and the industry are not in conflict but complement each other. "A complex modular approach would not meet the objectives", according to the Danish minister, who, like Italy and Sweden, wants to retain an eight-year protection period. France also defended maintaining the *status quo* of the eight-year base period.

Slovenia and Finland supported the proposal (six-year duration). Spain said it is prepared to accept seven years (with an additional 12-month period subject to conditions).

With regard to access to medicines, France said that it favors scenarios other than modulation of the protection period, such as "an obligation to submit a price and reimbursement dossier." To this end, a register could be set up to ensure that applications for prices and reimbursements have actually been submitted, according to the delegation. Finally, France advocated granting market exclusivity for orphan drugs. In addition, most of the ministers supported the idea of incentives for the development of medicines to meet unmet needs.

At the end of the debate, the Belgian Presidency of the Council took the view that a majority of Member States were in favour of modulation, "provided that the needs of innovation are respected." A minority of countries support the current framework. Various countries believe that access to medicines should not be linked to pricing and reimbursement. "We need an access solution, but we don't agree on how to achieve the objectives," said Frank Vandenbroucke, the Belgian minister.

Hungary had stated that its objective for its presidency of the second semester of 2024 was "to find solutions to facilitate access to medicines and strengthen the competitiveness of the industry. We hope to be able to make rapid progress on this issue".

The Council Working Group on Pharmaceutical and Medical Devices, in charge of examining the Pharmaceutical Package, took a closer look at the European Medicines Agencies (EMA) authorisation process on 28 and 29 October 2024. The majority of Member States were supportive of greater centralisation of the approval process, through the Committee for Medicinal Products for Human Use (CHMP) of EMA, which meet on a monthly basis. It was envisaged that more specialised committees, like the one on orphan medicines (COMP), advanced therapies (CAT) and paediatric medicines (PDCO) could be replaced by expert groups. The current structure is representation-based, with one representative per country, with an expert-based structure. Not all countries will necessarily be represented.

This shift would aim to involve more external experts, but with final decisions still being made by the CHMP. Member States could participate in expert groups based on their existing expertise, allowing them to focus resources strategically.

The matter was then passed to the Polish EU Presidency during the first semester 2025.

### Medicines shortages

Medicine shortages are both an issue covered in the legislative package and followed as a non-legislative action.

In the EU, most medicine shortages are dealt with at national level. However, the European Mediciines 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. Since April 2019, the task force has been running a pilot programme to establish a single point of contact (SPOC) network. This is to improve information sharing between Member States, EMA and the Commission on important medicine shortages of human and veterinary medicines and to coordinate actions to help prevent and manage shortages. In July 2019, EMA and HMA published guidance on detecting and reporting medicine shortages for marketing authorisation holders. The guidance is based on a survey on how issues related to shortages and availability of medicines are measured and communicated to the public in EU Member States, which was carried out by the HMA / EMA Task Force.

The COVID-19 pandemic highlighted the EU's long-existing structural problems related to the supply of medicines, and the dependency on third-country import 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 minimising 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 to 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. It followed a strong call by Member States at the June 2023 European Council, confirmed in Granada in October 2023, and from the European Parliament.

It contains seven key elements. A European Voluntary Solidarity Mechanism for medicines was launched in October 2023: the mechanism flags a Member State's needs for a given medicine to other Member States, which can respond by redistributing medicines from their available stock. A Union list of critical medicines was available at the end of 2023.This list was the first step to analyse the supply chain of selected medicines by April 2024. A dedicated Joint Action was launched in 2024 to promote effective use of these flexibilities.

Finally, the Commission set up a Critical Medicines Alliance operational in early 2024. The Critical Medicine Alliance adds an industrial policy pillar to the European Health Union. This aims 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" expected in 2025.

## Antimicrobial resistance

Throughout 2024, HOPE continued to monitor and engage in policy discussions to tackle antimicrobial resistance (AMR), both as an issue covered in the pharmaceutical legislation package and as a non-legislative file in the context of the ongoing implementation of the Commission's EU One Health Action Plan against AMR originally released in 2017.

Overall, the expanded One Health vision kept AMR high on the EU and global policy agendas. This became evident through the United Nations General Assembly (UNGA) High-Level Meeting on AMR held in New York on 26 September 2024, which resulted in the adoption of a Political Declaration. Already well ahead of the high-level meeting, a multi-stakeholder hearing took place in May, which enabled the European networks HOPE is engaged in (see below) to contribute their views.

In February 2024, HOPE attended the kick-off meeting of the second Joint Action on Antimicrobial Resistance and Healthcare Associated Infections (EUJAMRAI2, January 2024 – December 2027) in Paris in its capacity as a supportive stakeholder. JAMRAI2's goals are to elevate Europe as a model of best practices, supporting the implementation of concrete One Health measures. This is to be achieved by setting out an EU framework for stewardship in human, animal and environmental health; facilitating state-of-the-art IPC measures in Member States and associated countries; improving access to selected AMR-products for human and veterinarian use; and fostering an integrated One Health surveillance system on AMR.

HOPE participated in the two meetings in 2024 (29 February and 24 October) of the Commission's AMR One Health Network that was launched in the previous year. The October webinar discussed, along with the UNGA declaration, the implementation of the Council Recommendation on stepping up EU actions to combat AMR in a One Health approach released as part of the pharmaceutical legislation in June 2023. The Council Recommendation's 2030 targets call for a 20% reduction of the total consumption of antibiotics in humans; at least 65% of the total consumption of antibiotics in humans should be effective (use of the right antibiotic); and a reduction of infections of three key antibiotic-resistant bacteria, mainly applicable to hospitals. The Commission presented a preliminary list of indicators to monitor the EU and Member States' One Health actions against AMR, brought to stakeholders in the form of an online survey HOPE responded to. In addition, the Commission is undertaking a study on "Integrated Surveillance in One Health areas" to close gaps at Member State level and identify obstacles and enablers.

In July 2024, HOPE was invited by the European Patients' Forum to share its position as part of an interactive skills training for young patient advocates dedicated to AMR. The objective was to equip the target audience, composed of patient representatives from across Europe, with supplementary policy knowledge to get involved in defending patients' interests in this area.

In addition, HOPE participated in *ad hoc* meetings of the Stakeholder Network on AMR coordinated by the European Public Health Alliance and, as every year, HOPE supported

the European Antibiotic Awareness Day organised by the European Centre for Disease Prevention and Control (ECDC).

## Late payments

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

This consultation is 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 a large number of 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 have to 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 2466th 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 17 January 2024 the European Economic and Social Committee published its opinion: the Committee was concerned that the transformation of the current directive into a regulation might limit the flexibility of Member States and of the business environment at a time of multiple headwinds across the EU. It believed that the Commission, with its proposal, was attempting to tackle the issue of long payments instead of late payments by introducing excessively restrictive measures, instead of improving the current enforcement framework with more effective rules. It also believed that strict conditions on payment terms could potentially have an impact on commercial transactions within the single market and push business operations outside the EU. It would be easier to engage with suppliers from third countries which are allowed to accept longer payment terms. This could be a potential threat to Europe's competitiveness and should be avoided.

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.

To maintain consistency in payments practices across the single market, the Commission is expected to issue guidelines on the application of these rules to the specified product categories. To protect companies, particularly SMEs, against bad payers and to ensure the timely receipt of payments to avoid cash flow disruptions, the adopted text puts in place an automatic payment of accrued interest and compensation fees for late payments. MEPs agreed that the debtor would owe between €50 and €150 for each transaction (depending on the value) to compensate for the creditor's own recovery costs.

The proposal introduced new enforcement, redress and awareness-raising measures. It also encourages the use of e-tools to help shorten delays and financial literacy trainings for SMEs. Once a year, contracting authorities (e.g. government entities) would have to submit publicly accessible reports on their payment practices to the national enforcement authority. A European Observatory of Late Payment would also be set up to monitor, collect and share data on late payments and potential harmful practices.

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, provided that the debtor has received the goods or services in accordance with contractual agreement. Where the date of the receipt of the invoice or the equivalent request for payment is uncertain, the payment period should not exceed 30 calendar days from the date of receipt of the goods or services. This period should apply both to the transactions between undertakings and between public authorities and undertakings.

In commercial transactions between undertakings, where expressly agreed in the contract, the payment period may be extended up to 60 calendar days. In transactions between undertakings for the purchase of slow moving or seasonal goods, the payment period may be extended up to 120 calendar days from the date of the receipt of the invoice or an equivalent request for payment by the debtor, provided that the debtor has received the goods.

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 European elections, on 3 October 2024, IMCO Committee appointed MEP Ivars Ijabs (Renew, Latvia) as the new rapporteur. On 13 November 2024, IMCO Committee referral was announced in Parliament (1st reading).

## SOFT LAW AND OTHER INITIATIVES

Besides 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.

## 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).

The results of the case studies on the EU4Health cancer projects were presented by the project team and answered two questions:

- What are the lessons learnt and barriers in the application process and implementation of these projects?
- Can potential recommendations and suggestions for remedial actions be made considering the existing EU4Health Regulation?

Then the preliminary monitoring framework was presented by the project team on the indicators and data sources are available to measure the progress of the EBCP. The meeting was concluded by a discussion on which additional indicators may be needed to monitor the progress of the EBCP, and how to collect them.

### 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 EU network "National Comprehensive Cancer Infrastructures" should be operational in 2025 and is currently in the phase of "Support to action for networking and support to upgrading/ improving Comprehensive Cancer Infrastructures". The two joint actions started in November 2022 and ran for 24 months.

On 25 September, 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 1 November 2024, the second Joint Action of the EU Networks of Expertise on Cancer JANE-2 was launched. It will run until 31 October 2028.

The Joint Action CrANE ended in September 2024 and was followed by the launch of Joint Action "European Network of Comprehensive Cancer Centers" (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.

### Cancer Inequalities Registry

On 2 February 2022, the Cancer Inequalities Registry, a flagship initiative of Europe's Beating Cancer Plan, was released.

Under the registry, the first edition of the EU Country Cancer Profiles was published on 1 February 2023. The profiles will be published following a bi-annual cycle.

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.

## Cybersecurity actions for hospitals and healthcare providers

Although the design for the Commission's Action Plan on the cybersecurity of hospital and healthcare providers only saw the light of day in early 2025, stakeholder discussions about this topic took place throughout 2024. This provided HOPE with ample opportunity to present its work on cybersecurity to European health stakeholders including at a general meeting of the Commission's eHealth Stakeholder Group (EHSG) in February, a dedicated EHSG workshop that served to take stock of preliminary priorities for the Action Plan on 11 October, and at a webinar jointly organised by AIM (International Association of Mutual Benefit Societies) and EHFCN (European Healthcare Fraud and Corruption Network) in December 2024.

One of the triggers for the elaboration of the Action Plan was ENISA's first dedicated health threat landscape report (covering Jan 2021 – Mar 2023), which confirmed the increase of

cyber incidents affecting health organisations, in particular hospitals. Ransomware was one of the principal threats, both in the number of incidents and regarding its impact, e.g., data breaches, data theft and service disruption as had already been witnessed in several high-impact incidents in various EU countries. Commission President Ursula von der Leyen, in her political guidelines, thus set out to release an Action Plan within the first 100 days of her new 2024-2029 political mandate.

The increased discussions about the need for hospital/healthcare-specific measures were also linked with related work at the EU level including the proposals for a legal framework for a European Digital Identity, the regulation laying down measures for a high common level of cybersecurity at the EU's institutions, bodies, offices and agencies, and the EU Cyber Defence Policy.

## Mental health

Mental health has always been on HOPE's agenda. In 1999 HOPE started to organise annual seminars bringing together professionals, patients and institutions. HOPE was a partner in the Joint Action on Mental health and Wellbeing, which ran from 2013 to 2016. It closely follows this issue by regularly attending events organised at the Parliament by the MEP Alliance for Mental Health (established in 2009 as the European Parliament Interest Group on Mental Health, Wellbeing and Brain Disorders).

On that basis HOPE participated in the call for evidence opened from 18 January to 15 February 2023, of which a report was published in spring 2023. On 19 April 2023 during the Annual EU Health Policy Platform Meeting, HOPE followed the Thematic Network "Mental health in all policies" presenting its joint statement. And on 21 April, HOPE attended a stakeholder webinar organised by the Commission to further discuss the joint statement and give an update on its upcoming initiative.

On 7 June 2023, the Commission released a communication on "a new comprehensive approach to mental health". It consists of 20 flagship initiatives and €1.23 billion in EU funding from different financial instruments. This new approach draws on three guiding principles: adequate and effective prevention, access to high quality and affordable mental healthcare and treatment, reintegration into society after recovery.

It intends to look at mental health across all policies to recognise the multifaceted risk factors of mental ill health. The concrete actions planned are:

- Promote good mental health through prevention and early detection, including through a European depression and suicide prevention initiative, a European Code for Mental Health and strengthened research on brain health.
- Invest in training and capacity building that reinforces mental health across policies and improves access to treatment and care. Actions will include training and exchange programmes for professionals and technical support for mental health reforms at the national level.
- Ensure good mental health at work by raising awareness and improving prevention. This will be done for instance through EU-wide awareness-raising campaigns by the

European Agency for Safety and Health at Work (EU-OSHA) and a possible future EU initiative on psychosocial risks at work.

- Protect children and the young during their most vulnerable and formative years, in a context of increasing pressures and challenges. Measures include a child and youth mental health network, a prevention toolkit for children addressing the key health determinants of mental and physical health, and better protection online and on social media.
- Address vulnerable groups by providing targeted support to those most in need, such as the elderly, people in difficult economic or social situations and migrant/refugee populations. A special focus includes conflict-affected populations, notably people (in particular children) displaced from Ukraine and children in Ukraine subject to the trauma of war.
- Lead by example at the international level by raising awareness and providing quality mental health support in humanitarian emergencies.

One of these flagships, number 15, aims to support more and better trained professionals in the EU by achieving the target of around 2000 professionals trained across the EU by 2026 and on average 100 exchanges per year. Within this context, HaDEA launched on 12 June 2023 the call for tenders, "Capacity building on mental health: multidisciplinary training programme and exchange programme for health professionals."

Then on 12 July 2023, the Commission published a call for best and promising practices on mental health on its Best Practice Portal. This call supports the implementation of actions identified in the Commission Communication on a Comprehensive Approach to Mental Health.

Finally, the European ministers responsible for health met on 30 November 2023 in Brussels and approved conclusions on mental health.

## 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.

On 13 March 2024, the European released the report of the mid-term review of the 8th EAP. This report found that the EU objectives under the European Green Deal are attainable if the actions planned are fully implemented.

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.

## 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 2023 European Semester and reported on it via its monthly newsletter.

# CHAPTER 3

## Life and Governance

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.

## European programmes and projects

## I. HOPE AS A PARTNER - ONGOING PROJECTS

### 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.

Now entering its third year, SAFEST has compiled just over 200 patient safety recommendations through iterative research and consensus processes. In turn, these recommendations have been integrated into a guided self-evaluation process, which 10 hospitals across Europe (Spain, Czechia, Estonia, Portugal, and The Netherlands) are now implementing. Hospitals conducted feasibility and prioritisation exercises to select the recommendations that best fit their contexts and are now evaluating their implementation with the support of SAFEST researchers.

During 2025, the self-evaluation platform will be opened up to 100 hospitals across the world. The key aim of SAFEST is to ensure that the journey before, during and after surgery (often referred to as perioperative safety and care) is safer for patients beyond the project's duration.

HOPE is managing 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.

### 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. This innovative e-Health technology will be implemented in three countries (the Netherlands, Italy and Estonia) with hundreds of patients diagnosed with COPD and comorbidity.

The project was granted an extension of 6 months and will end in August 2025.

HOPE is work package leader on dissemination and communication. As the project is concluding in 2025, HOPE's activities on the policy recommendations and dissemination have been more active in 2024 with for examples connections to other projects.

## DIOPTRA

DIOPTRA is a Horizon Europe project, aiming to revolutionise colorectal cancer (CRC) screening via a holistic, personalised and accessible method for early detection. Its mission is to use new technologies for CRC risk assessment, screening, and progression while incorporating lifestyle and environmental factors to develop a unified holistic protocol for primary CRC screening using network modelling and an artificial intelligence-based decision support system.

Colorectal cancer remains one of the most diagnosed cancers worldwide. One of the biggest challenges in fighting CRC is detecting it early enough for treatment to be most effective. Traditional screening methods, like colonoscopies, can be invasive and uncomfortable, often leading people to avoid them altogether. DIOPTRA aims to make screening easier and more widely available by focusing on blood-based markers that can identify the disease. Thus, this non-invasive approach has the potential to significantly improve colorectal cancer screening in medical practice, thereby expanding population participation in screening beyond those currently reimbursed. Previous efforts in this field have been limited by the scope of the research—either too few participants or too narrow a focus on the biological markers in the blood that could indicate cancer.

In November 2023, DIOPTRA launched an ambitious new study designed to make early detection of CRC more accessible and effective. The study will leverage the power of AI to sift through enormous amounts of data to identify not just who is at risk of developing CRC, but also why they might be at risk. By combining the latest in blood testing technology with machine learning algorithms, DIOPTRA will dig deep into the factors that contribute to this type of cancer. These factors range from lifestyle and behaviour to intricate biological indicators. This comprehensive approach offers the promise of a more effective, efficient, and personalised healthcare strategy for preventing and treating CRC cancer.

The study focuses on four groups: healthy individuals, those with non-advanced adenomas, those with advanced adenomas, and CRC cases. It will involve at least 1,600 participants across eight clinical sites from Belgium, Bulgaria, Cyprus, Denmark, Greece, Slovenia, and Spain and will last for two and a half years.

## LUCIA

LUCIA is a Horizon Europe project focusing on the risks associated with developing lung cancer and its subtypes, as well as the methods best suited for prompt diagnosis. Lung cancer is the cancer with the highest mortality rate and although some factors, such as tobacco smoking, are well identified, some are still unknown. In the case of lung cancer, early detection can help reduce mortality by shifting the focus away from the late stage, a

largely incurable profile of the disease, to the early stage when more options are available to improve patients' outcomes and quality of life. However, current methods, like low-dose computed tomography (LDCT), are not administered with sufficient precision. This is due in part to an incomplete picture of the risk factors and cellular processes associated with the onset and prognosis of lung cancer.

The LUCIA project aims to constitute a toolbox to discover and understand (new) risk factors contributing to lung cancer development. This toolbox encompasses three domains: (1) the personal risk factors (i.e. a person's exposure to chemical pollutants and behavioural and lifestyle factors), (2) the external risk factors (i.e. urban, built and transport environments, social aspects, and climate), and (3) the cellular process (i.e. changes in genetics, epigenetics, metabolism and ageing).

In 2024, the LUCIA project met twice in-person, in Mannheim (Germany) in May and in Sevilla (Spain) in November. The project had its first review meeting on 30 September 2024, concluding its first reporting period.

HOPE is responsible for communication and dissemination in the project. As the project entered its second reporting period at the end of 2024, HOPE started working more on the policy activities for the project.

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

## FLASH

One of the lessons learnt from the COVID-19 pandemic is the importance of flexibility in funding and organisation of health systems. European countries responded quickly to this extreme event by expanding the number of financial resources available for healthcare and reallocating financial and human resources. However, there are several other challenges for healthcare systems that require efficient and flexible financing mechanisms to be successfully addressed.

FLASH, a 4-year project funded by Horizon Europe undertakes a comprehensive analysis of healthcare financing mechanisms in Europe. By employing a wide range of methodological approaches, it also provides evidence on the ability of existing financing mechanisms and contracts to address such challenges and study new solutions to achieve more effective, efficient, and equitable healthcare systems.

With a total investment of €4.9 million, the FLASH project brings together sixteen partners from nine European countries and intends to be a game changer in the European integrated healthcare system. Nine universities and research centres, one non-profit organisation, and seven SMEs will work together on these research challenges and lead the way to bring innovation to the general public and create a resilient European healthcare system.

## KEEPCARING

KEEPCARING ("Future Proofing Health- and Care Systems Safeguarding Health Care Workers in Hospital Settings") is a 4-year project (2024-2028) financed by the Horizon Europe Framework Programme further to the call HORIZON-HLTH-2023-CARE-04 'Resilience and Mental Wellbeing of the Health and Care workforce project'. Led by Amsterdam University Medical Centers, the consortium is composed of leading universities, hospitals, research organisations, SMEs offering digital solutions, and European associations representing hospitals and healthcare workers. The inaugural meeting took place in July 2024.

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. Using a co-creation approach, a multifaceted solution package (non-digital, digital, and AI-supported) will be developed to prevent burnout among (aspirant) healthcare professionals on the individual, team and organisational level. Stress is the biggest factor attributing to burnout among hospital healthcare workers.
HOPE's role will be to support tasks related to dissemination, communication and stakeholder engagement including the establishment of an effective strategy and framework and key messages for different target groups.

## 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) under the Horizon Europe Programme.

It aims to address health risks associated with climate change, such as heatwaves, air pollution, wildfire emissions, and pollen. Its 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.

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.

# II. HOPE AS ADVISOR

## ORPHANET

HOPE is a member of the Orphanet International Advisory Board. The body provides 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.

## Second Joint Action towards the European Health Data Space

In 2024, HOPE continued to provide stakeholder support to TEHDAS2, the Second Joint Action Towards the European Health Data Space (May 2024 – December 2026). Whereas the purpose of the previous Joint Action (TEHDAS1, 2021-2023) was to create a European governance model and create joint principles for the secondary use of health data as the basis for the European Health Data Space (EHDS) legislative proposal, its follow-up will focus on creating concrete guidelines and technical specifications for using health data across country borders. TEHDAS2 is carried out 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.

TEHDAS2 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 will, for instance, help to establish good practices and outline harmonised means of describing data supporting the discovery of health data and streamlining access to datasets. It will also create technical specifications for secure data processing environments and develop cooperation models and guidelines for data access and licensing fees.

For TEHDAS2, HOPE will participate in monthly webinars, providing dissemination support, providing expert inputs into public consultations, and attending (face-to-face or remotely) stakeholder forum meetings.

## Persons with intellectual disability

HOPE joined the advisory board of a project focusing on persons with intellectual disability (PWID). Panteion University of Social and Political Sciences of Athens and Margarita Vocational Training Centre in Athens initiated the project as part of the Erasmus Plus Ka2 call, with partners such as:

- TAMK: Tampere University of Applied Sciences (Finland)
- Fundació Campus Arnau d'Escala (Spain)
- Institud d'Asistencia Sanitaria (Spain)

- KAUNAS University of Applied Sciences (Lithuania)

One of the activities of the project (Activity 2.4) will lead to the development of policy recommendations on the rights and access of PWID to healthcare.

In order to ensure that the quality of the recommendations is the best possible, the advisory board that includes organisations that represent the different stakeholders of the project (hospitals, doctors, nurses, PWID, professional supporters, patients) was in 2024 in charge of reading the policy recommendations implemented by the project and give feedback on them, as well as supporting the dissemination of the project.

### HEAL internsHips in futurE hospitALs

HOPE is among the four stakeholders to review the work of the ERASMUS+ project HEAL (intersHips in futurE hospitALs-) led by Odense Universiteshospital (Denmark). The specific objective of the HEAL project is to develop, test and propose an innovative framework for high quality internships, which shows the direction for how traditional internships in hospitals can be combined with other innovative learning and teaching methods such as blended learning, peer learning, group work, simulation, online teaching, video training, covert mentoring, etc.

### 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.

In April-May 2024, the project organised five workshops with external stakeholders on governance, buildings, waste, telemedicine and patient's travel, and staff engagement. On 9 December 2024, the reference stakeholder group was invited to an online workshop presenting how the inputs from the five workshops contributed to the refining of the 10 sustainable solutions for healthcare that the project is developing. This meeting also presented intermediate results and the role of the reference stakeholder group in the next phases of the project.

## III. PROJECTS THAT ENDED IN 2024

### HosmartAI

The four-year HosmartAI project ("Hospital Smart Development based on AI") concluded in May 2024. Financed by the European Union's Horizon 2020 programme and involving 25 partners and eight large-scale pilots in five European countries (BE, IT, GR, SI, ES), HosmartAI developed digital and robot technologies powered by artificial intelligence (AI) in different healthcare settings and evaluated the results. The project applied a co-creation methodology to ensure that the proposed AI-based technologies could meet the needs of

patients, healthcare professionals and hospital / healthcare providers. The developed solutions targeted different medical aspects and conditions such as cancer, gastrointestinal disorders, cardiovascular diseases, thoracic disorders, neurological diseases, elderly care and neuropsychological rehabilitation, foetal growth restriction and prematurity.

During the final phase of the project, HOPE continued contributing to three work packages (WP1 – Requirements, Specifications and Reference Architecture, WP 6 – Dissemination, Communication and Ecosystem Building, WP 8 – Social, Ethical and Legal Issues). HOPE also participated in the final consortium meeting organised in Venice, Italy. The expert and ecosystem building workshops HOPE had co-organised with partners EIT Germany during the previous couple of years helped prepare the ground for business exploitation activities undertaken by the project partners to raise interest in the technologies and potentially bring them to market.

HOPE disseminated and informed about the project's results via its social media channels and newsletters and it provided inputs for the finalisation of deliverables in the relevant work packages.

## InnoFacilitator

The InnoFacilitator Project – Health InnoFacilitator European Facilitator Community Promoting Public Procurement of Innovation in Healthcare – kicked off in November 2022. It aimed to create a community to promote innovative procurement in the field of health through business support, tailor-made training courses, coaching for buyers and solution providers and with the creation of collaborative tools. The overall objective was to raise awareness, increase skills and inform stakeholders about innovative procurement and collaborate to co-designate the public procurement of innovative solutions (PPI).

InnoFacilitator was funded by Horizon Europe Programme 2021-2022 European Innovation Ecosystems and it ran for 24 months until 30 September 2024. Its consortium brought together seven European partners with expertise in innovation procurement coordinated by Medicen Paris Region). It gathered healthcare clusters such as MPR and Bioindustry Park Silvano Fumero (BIPCA SPA); innovation and PPI support company such as the Science & Innovation Link Office SL (SILO); and public/private healthcare buyers such as the *Réseau des acheteurs hospitaliers IDF* (GIP RESAH), the European Health Public Procurement Alliance (EHPPA) and HOPE.

HOPE was involved in several work packages: WP2 'Health InnoFacilitator Community Building', WP3 'Training, Awareness Raising, Strategic Support, and Stakeholder Engagement' and WP4 'Dissemination, Communication, and Exploitation'.

HOPE was responsible for supporting community building (WP2) and promoting the project among HOPE community and networks through communication support, awareness campaigns, scaling activities across Europe and using its community-platform technology (WP2, WP4). HOPE also helped identify and scout suppliers and buyers for the matchmaking event (WP3).

## XpanDH

The two-year (Jan 2023 – Dec 2024) Horizon Europe Coordination and Support Action XpanDH ("Expanding Digital Health through a pan-European EHRxF-based Ecosystem"), with over 25 participating partners, was concluded.

To support the implementation of the European Health Data Space (EHDS) legislation, XpanDH took a "network of networks" approach and built a vibrant ecosystem surrounding the promotion and adoption of the European Electronic Health Record Exchange (EEHRxF) format. This included various interactions with experts from across the healthcare sector.

Also simply referred to as 'the format', the EEHRxF was first recommended by the Commission in 2019 as a cornerstone of the EHDS for seamless and secure health data exchanges.

Established during the second half of 2023, the so-called X-Nets provided a forum for various health stakeholders (e.g., regulators and healthcare managers, hospitals on FHIR, patients) to discuss the existing gaps and identify avenues for promoting the format.

The second European EHR Exchange Format Expert Summit took place on 13 November 2024 in Brussels and online. Its sessions focused, inter alia, on handing over XpanDH's achievements and networks to closely related, ongoing initiatives such as the Xt-EHR Joint Action and the X-Share project. Overall, the summit demonstrated that awareness and acceptance of the format had grown substantially since the first event of December 2023. There is much interest in developing it further as stakeholders understand the benefits of harmonised data formats.

HOPE supported the project through its active participation in plenary and work package meetings (with tasks falling into WP5, "Growing a pan-European XpanDH ecosystem" and WP7, "Communication and Dissemination"), contributing to the Community of Doers (e.g., inputs into service recommendations for ePrescription/Dispensation) and a multistakeholder meeting of the X-Nets network (via a member representative), attending multiple webinars, supporting the final session of the Summit, and informing about the project's progress via newsletter articles and social media posts.

# IV. INTERNATIONAL INSTITUTIONS

## World Health Organization/Europe

### Regional Committee

Over the course of 2024, HOPE participated in a number of World Health Organization (WHO) meetings and initiatives, specifically on non-communicable diseases (NCDs), non-state actor engagement, and its annual regional committee summit.

Towards the end of the year, on 21 November, HOPE joined the Special Initiative on NCDs and Innovation at the WHO Regional Office for Europe virtual event "Science-based policymaking: actions with impact."

This interactive panel session drew on the experiences of three countries in the region in reducing premature mortality from NCDs: Estonia, Norway and Kazakhstan. The WHO/Europe has demonstrated the greatest progress in reducing premature mortality from NCDs of all WHO regions; however, this progress is uneven, and the COVID-19 pandemic slowed it down. The European Region is not on track to meet the targets of a 25% reduction by 2025 and a one-third reduction by 2030, targets which were agreed upon in the Global and European NCD Action Plans and the Sustainable Development Goals. Only ten countries have achieved the 2025 target ahead of time, while a few others are on track.

Prior to the panel on NCDs, HOPE joined online the regional committee for Europe on 30 October 2024. Dr Hans Kluge's was re-elected as WHO Regional Director for Europe. Dr Kluge set out critical areas of action for the upcoming 5 years, including national health security, non-communicable diseases, climate crisis, ageing and gender-based violence.

A framework for resilient and sustainable health systems in Europe 2025-2030 was launched, together with two landmark health emergency action plans: the Preparedness 2.0 strategy and action plan and the Emergency Medical Teams regional action plan 2024-2030. In addition, WHO/Europe held on 29 October 2024 a high-level briefing to engage Member States in adopting and implementing the One Health approach within their contexts.

On 28 October 2024, HOPE contributed online to the Inaugural non-State actor hybrid conference, "Celebrating and strengthening engagement opportunities to promote health in the WHO European Region."

The WHO Regional Office for Europe hosted the first non-State actor (NSA) networking and engagement event the day before the 74$^{th}$ session of the WHO Regional Committee for Europe (RC74). This is in recognition of the role NSAs play in all major WHO initiatives, including the Mental Health Coalition, the Novel Medicines Platform, the Strategic Partners' Initiative for Data and Digital Health and the Youth4Health Network.

Together with NSAs, the WHO Regional Office has worked over the past months to develop an NSA Engagement Plan to enhance and streamline NSA collaboration across the WHO European Region. The WHO/Europe drew up this plan in close consultation with NSAs, Member States in the Standing Committee of the Regional Committee, and WHO Regional Office for Europe staff.

During the consultations, NSAs and Member States also encouraged the Regional Office to create more opportunities for networking and NSA visibility in the preparation and during sessions of the Regional Committee.

HOPE has been part of the NSAs Engagement Plan since its inception. It participated in the 17 June 2024 presentation of the concept note. The Framework of Engagement with Non-State Actors (FENSA) was adopted during the Sixty-ninth World Health Assembly in resolution WHA69.10 in 2016. The engagement plan is aligned with FENSA.

The ongoing commitment to engagement with NSAs is also emphasised in other key documents, such as the Thirteenth General Programme of Work, 2019–2025 (GPW 13), the

European Programme of Work, 2020–2025 (EPW), and the upcoming Fourteenth General Programme of Work. WHO/Europe has already established several collaborative arrangements that include NSAs.

HOPE looks forward to further collaboration with the WHO/Europe in 2025.

## CONFERENCES AND EVENTS (CO-)ORGANISED BY HOPE

### Health Promoting Hospitals and Health Services-- Annual International Conference

The 30th International Conference on Health Promoting Hospitals and Health Services (HPH) was held in Hiroshima, Japan from 6 to 8 November 2024. The conference focused on health equity from diverse perspectives, considering threats to achieving it, which lie beyond the health sector, for instance, climate change, social exclusion, poverty, etc. Delegates explored how hospitals and other health services can facilitate quality care to all, for example, by implementing diversity management or social prescriptions, and by focusing on improving the health literacy of their patients. Special attention was given to vulnerable groups, from children to the elderly, in the discussion of how HPH strategies should differentiate when it comes to equity for these groups.

### SAFEST - 2nd annual collaborative webinar

The European Commission encourages all projects funded under the topic "Enhancing quality of care and patient safety" to participate in networking and joint activities, including workshops and knowledge exchanges. To mark World Patient Safety Day 2024, the SAFEST, DeliverEU, SafePolyMed, and BE-SAFE consortia hosted webinar to reflect together on the theme adopted by the World Health Organization: 'Improving diagnosis for patient safety'. In the context of perioperative care (SAFEST), diagnostic errors may occur across the entire pathway before, during, and after surgery. Conditions may be missed, wrongly identified, or miscommunicated. However, steps can be taken to improve diagnoses and outcomes. SAFEST's approach includes adopting evidence-based recommendations, encouraging healthcare institutions to evaluate periodically the measures they implement, and identifying areas for improvement.

### InnoFacilitator - Webinar and final conference

In its last year, the InnoFacilitator consortium organised two events. On 11 January 2024, partners held a webinar on IPR Management specifically linked to contractual issues in the context of open innovation and co-creation instruments. Intellectual roperty lawyer, Valentina Gazzari, and Trademark and Design Attorney lawyer, Elisabetta Guolo, guided the discussions.

On 18 June 2024, partners hosted a conference in Brussels, which gathered professionals in the procurement sector. Attendees had the opportunity to hear with EU project leaders

and Commission representatives, participated in interactive discussion sessions, and connected with key stakeholders in the field.

## State of Health in Europe - A Belgian Presidency event

On 4 June 2024, the Civil Society Organisations' Group of the European Economic and Social Committee (EESC) organised a hybrid conference on 'The State of Health in Europe' in partnership with the Centre Hospitalier Universitaire de Liège and the Hôpital Citadelle. The conference focused on Europe's commitment to the One Health initiative, digital innovations and their impact on health, the role of social investments in health systems, and the global fight against health inadequacies through the prism of European solidarity (e.g., rare diseases). The conference was held as part of the Belgian Presidency of the Council of the EU at the Théâtre de Liège in Liège.

## Climate Resilience - Webinar

On 13 May 2024, the Commission organised a webinar to discuss the European Climate Risk Assessment (EUCRA) report of the European Environmental Agency; specifically, the report's findings regarding health and health systems. Participants from civil society and non-profit advocacy groups explored examined together with policymakers, the role and responsibility of different actors in the healthcare system concerning climate change mitigation and adaptation. In addition to co-organising the event, HOPE was a panel discussant.

## 24th International Conference on Integrated Care

From 22 to 24 April 2024, the International Foundation for Integrated Care (IFIC) in partnership with IFIC Ireland, the International Journal of Integrated Care, the Department of Health, Northern Ireland, and Visit Belfast, hosted the 24th International Conference on Integrated Care (ICIC24). The theme was 'Taking the leap: making integrated care a reality for people and communities'. 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 2024, together with its members, HOPE wrote a report titled "Environment and climate engagement of HOPE members," building on an October 2023 paper on health in environment and climate adaptation policies.

HOPE also released its annual HOPE Agora Report, and published a Strategic Note on the European Health Data Space and AI Act implementation.

# PUBLICATIONS

## HOPE Report on Environment and climate engagement of HOPE members – selection 2024

Building on the report on health in environment and climate adaptation policies released in October 2023, this document compiled information from HOPE members on environment and climate engagement.

This report was organised through different subparts to give a clear overview of what our members have been doing recently in analysis, creation of strategies, planning, creation of awareness, provision of expertise, and provision of training.

## HOPE Agora Report

From 7 to 8 June 2024, HOPE held its annual Agora. The HOPE Agora report summarises the proceedings of the event, which focused on the theme, 'Keeping our health workforce!'. Participants were asked to observe how hospitals and healthcare services are working to meet challenges in retaining health and social care staff.

HOPE President Eamonn Fitzgerald and Vice-President Francis De Drée moderated days one and two. They welcomed almost 200 participants, speakers, HOPE members, national coordinators, and hosts from across Europe.

The policy and political discussions complemented the presentations of three researchers working on EU-funded projects linked to strengthening Europe's health workforce. First, Simon Dello from KU Leuven (Belgium), presented Magnet4Europe, a collaborative project between European and American hospitals studying the wellbeing and mental health of hospital health workers and how these influence turnover and retention.

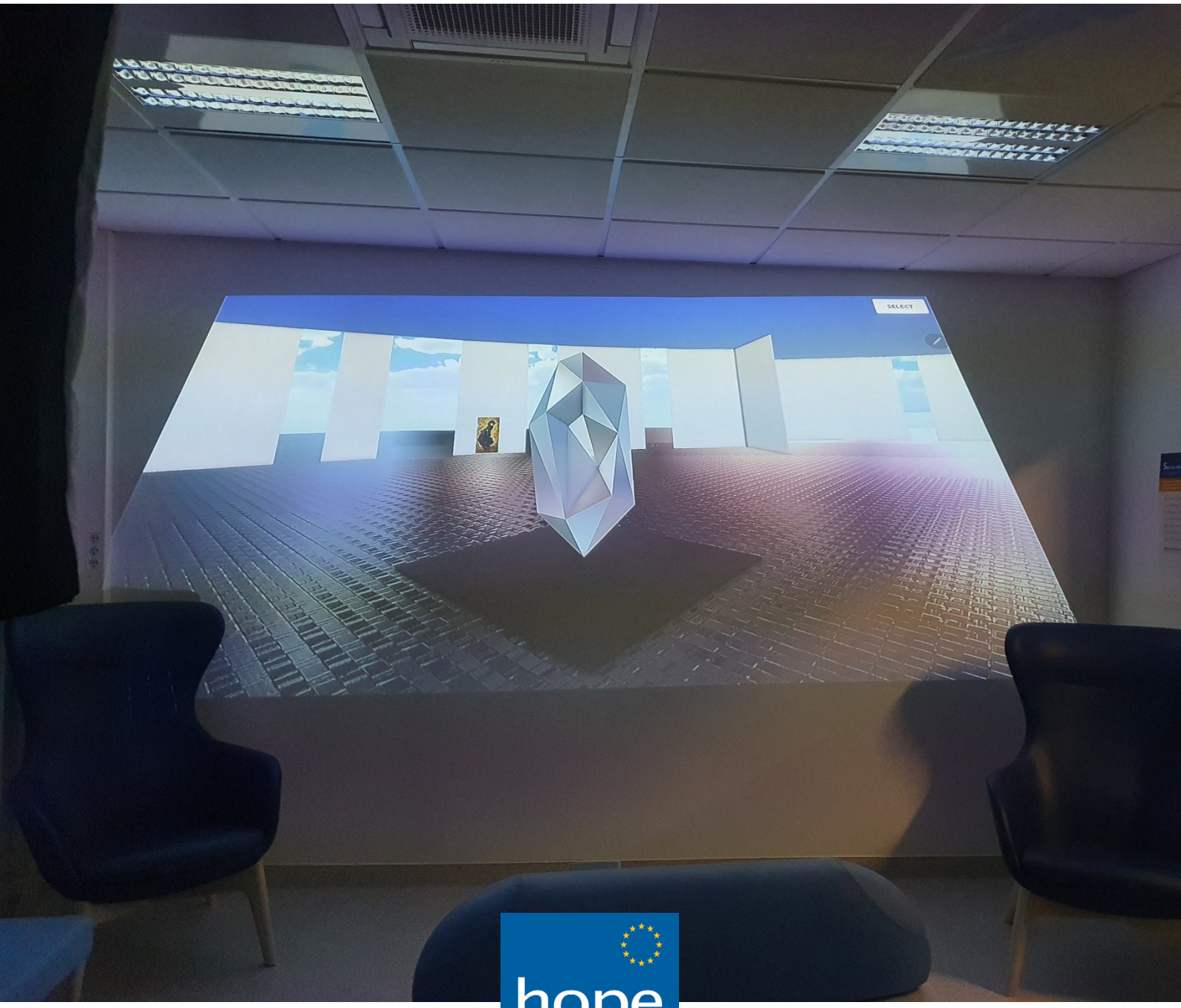
Sari Laanterä and Pirjo Syväoja from South-Eastern Finland University of Applied Sciences and Wellbeing Services County of South Savo, respectively, presented their efforts to help ensure the availability of the social and healthcare workers of the future. In a context of demographic change, where the expansion of the ageing population is outpacing the current birth rate in Finland, Laanterä and Syväoja's project is piloting working life-oriented education paths and models for competence development (e.g., micro-credits, online training modules, and certifications), as well as re-formatting job descriptions based on direct input from practitioners (e.g., nurses are encouraged to keep diary entries of their day-today tasks).

These introductory presentations laid the ground for the country-by-country best practice presentations and *World Café* discussions led by HOPE exchange participants.

## Strategic Note on EHDS and AI Act implementation

During the second half of 2024, discussions turned to the future implementation processes of the AI Act (formally endorsed in May 2024) and the European Health Data Space (final endorsement received in January 2025). Health stakeholders were informed by the European Commission – via the eHealth Stakeholder Group – and by the TEHDAS2 Joint Action that the end of the legislative process also marked the beginning of more practical work. Both matters are unique in the sense that they contain many provisions that are not yet fully defined: the EHDS alone includes over 30 Implementing Acts, the definition of which by the Commission will rely on the production of comprehensive and suitable technical specifications and guidelines. Moreover, the Commission announced that the eHealth Stakeholder Group would cease to exit following the end of its mandate and eventually become an expanded EHDS Stakeholder Advisory Forum (from 2027). This transition would make it possible to further discuss implementation challenges and opportunities in an inclusive way.

To prepare members for collecting stakeholder inputs pertaining to concrete implementation challenges at healthcare institutional and national/regional level, HOPE prepared an in-depth Strategic Note for them at the end of 2024, which will guide discussions during 2025. This note also included AI given that training algorithms is an integral feature of the EHDS, which ultimately also aims to make available a lot more personal electronic health data for innovation and research purposes.

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European Hospital and Healthcare Federation

General Report on the Activities of the
European Hospital and Healthcare Federation 2024