# General Report

on the Activities of the

# European Hospital and Healthcare Federation

## 2023

hope
European Hospital and Healthcare Federation

**Photo credits:**

Back cover and chapter illustrations: © Art dans la Cité 2023


ILLUMINART is an intereactive and innovative device proposed by Art dans la Cité.
It allows the projection of artworks in hospitals to improve patients' well-being.
Patients can choose and interact with the content projected.

Photo Chapter 1: Staff interacting with Composition color - Grondrecourt - Santiago Torres
Illustration Chapter 2: Composition color - Santiago Torres - Ehpad Grondrecourt le chateau
Illustration Chapter 3: Atelier Mathias - ABR Montreuil
Illustration Chapter 4: Watercolor landscape
Back page: 7 Gold Still

Images and vectors (including the front cover) in this publication are either free for use or created by Unsplash.com or via CANVA.

**General Report on the Activities of the European Hospital and Healthcare Federation - 2023**

HOPE
Pascal GAREL, Chief Executive
Avenue Marnix 30, 1000 Brussels
Belgium
www.hope.be

# General Report

on the Activities of the

# European Hospital and Healthcare Federation

2023

# Contents

Chapter 3



Chapter 4

# Introduction

In 2023, the second year of the Russian Federation's invasion of Ukraine, the consequences were still vivid: massive loss of life and trauma injuries among civilians, destruction of essential health services – including treatment facilities for chronic conditions, disruption of medical supply chains, destruction of health facilities, as well as Europe's largest displacement crisis since the Second World War. Moreover, the consequences of the COVID-19 pandemic that arose in 2020 continued to weigh on European health systems, economies, and daily life as it did in 2022.

On the EU legislative side, the new EU Health security framework, adopted in 2022, was working in particular with the new Health Emergency Response Authority. But negotiations continued between the European Parliament and the European Council on the legislative proposal on Artificial Intelligence and the European Health Data Space.

HOPE continued monitoring 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. HOPE also continued engaging in the discussions on post-Brexit EU-UK relations, in relation with various issues such as medicines supplies, research, patient safety, clinical trials, etc.

Some past topics found themselves back on the agenda due to the evaluation of current directives and regulations, the Blood Tissue and Cells Directive, the State Aid Package, the Restriction of Hazardous Substances, the pharmaceuticals legislation as well as 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 the climate to name but a few.

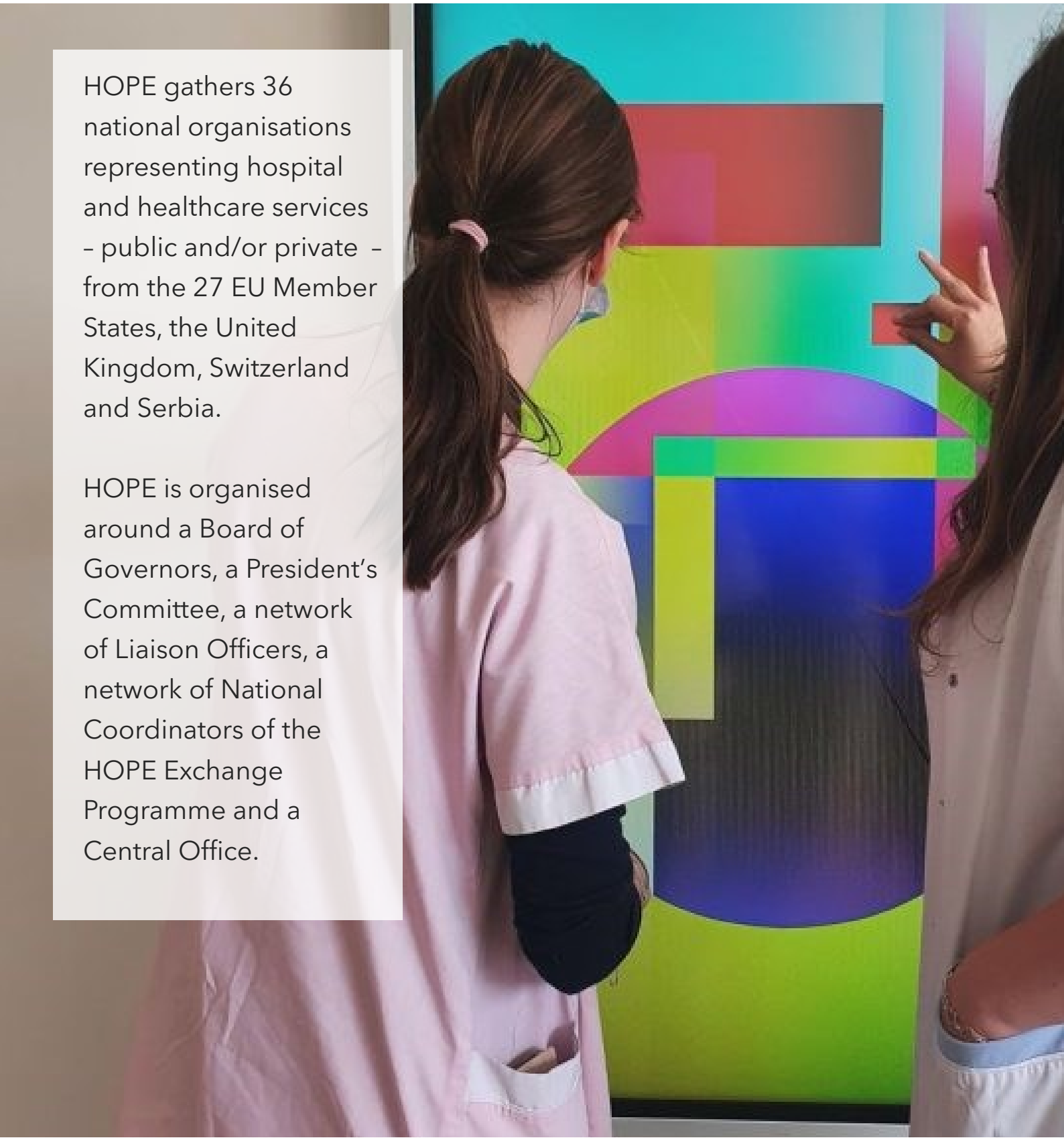
In 2023, HOPE also contributed to the EU non-legislative agenda through several European projects. H2020 projects TeNDER and PERISCOPE very successfully concluded, RE-SAMPLE and HosmartA further developed their activities in 2023 with HOPE as a partner. Two new projects had kicked off in 2022: SAFEST (Improving quality and patient SAFEty in surgical care through STandardisation and harmonisation of perioperative care in Europe) and InnoFacilitator Project (Health InnoFacilitator European Facilitator Community Promoting Public Procurement of Innovation in Healthcare). And four more started in 2023: FLASH (financing), XpanDH (digital), DIOPTRA (colorectal cancer) and LUCIA (lung cancer). 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 and representatives participated as speakers or helped organise several European events.

The HOPE Exchange Programme 2023 was concluded by the HOPE Agora that took place on 3 and 4 June 2022 in Brussels, focusing on the theme "Climate and Environment: Challenges for Hospitals and Healthcare Services."

# Chapter 1

# LIFE AND GOVERNANCE



HOPE gathers 36 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.

# Governance

Board of Governors meeting in Brussels

The Board of Governors (BoG) is composed of the President, the Governors, one from each European Union (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 2023: on 2 June and 16 November in Brussels. During the June meeting, Mr Eamonn Fitzgerald (Governor for Ireland), following the presidency of Dr Urmas Sule (Governor for Estonia), was elected President and Mr Francis De Drée (Governor Belgium) was elected Vice-President.

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 2023 were former presidents Ms Eva M. Weinreich-Jensen (Governor for Denmark) and Dr Urmas Sule (Governor for Estonia), as well as Ms Paloma Calleja Toledano (Governor for Spain). 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 24 April and on 20 October 2023 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 2023, HOPE Liaison Officers meetings took place: on 22 March and on 1 June in Brussels, and in Rome on 23 November. 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 Rome on 24 November to prepare the 2024 programme.

Located in Brussels, Belgium, the Central Office is managed by the Chief Executive, Mr Pascal Garel. Ms Ana Sofia Carbonell is part-time EU Project Officer. Ms Marie Nabbe is EU Affairs Officer. Mr Sascha Marschang is part-time Senior Advisor. Ms Laurie Andrieu part-time EU Policies and Communication Officer left in July 2023.

# GOVERNANCE AT THE END OF 2023

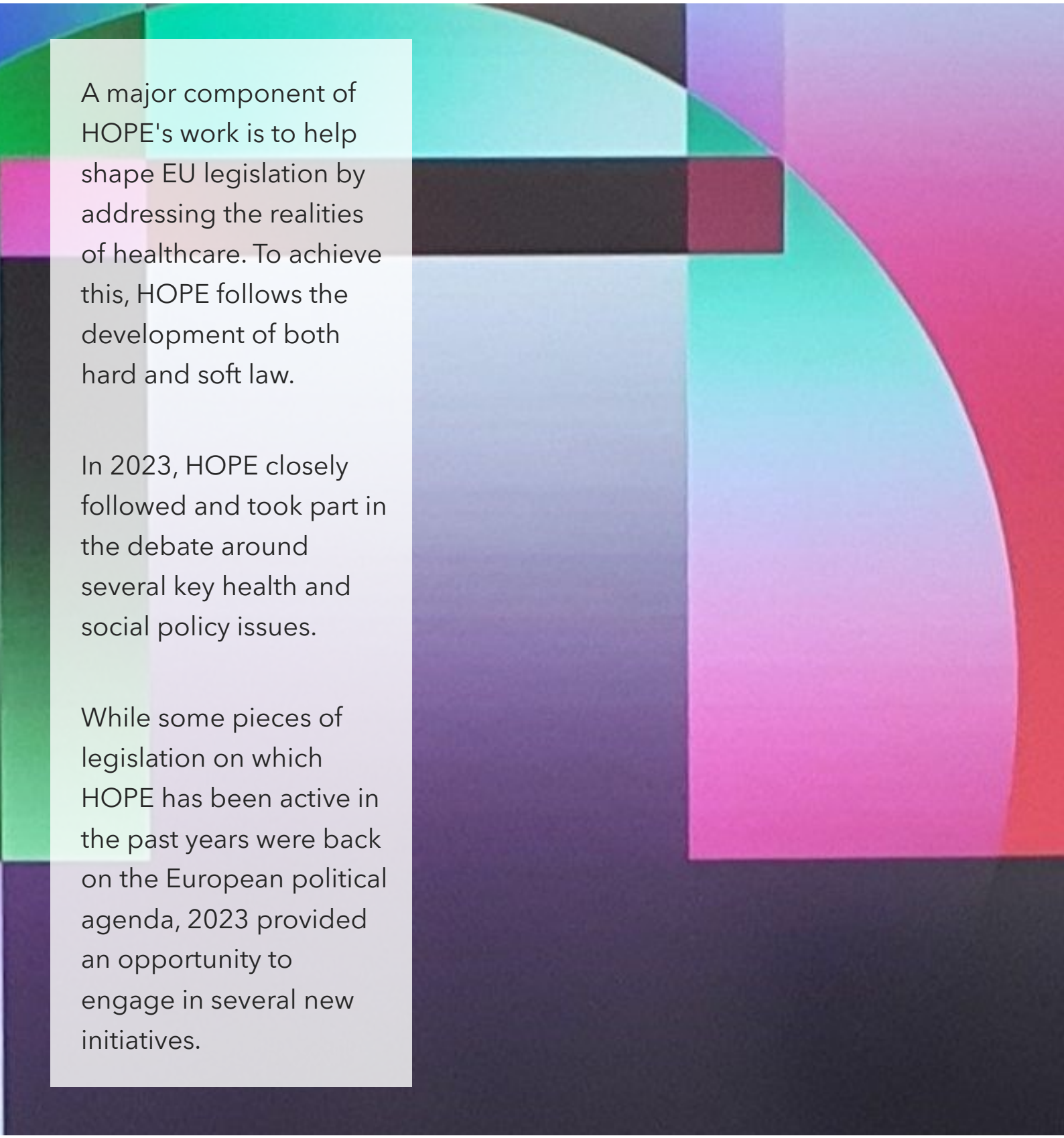
| | |
|---|---|
| President | Eamonn Fitzgerald, Ireland |
| Vice-President | Francis De Drée, Belgium |
| Chief Executive | Pascal Garel |

## GOVERNORS AND HEADS OF DELEGATION

| | |
|---|---|
| Austria | Nikolaus Koller |
| Bulgaria | Krasimir Grudev |
| Croatia | Željko Plazonic |
| Cyprus | Christis Loizides |
| Czech Republic | Miloslav Ludvik |
| Denmark | Eva Weinreich-Jensen |
| Estonia | Urmas Sule |
| Finland | Sari Raassina |
| France | Zaynad Riet |
| Germany | Gerald Gaß |
| 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 | Marián Bencat |
| Slovenia | Radivoj Nardin |
| Spain | Paloma Calleja Toledano |
| 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 2023, 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, 2023 provided an opportunity to engage in several new initiatives.

# 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 2023, among the major issues regarding EU political activity, five 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. Indeed in 2023, the European Commission proposed legislation on the last two topics.

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 European 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.

In addition, several other initiatives remain on the EU political agenda: the legislative proposal on Artificial Intelligence and the ePrivacy Package. 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.

# DIRECTIVES AND REGULATIONS

## 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 was finally signed on 23 November 2022. The Regulation (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.

The new rules include improved prevention, preparedness and response planning at EU and national levels. The Commission will be able to formally trigger stronger intra-EU cooperation and allow for the timely development and stockpiling of medical countermeasures. The legislation also clarifies the procedures for jointly procuring medicines and medical devices, including the possibility to limit parallel procurement and negotiation activities by participating countries, in the case of products purchased jointly at EU level.

### European Centre of Disease Prevention and Control Mandate

The signing of the Regulation took place on 23 November 2022. 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. In May 2021, HOPE had published a position paper on the proposal for a regulation to extend the mandate of the ECDC.

The ECDC will cooperate with the European Commission, national authorities and relevant EU bodies and agencies to ensure their activities are consistent and complement each other. It will also work in close cooperation with international organisations in the field of public health, in order to avoid duplication of efforts. In particular, the closer collaboration with the WHO will include areas such as monitoring and reporting on trends in communicable diseases and exchanging information on unusual epidemic phenomena or new communicable diseases of unknown origin, including those in third countries. The Centre will also:

- establish an EU Health Task Force of experts to assist with preparedness and response planning as well as with local response to outbreaks, in coordination with the European Union Civil Protection Mechanism and other international mechanisms,
- monitor the capacity of national health systems to detect, prevent, respond to and recover from communicable disease outbreaks, identify gaps and provide science-based recommendations,
- organise visits to the Member States to provide additional support to the national preparedness and response planning,
- ensure that experts and stakeholders, including civil society organisations, contribute to its advisory work,
- provide technical and scientific assistance to national authorities to develop their capacity to detect and sequence the genomes of infectious agents,
- monitor the uptake of vaccination against major communicable diseases across the EU, taking into account the specificities of national and regional vaccination schedules,
- facilitate fighting against misinformation on vaccination and the causes of vaccine hesitancy.

## 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. The new roles of the agency are:

- the responsibility for monitoring medicines shortages that might lead to a crisis situation;
- the reporting of shortages of critical medicines during a crisis;
- the coordination of EU/EEA countries with shortages of critical medical devices and in-vitro diagnostics in a crisis, after an initial transition period up to 2 February 2023.

### Health Emergency Preparedness and Response Authority

The European 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 is 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.

In 2022, HOPE was selected as a representative stakeholder for the HERA Civil Society Forum (CSF). The forum, as a sub-group of the HERA Advisory Forum, will help to ensure that the HERA receives regular input on the views and opinions of the civil society stakeholders. HOPE was accepted following a call for applications. In 2023, HOPE attended the meetings of the CSF and led the working group 3 on training and information, which aimed at providing information on the development of HERA's training programme activities. A discussion paper was adopted and published and endorsed by HOPE.

## EU-UK RELATIONS

On 7 December 2017, HOPE (with the support of its member the NHS Confederation) and a group of European organisations representing patients, healthcare professionals and the healthcare industry – the European Health Stakeholder Group – had called on the EU and UK to prioritise patients in the Brexit negotiations. The action has continued since with regular meetings organised at HOPE central office or online with European stakeholders.

The UK left the EU on 31 January 2020, when the withdrawal agreement entered into force marking the end of the period under Article 50 TEU and the start of a transition period that would last until 31 December 2020. The EU and UK negotiators in Brussels reached an agreement on 24 December 2020. The EU and UK signed the agreement on 30 December 2020. HOPE had been following those episodes, working at all stages – and will continue – to identify the possible consequences for its members.

The European Health Stakeholder Group met in HOPE office on 6 October 2023 for an exchange of views on a wide range of topics and an opportunity to keep the connection between colleagues in the UK and the EU. On 7 September 2023, the European Commission and the UK Government announced that they had reached an agreement on the association of the UK to Horizon Europe and Copernicus programmes from 1 January 2024. Malgorzata Czerwiec (UK research office in Brussels, UKRO) presented what this agreement will mean. UK organisations will be able to participate in Horizon Europe calls for proposals on the same terms as institutions from other Associated Countries (except for the EIC Fund and a limited number of restricted calls). Association to Copernicus, the EU Earth Observation programme, will enable the UK's access to a state-of-the -art capacity to monitor the Earth and to its services. It will also provide the UK research community with access to unique data, which is often required on Horizon Europe projects.

## 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.

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 European Parliament and the Council. The regulation provided for a delayed application of three years, during which the Commission has 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 (two additional organisations were selected as observers).

On 14 June 2023 HOPE attended the first meeting of this formal stakeholder body created under the Health Technology Assessment Regulation .

Then, on 25 October 2023, HOPE attended the workshop on HTA for oncology products and advanced therapy medicinal products (ATMPs). Following an introduction by Maya Matthews, Chair of the HTA Stakeholder Network, European Commission, several stakeholders presented challenges and solutions. Three breakout sessions were then organised: on how to approach best available evidence in oncology and ATMPs; how to handle the wide range of treatment standards in cancer in Europe; and on what kind of contextual information should be included in JCAs for oncology and ATMPs.

The second HTA Stakeholder Network meeting took place on 17 November 2023 in Brussels. HOPE participated in the meeting and breakout sessions. Article 22 of the HTA Regulation provides that reports on emerging health technologies (EHT) expected to have a major impact on patients, public health, or healthcare systems, shall be prepared. These reports shall address the estimated clinical impact for patients and the potential organisational and financial consequences of EHT for national healthcare systems. According to Article 22 these reports shall be based on existing scientific reports or initiatives on EHT and information from relevant sources. The provision then gives examples of such relevant sources and includes members of the Stakeholder Network.

The EHT subgroup of the HTA Coordination Group has been tasked with preparing the EHT reports. During the implementation period, the EHT subgroup starts with preparatory work for the EHT reports. Relevant existing scientific reports and initiatives on EHT and information from relevant sources continue to be mapped. During this mapping, a number of relevant horizon-scanning initiatives and sources have been identified.

Three questions were asked: How can stakeholders contribute as information sources to the report on emerging health technologies? What are the important issues for stakeholders regarding the joint work on medical devices? How to ensure appropriate conflict of interest management, including for stakeholder organisations, patients, clinical experts, and other relevant experts involved in the joint work? The outcome of the discussions will inform the continued preparatory work of the EHT subgroup.

## 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 European Commission and published in the EU Official Journal on 9 February 2016.

As of 9 February 2019, the Falsified Medicines Directive fully applied through the delegated act. From this date, the industry must affix a 2D barcode and an anti-tampering device on the box of prescription medicines. Pharmacies – including online pharmacies – and hospitals must check the authenticity of medicines before dispensing to patients.

HOPE followed closely the drafting of the delegated act, with particular attention on how the medicines verification system at the point of dispensing in hospitals is organised. HOPE stated that the only place where the verification could take place would be on arrival at the hospital and it urged the Commission to allow flexibility, to duly consider the different contexts in Member States. The delegated act has taken HOPE's position into consideration as it allows for verification and decommissioning at any time after arrival of the medicinal products into the hospital setting.

In February 2017 HOPE joined the European Medicines Verification Organisation (EMVO) as Associate Member together with the European Association of Hospital Pharmacists (EAHP). The EMVO is the not-for-profit organisation in charge of the medicines verification system management and governance created in February 2015.

On 10 January 2018, an EMVO Hospital platform was launched by HOPE and the European Association of Hospital Pharmacists. This was to facilitate the follow-up of the implementation of the Falsified Medicine Directive, and in particular the monitoring of hospital on-boarding. The internal discussions within EMVO have moved to secondary use that the industry supports, trying to convince the Commission, against the will of some other stakeholders including HOPE. There is still considerable tension in terms of governance as well.

In June 2023 a study on trends in the falsification of medicinal products and measures that are provided according to Directive 2011/62/EU was launched by the European Commission, Directorate General for Health and Food Safety (DG SANTE), to which HOPE contributed. The objective of the study is to assess the implementation of Directive 2011/62/EU (FMD), the measures laid down in DR (EU) 2016/161 and their effects (measures on safety features). It further seeks to evaluate the adequacy and functioning of the system in place against the objectives and targets set out in the DR (EU) 2016/161. As part of the study, they are launching a survey which addresses the actors of the legal supply chain of medicinal products (e.g., manufacturers, distributors, wholesalers, importers, brokers, pharmacists/persons authorised or entitled to supply medicinal products to the public).

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 IVD REGULATIONS

### 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 expresses 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 European 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 European 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 urges the European 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 introduces 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 depends 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).

Key elements of the proposal:

- For medical devices covered by a certificate or a declaration of conformity issued before 26 May 2021, the transition period to the new rules is extended from 26 May 2024 to 31 December 2027 for higher risk devices and until 31 December 2028 for medium and lower risk devices. The extension will be subject to certain conditions, so that only devices that are safe and for which manufacturers have already taken steps to transition to the rules provided for by the Medical Devices Regulation will benefit from the additional time.
- The proposal introduces a transition period until 26 May 2026 also for class III implantable custom-made devices, giving their manufacturers more time to obtain certification by a notified body. Also in this case, the transition period is subject to the application of the manufacturer for a conformity assessment of devices of this type before 26 May 2024.
- To reflect the transition periods put forward by these amendments, the proposal extends the validity of certificates issued up until 26 May 2021, the day when the Medical Devices Regulation became applicable.
- The Commission also proposes to remove the 'sell-off' date currently established in the Medical Devices Regulation and in the In Vitro Diagnostic Medical Devices Regulation. The 'sell-off' date is the end date after which devices that have already been placed on the market, and remain available for purchase, should be withdrawn. Removing this 'sell-off' date will ensure that safe and essential medical devices that are already on the market remain available.

On 16 February 2023 the European 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 officially adopted the amendment to the MDR and IVDR. It paved the way for the formal signing of the legislative text on 15 March 2023.

## 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.

On 14 March 2023, the new Unique Device Identifier (UDI) helpdesk was launched by the Commission. It aims to help the economic operators to implement the requirements introduced by the unique device identification system. On 22 March 2023, the European Commission published a new initiative in the form of a Draft Act on "Medical devices – single identifier for similar highly individualised devices".

The Medical Devices Coordination Group proposed a new work item: 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 2023HOPE 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. Many of these innovative products are developed within (university) hospitals and are brought to the market by startups. As the MDR requires a long and expensive route to the market; consultants and investors recommend aiming for the USA market first. This leads to a long and expensive route to bring new products to and keep existing products on the European market. Furthermore, for products intended to serve a small group of patients, the present MDR route is practically impossible as small numbers prevent suppliers from meeting the requirements of the MDR. This means that the solutions to be proposed have to be quite simple and also intrinsically cheap.

The proposal moving from avoiding all risks at market introduction towards a conditional market entrance with much more emphasis on post-marketing surveillance (PMS) is a solution to go forward. Today manufacturers are not transparent about PMS; their reaction when issues appear is quite often to deny and refuse to act. Another very important point is the definition of "orphan devices". It is impossible to give a hard definition as proposed; flexibility is needed. Medical devices are not always one-to-one coupled to a specific group of patients or diseases. The situation here is different compared to pharmaceuticals.

On 15 December 2023 HOPE participated in the meeting of the Medical Devices Coordination Group orphan device task force and in a first draught of the guidance on Clinical evaluation of orphan medical devices. This draft guidance will be 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 (see chapter 8.2 of the draft guidance regarding the relevance of registries). The co-chairs of the task force plan to organise a meeting with ERN representatives in January or February dedicated to the use of registry data with a view to addressing one of the main challenges for orphan devices, i.e. the limited available clinical data.

During the last days of 2023 HOPE worked with the Commission to prepare its proposal for revisions amending Regulations (EU) 2017/745 and (EU) 2017/746 regarding the gradual rollout of EUDAMED (the EU database for medical devices) information obligation in the event of supply being interrupted and the transitional provisions for certain in vitro diagnostic medical devices (published in January 2024).

## DATA ACT

Following the Data Governance Act (DGA) adopted in 2022, the Data Act Regulation published in February 2022 is the second main legislative initiative resulting from the Commission's 2020 European Strategy for Data. While the DGA creates the processes and structures to facilitate data sharing by companies, individuals and the public sector, the Data Act clarifies who can create value from data and under which conditions, a key digital principle for a solid and fair data-driven economy.

In the European Parliament, the Industry, Research and Energy Committee (ITRE) led the file under Rapporteur Pilar Del Castillo Vera (EPP, Spain), succeeding the adoption of a previous Own-Initiative Report on this subject.

At EU Council level, ministers continued negotiations in 2023 under the Swedish Presidency, during which a provisional agreement could be established prior to its final endorsement under the Spanish Presidency.

HOPE followed and reported on the final stages of the Data Act negotiations in 2023, during which EU policymakers gradually found agreement on essential issues such as the scope of the proposal (allowing users of connected IoT devices to gain access to data generated by their use, held by manufacturers); data sharing, compensation and dispute settlement (including preventing abuse of contractual imbalances in data-sharing contracts); protection of trade secrets and IPR; the conditions according to which data must be provided to public sector entities; enabling customers to switch between different data-processing service providers (cloud providers) and additional safeguards against unlawful data transfers; and the interplay between the Data Act, DGA and GDPR.

The Data Act entered into force on 11 January 2024 and will subsequently start to apply across Member States on 11 September 2025.

## PRODUCT LIABILITY

In order to help adapt liability rules to the digital age, to the circular economy and to the impact of global value chains, the Commission published a draft directive on liability for defective products ("Product Liability Directive" - PLD). This directive 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 revision of the products liability regime is the first in forty years and the consequences for the industry are significant. Despite belated lobbying activity from industry, on 14 December 2023, EU policymakers reached a political agreement on the PLD. 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.

The PLD will apply to all products placed on the EU market 24 months after it enters into force. EU countries will have until then to transpose the directive into national law.

## SAFETY OF PUBLIC PLACES

On 18 October 2017, the European 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 European 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 will then need 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.

## 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 Climate Law includes a process for setting a 2040 goal, which in the Work Programme of the Commission for 2024, published on 17 October 2023.

## ENERGY

### Energy Efficiency Directive

The 2012 EU Energy Efficiency Directive 2012/27/EU established a set of binding measures to help the EU reach its 20% energy efficiency target by 2020. This means that overall EU energy consumption should exceed 1483 million tonnes of oil equivalent (Mtoe) of primary energy or 1086 Mtoe of final energy. Under the directive, all EU countries are required to use energy more efficiently at all stages of the energy chain, including energy generation, transmission, distribution and end use. HOPE contributed at that time to the discussion.

Under the European Green Deal, the Commission has committed to stronger action on climate change and will assess how the EU's greenhouse gas emissions could responsibly be reduced by at least 50% to 55% by 2030.

On 3 August 2020 the European Commission released a Roadmap on the EU Energy Efficiency Directive (EED) to proceed to its evaluation and review. The review aims to provide insights into how the EED could be revised to: achieve a higher level of greenhouse gas reduction by 2030; contribute to other European Green Deal initiatives.

On 14 July 2021, the European Commission adopted a package of proposals to make the EU's climate, energy, land use, transport and taxation policies fit for reducing net greenhouse gas emissions by at least 55% by 2030, compared to 1990 levels. The feedback period ran until 19 November 2021. The Energy Efficiency Directive is part of the 'Fit for 55 Package'.

On 10 March 2023, the European Parliament and the Council reached a provisional agreement. The Parliament adopted the revised Energy Efficiency Directive on 11 July 2023 and 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.

### Energy Performance of Buildings Directive

On 15 December 2021, the Commission published the proposal for a directive of the European Parliament and the Council on the energy performance of buildings. The feedback period ran from 15 December 2021 to 28 February 2022. On the same day, the Members of the European Parliament set out recommendations in a non-binding report ahead of the revision of the directive. The Energy Performance of Buildings Directive is part of the 'Fit for 55 Package'.

On 25 October 2022, the Council reached an agreement on a proposal to revise the Energy Performance of Buildings Directive. On 9 February 2023, the ITRE Committee in the European Parliament adopted its position on the Energy Performance of Buildings Directive. In plenary session, the European Parliament adopted the amendments to the proposal on 14 March 2023, by 343 votes to 216, with 78 abstentions. A deal was reached by the European Parliament, and the Council reached a deal on 7 December 2023.

## EMISSIONS TRADING SCHEME

Set up in 2005, the EU ETS is the world's first international emissions trading system. HOPE contributed at that time to the discussion, identifying the few hospitals concerned. The scheme was divided into a number of 'trading periods'.

The first ETS trading period lasted three years, from January 2005 to December 2007. The second trading period ran from January 2008 until December 2012, coinciding with the first commitment period of the Kyoto Protocol. The third trading period began in January 2013, ending in December 2020. The legislative framework of the EU ETS for its next trading period (phase 4: 2021- 2030) was revised in early 2018 to enable it to achieve the EU's 2030 emission reduction targets and as part of the EU's contribution to the Paris Agreement.

In line with the European Green Deal and the EU's objective to become the first climate neutral economy by 2050, the Commission adopted on 21 September 2020 the revised EU Emission Trading System State Aid Guidelines in the context of the system for greenhouse gas emission allowance trading after 2021 (the "ETS Guidelines"). They entered into force on 1 January 2021 with the start of the new ETS trading period, and replace the previous guidelines adopted in 2012.

The Commission's work programme 2021 released on 19 October 2020 mentions the revision of the EU Emissions Trading System (ETS), as well as a legislative proposal for ETS as an own resource.

The Commission prepared an inception impact assessment (roadmap) for the revision of the EU ETS, followed by a public consultation from 13 November 2020 to 5 February 2021. A consultation on options for including the aviation sector into the EU ETS was held from 1 October 2020 to 14 January 2021.

A proposal for a directive was released by the Commission on 14 July 2021 as part of the 'Fit for 55 Package'. The rapporteur presented his draft report in January 2022. On 17 May 2022, the ENVI Committee adopted five reports of the "Fit for 55 in 2030 package", including one on ETS. On 9 June 2022, MEPs rejected the report on the revision of the ETS. The reform was referred back to the Committee. On 29 June 2022, the European Council reached a general approach on the revision of the ETS. On 18 December 2022, the Council and the European Parliament reached a provisional political agreement on the EU emissions trading system.

The agreed text was endorsed by the COREPER on 8 February 2023. It was approved by the ENVI Committee on the same day.

The Parliament approved the text in plenary on 18 April 2023 and the Council adopted it on 25 April 2023. The text was published in the Official Journal of the European Union on 16 May 2023 and it will enter into effect on 6 June 2023, 20 days after its publication.

Following the revision of the ETS Directive, the European Commission now needs to update several regulatory acts for implementation of the ETS. This initiative is needed to develop minimum requirements for the content and format of climate-neutrality plans. The Commission adopted the implementing regulation on 31 October 2023.

## STATE AID

From a state aid perspective, health and social services form a subgroup of services of general (economic) interest ("SG(E)I"). They include medical care provided by hospitals and other healthcare providers, long-term care, childcare, access to and reintegration into the labour market, social housing and the care and social inclusion of vulnerable groups. State aid control comes into play when these services are provided as an economic activity on a market and are, at least partially, financed through public resources.

The European Commission's state aid practice aims to prevent public interventions from distorting the level playing field for operators. It ensures that SGEI compensation goes to genuine SGEI and that there is no overcompensation or cross subsidisation of commercial activities. In principle, compensation measures for health and social services are subject to EU state aid rules and, more particularly, the four texts that the Commission adopted as part of its 2012 SGEI package (SGEI Communication, SGEI Decision, SGEI Framework and SGEI de minimis Regulation, which is the only text expiring on 31 December 2020). HOPE successfully lobbied for the exemption of notifications concerning hospitals. The SGEI de minimis Regulation applies to compensation measures which do not exceed EUR 500 000 over any period of three fiscal years granted to undertakings providing a SGEI and therefore shall not be deemed to constitute state aid in the sense of Article 107 paragraph 1 Treaty of the Functioning of the European Union (TFEU).

Compensation measures for health and social services – to the extent that they constitute state aid and exceed the (SGEI) de minimis threshold – usually fall under the SGEI Decision, regardless of the aid amounts involved. Thanks to HOPE lobbying, aid granted under the SGEI Decision does not need to be notified if the conditions therein are fulfilled. State aid measures which do not fulfil all the conditions of the SGEI Decision may be declared compatible with the internal market under the SGEI Framework, subject to prior notification.

In June-July 2019, the Commission opened a Roadmap consultation. The purpose was to check if the rules on health and social services of general economic interest ('the services') meet their objectives under the 2012 services package. The evaluation also assessed how the regulation on small-scale government subsidies (de minimis state aid) for such services has been applied. The roadmap was complemented by a public consultation open from July to December 2019 to which HOPE contributed.

In 2020, the consulting firm EY was contracted by the European Commission (Directorate General for Competition) to undertake a Study on Market Trends in the health (with a focus on hospitals) and social housing sectors and the EU state aid implications In September 2021, the Commission published an external study on market trends in healthcare and social housing and EU State aid implications.

The following step was the publication in December 2022 of a roadmap of the Commission to which HOPE replied welcoming the revision of the SGEI de minimis ceiling as the current one is too low.  There were also several inconsistencies with the general de minimis regulation, relating to the concepts of 'undertaking', 'undertakings in difficulty', and mergers and acquisitions. The introduction of a mandatory register that is mentioned should be truly aimed at reducing the administrative burden.

The European Commission launched a call for evidence, open for feedback from 12 December 2022 to 9 January 2023, and to which HOPE replied welcoming the revision of the SGEI de minimis ceiling as the current one is too low.

The European Commission published a Communication State Aid – review of rules on exemptions for small amounts of aid to services of general economic interest (europa.eu) on 19 April 2023. In the proposal the total amount of de minimis aid granted per Member State to a single undertaking providing services of general economic interest shall not exceed EUR 650 000 over any period of 3 fiscal years.

## WORKERS' PROTECTION FROM EXPOSURE TO HAZARDOUS PRODUCTS

On 16 December 2021, the Council and the European 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.

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 European 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 have 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 European 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
- or 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 European 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.

# PROPOSED LEGISLATIONS

## 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 European Commission organised on 28 October 2019 a conference to present the findings and give stakeholders, including HOPE, an opportunity to discuss them.

On 17 November 2020, the European Commission launched an initiative for a 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 aims to address the (re-)emergence of communicable diseases, including lessons learnt from the COVID-19 pandemic. It also wants 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 and the European Commission during the evaluation of the EU legislation on blood, tissues and cells.

On 14 July 2022, the European 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 implies a broader scope to cover all substances of human origin, with the exception of solid organs, including human breast milk. It envisages updating the technical guidelines on the basis of 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, with regard to innovation, the proposal aims 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 in 2022.

On 2 March 2023 the rapporteur Nathalie Colin-Oesterlé (EPP, FR) presented at the European Parliament's Committee on the Environment, Public Health and Food Safety (ENVI) her amendments and shadow rapporteurs commented it. The deadline for amendments was 8 March 2023. The vote in ENVI was planned for June 2023 and in plenary in September. On 2 March 2023, the European Parliament's ENVI Committee debated on the draft report. On 18 July 2023, the ENVI had adopted its position. The report by Nathalie Colin-Oesterlé, which proposed amendments to the European Commission's initial proposal, was adopted with 59 votes in favour, 4 against and 4 abstentions.

On 23 May 2023, HOPE attended an event on "Substances of Human Origin (SoHO) Regulation: the future of donation and supply – The views of SoHO professional scientific associations" at the European Parliament in Brussels. The event was co-organised by the Common Representation of Substances of Human Origin (CoRe SoHO) and co-hosted by MEP Dolors Montserrat (EPP, ES) and MEP Nicolás González Casares (S&D, ES). The event discussed the "Commission proposal for a regulation on standards of quality and safety for substances of human origin intended for human application" released in July 2022.

During the plenary session of the European Parliament on 12 September 2023, MEPs adopted the report on new rules governing the use of SoHO with 239 amendments to the text by the European Commission. The report was adopted with 483 votes in favour, 52 against, and 89 abstentions. MEPs insist that donations of those substances must always be voluntary and unpaid, with donors able to receive compensation or reimbursement for losses or expenses incurred during the donation process. They stress that compensation should not be used as an incentive to recruit donors, nor lead to the exploitation of vulnerable people. To ensure the EU has its own independent supply of these substances, MEPs want an EU strategy to ensure their availability, an EU list of critical SoHOs, and the establishment of "national emergency and continuity of supply plans."

On 26 October 2023 the Council agreed its negotiating mandate on the proposed regulation on blood, tissues, and cells. The compromise text guarantees increased harmonisation to facilitate cross-border exchanges and access to therapies prepared with substances of human origin, including through the creation of an EU SoHO coordination and advisory body. This includes common EU-wide procedures for the authorisation and assessment of preparations of substances of human origin intended for clinical use. It also provides for strengthened oversight systems. The national competent authorities, staffed with qualified and experienced personnel, will supervise activities related to substances of human origin in an independent and transparent manner. They will also be responsible for the authorisation of the organisations performing those activities. Additional authorisation and inspection requirements will apply for entities that both process and store, release, import or export substances of human origin. The principle of voluntary and unpaid donation is also stressed in the compromise text, to safeguard this important principle. The agreement on the Council's negotiating mandate allows the presidency to start talks as soon as possible with the European Parliament on the final text. The Spanish presidency reached a provisional agreement with the European Parliament before the end of the presidency term.

On 15 November 2023 HOPE participated in 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 are 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.

The project is structured in two main workstreams:

- Mapping current activities that contribute to the safety, quality, efficacy and optimal use of the different types of SoHO in EU hospitals, and identifying the actors involved in the specific activities.
- Developing recommendations and guidance to improve the organisation and management of SoHo in EU hospitals (the development of the recommendations and guidance will come after the identification of best practices in SoHO management through EU hospitals and a stakeholder consultation that will support the refinement of the recommendations and guidance).

The aim of this kick-off meeting, which was also attended by the project sponsor, DG SANTE, was to provide you with more information about the project and the participatory activities foreseen.

## CYBERSECURITY

Among the important components of the EU's cybersecurity policy are the Cybersecurity Act and the Cybersecurity Strategy for the Digital Decade. The Cybersecurity Act entered into force in 2019 granted a permanent mandate to the European Cybersecurity Agency (ENISA) with expanded resources and tasks. The EU's Cybersecurity Strategy for the Digital Decade was released by the European Commission in 2020 as the centre piece of a second cybersecurity package following the initiation of EU level coordination in 2013. Moreover, as part of the EU Digital Strategy and policy roof for various initiatives, the Recovery Plan for Europe and the Security Union Strategy 2020-2025 contains regulatory, investment and policy initiatives to boost resilience and technological sovereignty, to increase operational capacity (to prevent, deter and respond to threats), and to foster global cooperation.

Throughout 2023, HOPE gathered intelligence and closely followed cybersecurity developments at EU and national level. The debate over the growing number of cyber threats affecting hospitals and healthcare institutions continued to gain traction as key components of the EU's Cybersecurity Framework made progress on their way through the policy cycle (see below), and the revised directive on measures for high common level of cybersecurity across the Union (NIS2 Directive), as well as the directive on the resilience of critical entities (CER Directive), agreed upon in 2022 and covering various sectors including healthcare, entered into force. Crucially, NIS2 obliges the EU Member States to adopt a strategic, comprehensive and collaborative approach to cyber protection, including by establishing national competent authorities and computer security incident response teams (CSIRTs) tasked with monitoring and analysing threats and incidents. In addition, EU-CyCLONe (EU cyber crisis liaison organisation network) is a supranational cooperation network for Member States' national authorities in charge of cyber crisis management to prepare for large-scale incidents. The Council's conclusions on developing the EU's cyber posture and adoption of the Framework for a Coordinated EU Response to Hybrid Campaigns of 2022 also strengthened the demand for increased EU cooperation and a coordinated, multi-stakeholder response.

## Cyber Resilience Act

The European Commission's proposal for a Cyber Resilience Act wasreleased on 15 September 2022. It is a regulation aiming to set horizontal cybersecurity requirements for manufacturers and vendors of products with digital elements, complements the NIS2 Directive and establishes connections with the EU's Medical Devices / In Vitro Diagnostics Devices Regulations, the Radio Equipment Directive, the AI Act and European Health Data Space proposals. The Cyber Resilience Act will apply 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 proposes 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 will need to comply with strict conformity requirements, considering cybersecurity risks during all phases. This includes Electronic Health Record (EHR) systems under the EHDS. The lead committee in the European Parliament is the Industry, Research and Energy (ITRE) Committee with MEP Nicola Danti (Renew, Italy) as Rapporteur.

HOPE published a short Position Paper on the Cyber Resilience Act in January 2023, requesting clarification of the CRA's scope and its relevance to everyday hospital and healthcare functions, its relationship with other EU legislative subjects and how it relates to cloud services and open-source software.

## Cyber Solidarity Act

In April 2023, the European Commission added another piece to its cybersecurity framework with the publication of the Cyber Solidarity Act. This proposes common action to foster resilience against threats and incidents and strengthening the link between EU security policies and the cybersecurity ecosystem. A key component is the establishment of a European Cyber Shield composed of national and cross-border Security Operations Centres (SOCs) making use of AI and advanced data analytics to detect and share warnings on threats and incidents, thereby allowing a timely response. In the Parliament, the Cyber Solidarity Act is also led by ITRE under Rapporteur MEP Lina Gálvez Muñoz (S&D, ES, which adopted its draft report on 7 December 2023. The proposed amendments address, among others, budgetary questions, support for public -private threat information sharing, access to cyber threat intelligence for SOCs, time limits for responding to EU Cyber Reserve requests and its tasks and oversight.

However, the Transport, Telecommunications and Energy Council (TTE) session of 5 December revealed some scepticism at Member State level, with digital ministers requesting more technical work before a negotiating mandate can be reached. Subjects of concern included accessibility of the Cyber Reserve to third countries, the role of the CSIRTs, and risks of duplications of national and cross-border entities.

ENISA's threat landscape report for the health sector covering January 2021 - March 2023 confirms the increase of cyber incidents affecting health organisations. In this period, health providers reported 53% of the total incidents (European hospitals alone accounting for 42% of cases, while notifications by health authorities, bodies and agencies amounted to 14%, whereas health research entities and supply chain and service providers reported 11%. It is unclear how strongly the European health sector is affected compared to other vulnerable sectors such as banking and manufacturing. ENISA highlights that ransomware was one of the principal threats (54%), both in the number of incidents and regarding its impact on health organisations. 43% of ransomware incidents were coupled with data breaches or data theft as well as service disruption. Patient data were the most targeted assets (30%).

Clearly, ENISA's role is expanding: under NIS 2, it will maintain a European vulnerability database, create a registry of service providers and publish biannual reports; the Cyber Resilience Act adds information gathering, relay and incident mitigation tasks based on notifications received from manufacturers of actively exploited vulnerabilities in products with digital elements; the Cyber Solidarity Act endows it with further responsibilities for developing cybersecurity skills and a European attestation scheme.

Further cybersecurity-related actions at the EU level affecting individuals and public administration include the proposals for a legal framework for a European Digital Identity (to enable secure use of public and private online services using mobile apps), the regulation laying down measures for a high common level of cybersecurity at the institutions, bodies, offices and agencies of the Union and the EU Cyber Defence Policy.

Given the complex interlinkages between different pieces of cybersecurity legislation, following discussions with national and regional member representatives, HOPE published its Position Paper on the EU Cybersecurity Framework in December 2023, which takes a horizontal view of an evolving ecosystem. It calls on EU policymakers to consider the following points of relevance to hospitals and healthcare organisations needing to build up resilience to cyber threats:

- make available additional EU funding for cybersecurity implementation measures so that hospitals and healthcare institutions can assume multifaceted responsibilities;
- ensure that the Cybersecurity Skills Academy places a strong emphasis on skills development and education in the healthcare sector, while safeguarding that all relevant EU funds and programmes are effectively used to boost cybersecurity know -how, leadership and expertise;
- consider the fragmented nature of European health systems: cybersecurity measures should support ongoing transition processes and system upgrades;
- embed the EU cybersecurity framework in current and future EU legislation relevant to digital healthcare;

- actively involve HOPE and its members in discussions about the challenges posed by cyber threats affecting hospitals and healthcare institutions;
- ensure EU-funded cybersecurity research results, toolkits and solutions are promoted, accessible to, and used by hospitals and healthcare institutions; and, as a first step forward,
- place particular emphasis on improving basic identification and authentication measures and skills, including use of secure passwords and more uniform procedures regarding the use of healthcare IT tools and systems.

It is expected that the Cyber Resilience Act and Cyber Solidarity Act proposals will only be finalised during the next EU policy cycle 2024-2029, which means HOPE should have opportunities to advocate its position as the debate goes on.

## ARTIFICIAL INTELLIGENCE

In 2023, HOPE continued to monitor and deepen its understanding of the health-relevant implications of the increased deployment and introduction of technologies using artificial intelligence (AI) and robotics. The so-called AI Act, released by the European Commission in April 2021, proposes different rules for AI systems based on a risk-based approach (minimal, limited, high-risk and unacceptable). It became one of the most discussed subjects in Brussels given that certain AI applications – especially generative solutions like ChatGPT – became more widely known and demonstrated their potential in a tangible way to ordinary people and professional end users.

Throughout the year, the designated AI Act Rapporteurs representing the two lead committees in the European Parliament, Brando Benifei (S&D, Italy) for IMCO – Internal Market and Consumer Protection and Dragos Tudorache (Renew, Romania) for LIBE – Civil Liberties, Justice and Home Affairs, whose joint report had already been released in the previous year (April 2022), worked relentlessly against the backdrop of an increasingly heated media debate. AI's proponents claimed it could significantly change the effectiveness of health systems operations (e.g., more accurate diagnoses, more tailored treatment options, better capacity for dealing with public health emergencies) while its detractors cautioned against relying too much on the decisions of potentially biased algorithms whose logic is difficult if not impossible to grasp for individuals charged with their oversight.

The key challenge was to nail down a text that could 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. The original European Parliament report argued in favour of the risk-based approach and restricting the obligations imposed by the AI Act to forbidden practices, high-risk AI systems, and those requiring transparency.

However, this triggered a vast set of amendments and lengthy negotiations, inter alia centring on the definition of AI, deciding on appropriate exceptions for certain systems (including general purpose AI), alignment of legal provisions with those of the GDPR, clarifying and rebalancing the chain of responsibility, as well as agreeing on important governance and enforcement aspects (e.g., role of AI Board).

To be in a better position to contribute to the policy process and debate, at the start of the year HOPE joined a Thematic Network under the European Health Policy Platform, led jointly by Health Action International and Brunel University London Centre for AI. This platform approached the discussion from a fundamental rights-based, civil society perspective closely aligned with HOPE's Position Paper on AI dating back to 2021. As part of this collaboration, HOPE co-signed a Joint Statement, "The Impact of Artificial Intelligence on Health Outcomes for Key Populations: Navigating Health Inequalities in the EU" in June 2023, which proposed several measures including:

- improving digital infrastructure, opportunity, means, access and services to innovative treatments and therapies across Europe;
- implementing professional training among duty bearers and health practitioners on AI risks for key populations;
- promoting the use of just, transparent, fair, and ethical AI to reduce health inequalities;
- improving the breadth and quality of datasets to counter algorithm bias and under-representation of key population groups;
- involving people with lived experience in all stages of the development of AI; and, where legally appropriate,
- ensuring separation of data uses between health and other areas, e.g. immigration or law enforcement, that could negatively impact the health outcomes and rights of undocumented migrants and other key population groups.

HOPE continued to participate in the network following the end of its formal mandate, with follow-up communications planned for 2024.

Trilogue discussions continued to be held by the Spanish Council Presidency under which, on 8 December 2023, EU policymakers finally reached political agreement by settling their differences on over twenty open issues. The negotiations focused in particular on the AI Act's law enforcement chapter (e.g., AI systems used for military and defence purposes); defining prohibited practices (such as emotion recognition, predictive policing software, biometric recognition other than in a few exceptional cases); the access, reporting and impact assessment obligations for high-risk use cases (deployment of AI systems in sensitive areas like education, employment, migration and border control, essential public services including 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.

However, extensive technical work remains to be done in 2024 to refine certain details (definitions and exceptions, scope of provisions), and the publication of the final AI Act is not expected before the summer of 2024, after which most of its elements would apply two years after entry into force.

### AI Civil Liability

In response to a European Parliament own-initiative resolution adopted in October 2020, the European Commission published a proposal for a directive on adapting non-contractual civil liability rules to artificial intelligence (the 'AI liability directive') on 28 September 2022. As a complement to the AI Act, the Commission proposes to modernise the EU liability framework to introduce new rules specific to damage caused by AI systems. The new rules intend to ensure that persons harmed by AI systems enjoy the same level of protection as those harmed by other technologies in the EU. The AI liability directive 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.

Although designed to ensure legal certainty, enhance consumer trust, and assist consumers' liability claims for damage caused by AI-enabled products and services, other stakeholders and academics are questioning, inter alia, the adequacy and effectiveness of the proposed liability regime, its coherence with the new AI Act, its potential detrimental impact on innovation, and the interplay between EU and national rules. In Parliament, the issue has been assigned to the Legal Affairs Committee (JURI), with Axel Voss (EPP, Germany) as rapporteur. However, the delays affecting the AI Act negotiations have also influenced the progress of the AI liability directive, which stalled in 2023.

## EUROPEAN HEALTH DATA SPACE

In 2023, the discussion on the European Commission's proposal for a Regulation on a European Health Data Space (EHDS), released on 3 May 2022, gathered steam and galvanised the health policy community. The growing recognition that more effective health data sharing could become one of the keys for improving ailing health systems catapulted the EHDS to the top of health-relevant EU legislative topics. The primary use of health data focuses on data use for citizens and healthcare professionals at the national and EU levels, and on fostering a single market for electronic health record systems (EHRs). The secondary use of data is meant to provide a consistent, trustworthy, and efficient data pool for research and innovation, policy-making, and regulatory activities. The EHDS is the first of nine European sector and domain-specific data spaces set out in the Commission's 2020 communication, "A European strategy for data."

HOPE continued to monitor all relevant EHDS developments, facilitated by regular information exchanges with policy partners representing the interests of healthcare professionals, patients, public health, and payers. Following an internal analysis of the key points relevant to the hospital and healthcare community, HOPE released its EHDS Position Paper in January 2023. Adopting a health equity perspective and underlining the importance for the EHDS to foster tangible improvements for health providers and patients (including individuals with low levels of digital literacy), HOPE's position:

- espoused the need for inclusion of hospital and healthcare stakeholders in building the EHDS;
- warned that the vast set-up, transformation and implementation costs required could be crippling for many hospitals and healthcare institutions already suffering from years of underfinancing, in turn leading to further closures;
- called for leaving room for national practices and specificities to ensure that the EHDS would not obstruct well-established data operations or lower existing standards;
- requested explanations pertaining to the technical responsibilities of health data holders, the feasibility of the proposed timelines, and safeguarding the quality of certain data sources (e.g., wellness apps); and
- proposed clarifying the interplay with other importance pieces of EU digital legislation including the General Data Protection Regulation (GDPR) and ePrivacy Directive, the Data Governance and Data Acts, the AI Act, the Cybersecurity package, the Medical Devices / In Vitro Medical Devices Regulations, and EU Digital Identity framework.

As EHRs are very fragmented across the EU, the Commission proposed the European Electronic Health Record Exchange Format (EEHRxF) as the basis for specifications related to the registration and exchange of electronic health data.

In the European Parliament, the lead Rapporteurs of the subject, MEP Tomislav Sokol (Croatia, EPP - ENVI Committee) and MEP Annalisa Tardino (Italy, ID - LIBE Committees) promoted their vision of the EHDS based on their committees' joint report released in February 2023. Among the main points of the EP report was a demand to provide greater EU funding for EHDS implementation at Member State level, the proposal for an opt-out option for patients regarding secondary uses of health data, and third-party assessments for EHR systems.

In addition, opinions were given by the Parliament's ITRE Committee led by MEP Cristian Buşoi (Romania, EPP) and the IMCO Committee led by Andrey Kovatchev (Bulgaria, EPP) in May 2023. The former called for wide access to health data for regulatory authorities and for adoption of EU-wide standards. The latter focused largely on use of international EHR standards and proposing setting time-based targets for implementation and progress on cross-border health data interoperability and the relevant infrastructure.

Acting as the main spokesperson for the Parliament, Mr Sokol repeatedly defended his perception that health data sharing for primary uses (i.e., patient summaries, ePrescription/eDispensation, laboratory results and related reports, medical images and related reports, hospital discharge reports) would be politically uncontroversial, arguing the main bone of contention lay in secondary use areas, primarily health research. HOPE contributed to the evolving debate during meetings and online webinars organised by the EU and other stakeholders, pointing out that the issues at play depended on national and regional circumstances.

HOPE co-signed two joint statements as a direct result of our collaboration with civil society partners and in reaction to the Parliament's reports. The first stressed that societal benefits must be prioritised over those of the market in terms of generating public returns on data investment and not further strengthening the IP rights and trade secrets regime (March 2023). The second focused on healthcare professionals and providers. It was calling for an explicit reference to the ethical principle of respecting patient confidentiality and professional secrecy in the draft regulation, exclusion from onerous secondary data tasks, limited liability only for self-collected data and making available additional funding for EHDS-related digitisation costs (June 2023). These statements also supported broad health stakeholder representation in the EHDS governance structures and cautioned against a rushed legislative process given the complexities at play.

HOPE engaged in the amendment process by proactively gathering intelligence and submitting two sets of proposals for improving the text, some of which were taken up in the revised EP report (e.g., concerns related to data holders' responsibilities, rectification of patient data, implementing acts, EHR conformity assessments).

At Member State level, meanwhile, the 2023 Swedish and Spanish EU Council Presidencies continued negotiations where the previous Czech Presidency had left off, in pursuit of establishing consensus. Both released a couple of compromise texts that were discussed in-depth and subsequently altered by digital ministers. The progress report released by the Swedish Presidency at the end of May 2023 noted, among other achievements, that its work led to the replacement of the advisory procedure with an examination procedure in all implementing acts, resulted in the deletion of delegated acts, proposed that Member States should regulate the use of wellness apps in their health systems, and found consensus on the clarification of GDPR links and certain definitions. The Spanish Presidency, meanwhile, proposed an opt-out option for patients also covering the primary uses of health data exchanges.

The following points remained among the most contentious:

- external evaluation or self-certification by providers (or users themselves) for EHR systems;
- allowing patients to alter or hide some of their health data from healthcare professionals, such as, for example, sexually transmitted diseases and if so, whether healthcare professionals should see that some of the data was restricted, without specifying details;
- finding the right balance between having representative datasets valuable for secondary uses and protecting data and privacy patients, and deciding who and to what extent may access the data pool;
- dealing with intellectual property (IP) rights and trade secrets;
- the extent to which Member States may set own rules, e.g. regarding opt-outs for patients;
- the EHDS launch date (the Commission originally proposed 2025, whereas some Member States might need an additional 7 years for registering data into EHRs following implementation).

Despite these differences, political agreements could be found at Parliament and Council level at the end of the year. The Council settled its negotiating position on 6 December 2023, notably proposing the creation of two steering groups, made up of member-state representatives, to manage the MyHealth@EU and HealthData@EU infrastructures for primary and secondary data exchanges. In this design, other stakeholders may only be invited as observers to discuss relevant issues without formal decision-making rights. The mandate also expands the role of Member States in the proposed EHDS governing board and requires national digital health authorities to publish an activity report every two years. The exchange format would be split into two profiles, for national and for cross-border uses.

Following the lead Committee's vote on 28 November, the plenary vote took place in the European Parliament on 13 December 2023, adopting the report by a large majority. The final EP position included an advisory forum consisting of different stakeholders who would make recommendations to the EHDS board. It also stressed the importance of data protection by ensuring compliance with the EU GDPR and providing for penalties in cases of misuse of personal health data. Storing health data in the EU would be mandatory. Concerning data shared from clinical trials, only those subject to the transparency provisions outlined in current Union law should be accessible. Moreover, an explicit consent or opt-in would be needed to access certain sensitive patient data, such as genetic and genomic information.

Interinstitutional negotiations take place in 2024 in the run-up to the EU Elections, which could be too little time for settling the differences between the co-legislators.

## ePRIVACY

On 10 January 2017, the European Commission published its proposal for a regulation on the respect for private life and the protection of personal data in electronic communications (ePrivacy package) that also concerns healthcare providers. It will replace Directive 2002/58/EC and specify the General Data Protection Regulation (GDPR). The objective of both initiatives is to reinforce trust and security in the Digital Single Market, while providing flexible regulatory tools to enable innovation.

The measures presented by the Commission aimed to update current rules, extending their scope to all electronic communication providers. They also aim to create new possibilities for processing communication data and reinforcing trust and security in the Digital Single Market. At the same time, the proposal wishes to align the rules for electronic communications with the GDPR. Among other things, the ePrivacy Regulation is meant to enhance security and confidentiality of communications and define clearer rules on tracking technologies such as cookies (including for giving consent), as well as on spam.

In the European Parliament, the subject was assigned to the Civil Liberties Committee (LIBE) and the initial rapporteur, MEP Marju Lauristin (Estonia, S&D), presented its report in June 2017. The EP confirmed the committee's negotiating mandate in October 2017 and since then, Birgit Sippel (Germany, S&D) has taken over as rapporteur. She was reappointed in 2019.

The European Data Protection Authorities (DPAs), assembled in the EDPB (European Data Protection Board), also adopted an opinion on the interplay between the e-Privacy Directive and GDPR (in particular on the competences of DPAs), calling not to lower the level of protection offered by the current e-Privacy Directive.

Following intense discussions and multiple revisions submitted by various EU Presidencies between 2018 and 2020, trilogues finally began on 20 May 2021. Disagreement centred on issues including the nature of the relationship between e-Privacy and the GDPR; privacy settings; the legal grounds for data processing other than consent, as well as 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 justifying restrictive measures.

In 2023, HOPE continued to keep an eye on any pertinent developments, our 2018 Position Paper having drawn attention to several points related to healthcare: public networks will need to comply with the new legislation; healthcare providers who contact their patients by text/email using a public network will have to comply; and emergency services will need enough breathing space to be able to meet their responsibilities when responding to medical emergencies or data. However, following some technical progress made in 2022, the subject remained largely inactive under the 2023 Swedish and Spanish Presidencies.

## 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 November 2017, the European Commission launched a consultation on pharmaceuticals in the environment. This was part of a study to help develop a strategic EU approach in this field and to support the United Nations Sustainable Development Goals (SDG), in particular SDG 6 ("Clean Water and Sanitation"). It also works towards EU legislative goals such as the "good status" objective in the Water Framework Directive. HOPE answered the consultation in February 2018.

In this respect, on 11 March 2019, the European 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" that the Commission presented, identifies six action areas concerning all stages of the pharmaceutical life cycle, where improvements can be made: actions to raise awareness and promote careful use, improve training and risk assessment, gather monitoring data, encourage “green design”, reduce emissions from manufacturing, reduce waste and improve wastewater treatment. The text addresses pharmaceuticals for human as well as for veterinary use.

On 12 December 2019, the European Commission released a fitness check of the Water Framework Directive, its associated directives, and the Floods Directive. This check concluded that they are overall fit for purpose, with some room for greater effectiveness but on 21 July 2020, following a consultation, the European Commission launched a roadmap on the revision of the directive on ‘Water pollution – EU rules on urban wastewater treatment’. One of the issues that need to be addressed is the presence of pharmaceuticals in wastewater. HOPE participated in the consultation in May 2021. On 26 October 2022, the European Commission tabled its proposal on the Urban Wastewater Treatment Directive.

In the Parliament, the Urban Wastewater Treatment Directive file was referred to the ENVI Committee which appointed Nils Torvalds (Renew Europe, Finland) as rapporteur on 12 January 2023. The ENVI Committee adopted its legislative report on 20 September 2023. The report supports the proposed extended producer responsibility (EPR) scheme, while requiring complementary national financing (up to a maximum of 20 %) for the upgrade of urban wastewater treatment plants, to avoid unintended impacts on the availability, affordability and accessibility of vital products like medicines. Parliament's plenary adopted the report on 5 October 2023, with 420 votes in favour, 62 against and 84 abstentions. The matter was referred back to ENVI for interinstitutional negotiations. The Council adopted its general approach on the subject on 16 October 2023. Trilogue negotiations were ongoing at the end of 2023.

## FLUORINATED GREENHOUSE GASES

On 15 September 2020, the European Commission launched a public consultation for the review of EU rules on fluorinated greenhouse gases adopted in 2014. HOPE contributed to the discussions that took place before the adoption of the rules.

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.

This initiative will review these rules and update them in view of: the European Green Deal and climate law; recent international obligations on hydrofluorocarbons/HFCs (Montreal Protocol); progress made and lessons learnt.

On 11 December 2020, HOPE took part in a discussion organised by the International Pharmaceutical Aerosol Consortium (IPAC) with representatives from the European Commission (DG CLIMA), the European Federation of Allergy and Airways Diseases Patients' Associations (EFA), the European Respiratory Society (ERS) and the German Environment Agency (UBA).

HOPE's Chief Executive reiterated that HOPE used to work on the F-gases regulation because hospitals are among the biggest consumers of air conditioning and refrigerants. He stressed that patients' health should be the main item to consider regarding the regulation on the inhalers using F-gases. As EFA showed, many patients suffering from asthma and COPD rely on emergency relief (one in three COPD patients are admitted to the emergency room every year). This should be avoided as it can be an ordeal for patients to be hospitalised, but it also has a great environmental cost. He also stressed the importance of the affordability and accessibility of an alternative treatment if a change should occur in the next years.

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.

In the European Parliament, the proposal has been referred to the ENVI Committee which appointed Bas Eickhout (Greens/EFA – Netherlands) as a rapporteur. On 10 October 2022, the rapporteur tabled a draft report on the subject. In the Council, discussions have started in the Working Party on the Environment. The European Economic and Social Committee adopted its position on 15 June 2022. It welcomes the proposal yet points to the possibility for higher ambition, highlighting specifically the opportunity of promoting low-GWP (global warming potential) natural refrigerants. The European Committee of the Regions has decided not to draw up an opinion on the proposal.

On 30 March 2023, MEPs adopted their position on revising the EU's legislative framework on F-gases emissions with 426 votes in favour, 109 against and 52 abstentions. On 5 April 2023, Member States agreed to start negotiations with the European Parliament on the regulation on F-gases, along with the regulation on ozone-depleting substances (ODS).

On 5 October 2023, the Council and the European Parliament reached a provisional agreement on strengthened rules to massively reduce GHG emissions from F-gases and ODS. The text is now awaiting endorsement from both institutions and will come into force 20 days after its publication in the Official Journal of the EU.

## PHARMACEUTICAL LEGISLATION

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 is much more than a crisis-response instrument, it draws lessons from the initial response to the COVID-19 pandemic and aims to make Europe's pharmaceutical sector better prepared and more resilient. The strategy supports 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, which will be launched over the coming years. Actions will cover the whole ecosystem of pharmaceuticals. 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.

A further step was for HOPE to join workshop organised on 19 January 2022 by Technopolis Group on the results of its study in support of the European Commission evaluation and impact assessment of the EU general pharmaceutical legislation. Throughout the year HOPE continued its analysis in close collaboration with other European associations.

The European 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 revision includes proposals for a new directive and a new regulation, which revise and replace the existing pharmaceutical legislation, including the legislation on medicines for children and for rare diseases. The key elements of the proposal are 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 will be facilitated, and market authorisation procedures simplified. Measures for greater transparency of public funding of medicines development will be introduced and the generation of comparative clinical data will be incentivised.
- Innovation and competitiveness: The scientific evaluation and authorisation of medicines will 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 can be extended in the following cases: if medicines are launched in all Member States, if they address unmet medical needs, if comparative clinical trials are conducted, or if a new therapeutic indication is 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 will 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 will be established, and supply chain vulnerabilities of these medicines will 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, will 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 proposals for the reform of pharmaceutical legislation on 26 April. The discussion showed that they called for a balance between access to medicines for all Member States and maintaining a strong pharmaceutical industry.

The Council of the EU 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 European Parliament decided on 14 September 2023 to refer the proposals to the committees responsible.

The ministers for the internal market and industry scrutinised the pharmaceutical package on 25 September 2023 in a session of the Competitiveness Council. This was requested by Germany and Austria. A position paper drafted by industry ministries in Germany and Austria expressed worries for business with the package proposed by the Commission. According to POLITICO, considering the progressive line at least of the Austrian ministry of health, this will complicate an already complex negotiation. Austria and Germany presented their concerns with the proposed pharma revision. This exchange is publicly available. 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. Some other Member States do not want to duplicate the debates stating that this is an EPSCO topic.

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.

## ACCESS TO MEDICINES

HOPE has been working for several years on the topic of expensive medicines. It adopted a first position paper in 2017, contributing to the OECD consultation and the broader discussion.

In 2018, the independent Expert Panel on effective ways of investing in health adopted two relevant opinions, to which HOPE contributed, related to access to healthcare, innovative payment models for high-cost innovative medicines and performance of primary care: opinion on innovative payment models for high-cost innovative medicines; opinion on benchmarking access to healthcare in the EU.

On 14 September 2018, the European Commission and the European Medicines

Agency (EMA), with support from HOPE, organised in Brussels a multi-stakeholder event on biosimilar medicinal products to promote the sharing of knowledge and best practices in biosimilars use and uptake. On 14 May 2019, the Council adopted a regulation, which introduces an exception to the protection granted to an original medicine by a supplementary protection certificate (SPC) for export purposes and/or for stockpiling. Thanks to the exception, EU-based manufacturers of generics and biosimilars are entitled to manufacture a generic or biosimilar version of an SPC-protected medicine during the term of the SPC, either for exporting to a non-EU market where protection has expired or never existed (or during the six months before the SPC expires) or for creating a stock that will be put on the EU market after the SPC has expired. Until June 2022, the regulation affected only those SPCs that had been applied for on or after the date of entry into force of the regulation (June 2019). Since then, the regulation has affected SPCs applied for before June 2019, but which have become effective after June 2019.

On 4 March 2021, the European Commission committed to launching a pilot scheme to better understand the root causes of deferred market entries for centrally authorised products. This pilot is part of the Pharmaceutical Strategy and involves the European Medicines Agency (EMA) and Member States as well as future marketing authorisation holders. It ran for 18 months, concluding in 2022. It was supported by the Human Pharmaceutical Committee. The pilot's overall objective was to improve regulators' knowledge of the planned marketing of centrally authorised medicinal products (CAPs) and of the reasons behind delayed market launch by engaging with prospective marketing authorisation holders through voluntary sharing of their marketing intentions for specific types of CAPs in the pre-authorisation phase. The pilot provided further knowledge base to the Directorate General for Health and Food Safety (DG SANTE), the EMA and national competent authorities, on the planned rollout of the medicinal products undergoing a marketing authorisation application.

HOPE attended the stakeholder workshop on the Transparency Directive 89/105/EEC that took place on 29 June 2023 organised by Unit D2 'Medical products: quality, safety, innovation', DG SANTE. The Council Directive 89/105/EEC is related to the transparency of measures regulating the prices of medicinal products for human use and their inclusion within the scope of national health insurance systems, better known as the "Transparency Directive". This workshop is part of a series of consultations which will also include a public survey of stakeholders (non-state actors) and Member States.

## MEDICINE SHORTAGES

Medicine shortages can occur for many reasons, such as manufacturing difficulties or problems affecting the quality of medicines that can impact on patient care.

In the EU, most medicine shortages are dealt with at national level. However, EMA can be involved in certain situations, for example, when a medicine shortage is linked to a

safety concern or affects several Member States. Regulatory authorities within and outside Europe are increasingly working together to prevent shortages and to limit their impact whenever they occur through the European medicines regulatory network.

EMA and the Heads of Medicines Agencies (HMA) also 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 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 European 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 novel coronavirus has 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 European 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's capacity.

In the Pharmaceutical Strategy for Europe, the European 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 follows a request by the European 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 European Parliament and the Council.

On 17 October 2022, the European Commission published a staff working document to present the main findings and proposed solutions of the Structured Dialogue on the Security of Medicines Supply in which HOPE participated. Indeed, as part of the 2020 Pharmaceutical Strategy, the Commission had set up a such a dialogue. It gathered actors in the pharmaceuticals manufacturing value chain, public authorities, patient and health nongovernmental organisations and the research community.

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 is a communication that builds on the work under the European Health Union, notably the reinforced mandate of the European Medicines Agency and the recently published pharmaceutical reform. It follows 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 is the first step to analyse the supply chain of selected medicines by April 2024. This analysis will then show where additional measures are needed. Member States can use regulatory exemptions to allow medicines to reach patients in a timely manner, including extending shelf life or the quick authorisation of alternatives. There will be a dedicated Joint Action in 2024 to promote effective use of these flexibilities. There will be an EU joint procurement for next winter for antibiotics and treatments for respiratory viruses.

Finally, the Commission intends to set up a Critical Medicines Alliance to be operational in early 2024. The Critical Medicine Alliance will add an industrial policy pillar to the European Health Union. This will allow 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 will focus on a targeted number of critical medicines with the highest risk of shortages and impact on healthcare systems. This could pave the way for a possible "Critical Medicines Act" in the future. To that end, the Commission launched a dedicated, preparatory study at the end of 2023, paving the way for an impact assessment.

## ANTIMICROBIAL RESISTANCE

In 2023, HOPE proceeded with its work supporting an enhanced implementation of the EU One Health Action Plan against Antimicrobial Resistance (AMR), released by the European Commission in 2017. In particular, it advocated points contained in the HOPE 2020 Position Paper and by contributing to the regular meetings and outputs of a pan-European Stakeholder Network on AMR led by the European Public Health Alliance (EPHA). The Stakeholder Network currently has over 20 active members from civil society, the research and policy community. In October 2023, EPHA presented a "Civil Society Joint Statement on the Roadmap on AMR for the WHO European Region 2023–2030" endorsed by HOPE during the 73rd session of the WHO Regional Committee for Europe in Kazakhstan.

Moreover, HOPE was selected as a member of the expanded AMR One Health Network group of experts, which held its inaugural meeting on 21 September and offers participants the opportunity to share their perspectives, obtain first-hand accounts of the latest scientific knowledge and national AMR situations, and engage in subgroups preparing future work.

Throughout the year, HOPE monitored European and international AMR developments and informed about important milestones, such as the Commission's One Health conference held in Luxembourg on 13 November, shortly before the annual European Antibiotic Awareness Day coordinated by the European Centre for Disease Prevention and Control (ECDC), now embedded in the parallel World Antibiotic Awareness Week organised by WHO.

Although much work remains to be done at national level (e.g., updating National Action Plans), HOPE was pleased to observe a noticeable shift towards a more comprehensive One Health approach in 2023 – partially thanks to a dedicated directorate in DG SANTE – which also integrates climate change and environmental aspects as opposed to only focusing on human and animal health. Hence the Luxembourg conference featured committed speakers from the EU Institutions, the research community and international AMR champions and politicians.

The most important example of this reorientation is the Council Recommendation on stepping up EU actions to combat AMR in a One Health approach, the proposal for which was released by the Commission as an annexe to the revised EU Pharmaceutical legislation prior to formal Council adoption on 13 June 2023. HOPE had provided inputs for this initiative in the previous year by responding to a call for evidence and it contributed comments to the European Parliament's June 2023 Resolution for a coordinated EU response to health threats posed by antimicrobial resistance, which included recommendations for the Council.

Overall, the Council Recommendation seeks to encourage the prudent use of antimicrobials through a series of voluntary measures including:

- concrete targets to reduce antimicrobial use by 2030, including a 20% reduction in total human consumption of antibiotics and a 50% reduction in overall EU sales of antimicrobials used for farm animals and aquaculture;
- strengthening of National Action Plans to help implement these targets and monitor the use of antibiotics at national level, including indicators to assess progress;
- better surveillance of AMR and antimicrobial consumption (AMC) at all levels, including hospitals and long-term care facilities;
- efforts to improve the health and welfare of food-producing animals to decrease the spread of infectious diseases in farming;
- awareness raising among the public and professionals working in the human health

and veterinary sectors, including training for health professionals and communication campaigns.

Importantly, the revised pharmaceutical legislation and Council Recommendation provide for incentives to reward successful development and secure access to effective antimicrobials: the former proposes a voucher scheme, which could be complemented by financial pull incentives in the form of procurement mechanisms (e.g., revenue guarantee, market entry rewards combined with revenue guarantees, lump-sum market entry rewards and milestone payments).

A follow-up to the Joint Action on Antimicrobial Resistance and Healthcare Associated Infections (JAMRAI, Sep 2017 – Feb 2021), of which HOPE is a supporting partner, will be launched in early 2024, funded by €50 million under the EU4Health programme.

## LATE PAYMENTS

On 12 January 2023, the European Commission launched a consultation on late payments – update of EU rules (europa.eu) 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 European 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."

# 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 recommendations and opinions, as well as white and green papers, Commission communications, consultations and programmes.

## VACCINES

The European Commission Directorate-General Health and Food Safety (DG SANTE) has been working for several years on an EU initiative to address vaccine hesitancy, to strengthen vaccine programmes, and to increase EU cooperation on vaccination.

It published a roadmap in December 2017 and in 2018 public and stakeholders consultations and a set of recommendations on how the EU can strengthen cooperation in the fight against diseases that can be prevented by vaccines. The European Joint Action on Vaccination (EU□JAV), coordinated by France (National Institute of Health and Medical Research, INSERM, with the support of the Ministry of Health), was then launched on 4 September 2018 in Paris. On 23 May 2019 the European Commission released the 'Roadmap for the Implementation of Actions Based on the Commission Communication and the Council Recommendation on Strengthening Cooperation against Vaccine Preventable Disease'. It was a timeline for action through 2022.

On 12 September 2019, the European Commission and the World Health Organization (WHO) co-hosted the world's first Global Vaccination Summit in Brussels. On this occasion, European associations of healthcare professionals established the Coalition for Vaccination to commit to delivering accurate information to the public, combating myths and exchanging best practices. The coalition is co-chaired by the Standing Committee of European Doctors (CPME), the European Federation of Nurses Associations (EFN) and the Pharmaceutical Group of the European Union (PGEU). This Global Vaccination Summit led to the publication of a document: "Ten Actions Towards Vaccination For All". HOPE has joined the coalition as an associated member and regularly supports communication campaigns on vaccination.

## CANCER

### Europe's beating Cancer Plan

On 3 February 2021, Europe's Beating Cancer Plan was presented at a press conference by the Vice-President Margaritis Schinas together with the European Commissioner for Health and Food Safety, Stella Kyriakides.

It is a holistic plan funded with €4 billion from EU4Health programme, Horizon Europe

and the Digital Europe programme. During the informal video conference of health ministers on 16 March 2021, ministers expressed their strong support and commitment to Europe's Beating Cancer plan. Many delegations emphasised that the plan was complementary to their national strategies and stressed the need to take into account the different starting points in Member States.

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.

Cancer is one of the strands of the EU4Health Work Programme for 2023, the full budget for cancer is €187.3. The budget is divided into 7 areas:

- Cancer prevention €1.5 million
- EU network of comprehensive cancer infrastructures €130.5 million
- Implementation of cancer screening programmes €38.5 million
- Mental health and cancer €10.0 million
- Quality of life of cancer survivors €1.5 million
- Reducing cancer inequalities €2.5 million
- Implementation of strategic agenda for medical ionising radiation €2.8 million

The European 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.

On 6 November 2023, HOPE participated in the meeting that presented the study on mapping and evaluating the implementation of the Europe's Beating Cancer Plan (EBCP). This is part of a specific contract No HaDEA/2022/P3/06 implementing framework contract No SANTE/2021/OP/0002 is in the hands of several consultancies.

Following presentation of the study approach by the project team, the preliminary results on the future-proofing analysis by the project team were presented:

- What are the recent and anticipated technological, political and societal developments which may affect the implementation of the EBCP?
- To what extent is the EBCP adequate to address these developments and which

actions could be strengthened or prioritised?

Then the project team continued with a presentation of the preliminary results on the country analysis by:

- What are the national strategies and measures to fight cancer and to what extent are they aligned with the EBCP?
- What are the barriers for implementation of these measures at national level?
- How could the European Union further support, coordinate and complement Member States' efforts against cancer?

### 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 will cover the following activities:

- Support to the establishment or improvement of national Comprehensive Cancer Centres or Networks,
- Establishment of new cancer (reference) networks of expertise focusing on cancers and cancer conditions not yet covered by established ERNs building on the preparatory work and conceptualisations developed through the JANE Joint Action and development of potential additional networks which will also ensure synergies and interoperability with the existing data infrastructure for ERNs,
- Integration of the new (reference) networks of expertise and the established ERNs on rare cancers.

The two joint actions started in November 2022 and will run for 24 months.

### Cancer Inequalities Registry

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

- a data tool, already available;
- reports focusing on the assessment of the country-specific situation, published at the end of 2022;
- analytical reports comparing performance at EU level.

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. An analytical report on the state of cancer care performance across the EU will be published every other year, starting in 2024.

## 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 European 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 European Commission to further discuss the joint statement and give an update on its upcoming initiative.

On 7 June 2023, the European 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 illhealth. 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 re-

forms 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 European 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 & ENVIRONMENT

HOPE participated in the launch event of the European Climate Pact on 16 December 2020. The Climate Pact is part of the European Green Deal. It is an EU-wide initiative that invites people, communities, and organisations to connect and share knowledge; learn about climate change; develop, implement and scale up solutions.

In 2022, HOPE endorsed the Joint Statement "Moving towards the right to 'health for all' by training the public health and wider health workforce on climate change and health,"

led by the Association of Schools of Public Health in the European Region (ASPHER). This joint statement was part of the Thematic Networks 2021, on the topic "Climate and Health Education in Europe."

On 2 May 2022 the 8th Environment Action Programme entered into force, as the EU's legally agreed common agenda for environment policy until 2030. On 26 July 2022, the Commission adopted a monitoring framework with headline indicators. Based on these, the European Environment Agency (EEA) assesses progress towards the 8th EAP objectives in annual reports published every December. The first monitoring report of the 8th EAP was published on 18 December 2023.

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.

## 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

# KNOWLEDGE AND EXCHANGE

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

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

# EU Programmes and Projects

## HOPE AS A PARTNER: ONGOING PROJECTS

### SAFEST

On 1 June 2022, HOPE and consortium partners kicked off SAFEST (Improving quality and patient SAFEty in surgical care through STandardisation and harmonisation of perioperative care in Europe), a four-year project funded under the new cycle of the EU framework for research and innovation, Horizon Europe.

When considering surgical safety, SAFEST will look at the entire journey before, during, and after surgery (often referred to as perioperative safety and care). Indeed, several studies have shown that most adverse events linked to surgery occur outside the operating room.

HOPE is leading tasks on communications. We contribute to other work packages with surveys, and will identify existing perioperative standards as part of a multidisciplinary group. During, HOPE has expanded the project website and produced and diversified the communication content. HOPE helped organise a workshop with the other projects funded under the same call that funds SAFEST. We support our partners in their efforts to draft and disseminate materials, particularly those targeting patients in lay language.

### 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 kick-off meeting was held on 10 and 11 March 2021.

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.

HOPE is work package leader on dissemination and communication. In 2023, HOPE released three newsletters with the help of partners, in May, June and October. The consortium met twice: in March in Rome and in September in Greece. The year 2023 also saw another collaboration with the sister projects RETENTION and MES-CoBraD for a second webinar. This was the opportunity for the experts to share their experiences and insights on acquiring, analysing, and applying real-world data within their respective projects, and to address the challenges of collecting, anonymising, harmonising and combining data.

As the project is actively moving towards the last phase, HOPE started the work on the policy recommendations and on the identification of the ecosystem to disseminate the project.

## HOSMARTAI

Financed by the European Union's Horizon 2020 programme and involving eight large-scale pilots implemented in five European countries (BE, IT, GR, SI, ES), the four-year HosmartAI ("Hospital Smart development based on AI") project aims to develop and introduce new digital and robot technologies powered by artificial intelligence (AI) into various healthcare settings and evaluate the results. It applies a continuous co-creation methodology to ensure that the proposed AI-based technologies will meet the actual needs of patients, healthcare professionals and hospital / healthcare providers. The solutions target 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.

The year 2023 marked the third year of the project, during which HOPE remained actively involved alongside 24 other partners, by 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). This included HOPE's participation in two face-to-face plenary meetings (May 2023: Madrid, Spain; November 2023: Maribor, Slovenia), inputs into regular work package calls and, together with WP-6 lead EIT Germany, the organisation of a joint project booth and external stakeholder workshop at Medica in Düsseldorf, Germany, the world's preeminent medical technology trade fair.

The Medica workshop, "AI and robotics for smart hospitals and care centres", represented a follow-up to another workshop organised in Eindhoven in 2022, during which initial feedback was sought from AI experts representing industry, hospitals and academia on how the pilot solutions could be improved during the final development stages and their impressions on market potential and challenges.

At Medica, a "speed-dating" format was chosen to link up representatives of the pilots with additional stakeholders potentially interested in initiating more concrete AI and robotics collaborations and deepening the pilots' understanding of existing market opportunities and barriers. This led to over 100 conversations between the project partners and external parties. In addition, the HosmartAI partners were given the opportunity to present their work at a project booth shared with two other EU projects focused on AI (AICCELERATE and AIDPATH) and to engage in networking meetings with other registered Medica exhibitors and guests.

The fourth and fifth HosmartAI newsletters were issued in May and October 2023, and HOPE continued to disseminate and inform about the project milestones via its social media channels and internal communication tools. In addition, HOPE reviewed and co-drafted various communication materials to promote the workshop and strengthen the pilots' narratives for business exploitation purposes.

## INNOFACILITATOR

The InnoFacilitator Project – Health InnoFacilitator European Facilitator Community Promoting Public Procurement of Innovation in Healthcare – kicked off in November 2022. It aims 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 is to raise awareness, increase skills and inform stakeholders about innovative procurement and collaborate to co-designate the public procurement of innovative solutions (PPI).

InnoFacilitator is funded by Horizon Europe Programme 2021-2022 European Innovation Ecosystems and it will run for 24 months until 30 September 2024. Its consortium brings together seven European partners with expertise in innovation procurement coordinated by Medicen Paris Region). It gathers 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 is 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 is 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 helps identify and scout suppliers and buyers for the matchmaking event (WP3).

## 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 will focus 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).

The project kicked off in February 2023 at Technion University (Haifa, Israel). A second in -person consortium meeting took place in San Sebastian (Spain). This second meeting was also the occasion for the project's first webinar.

HOPE is work package leader for communication and dissemination. The social media accounts were launched in February 2023 on three platforms, while the website went live in May 2023. The project released its first newsletter in June 2023.

The LUCIA project is also part of two clusters under the Mission Cancer: the Understanding (risk factors & determinants) cluster, and the Prevention & Early Detection (screening) cluster. Both clusters released a presentation video and brochure at the end of 2023. LUCIA organised the first in-person meeting for both clusters in San Sebastian (Spain) in September 2023.

## 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 health care 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 nonprofit 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.

## XPANDH

At the end of January 2023, the two-year Horizon Europe Coordination and Support Action XpanDH ("Expanding Digital Health through a pan-European EHRxF-based Ecosystem") was formally launched. The following month, HOPE attended the first in-person consortium meeting organised by the project lead ISCTE Knowledge and Innovation Centre (University of Lisbon) and involving over 25 partners.

In support of the European Health Data Space (EHDS) implementation, XpanDH has been designed to tackle a number of key challenges, such as the fragmented nature of digital health tools used across Europe (despite the introduction of the MyHealth@EU infrastructure facilitating cross-border data exchanges for certain uses), the low interoperability of solutions used by healthcare providers within the Member States and cross-border, and the lack of common definitions. To counteract the status quo, the project will leverage an established network of networks and a vibrant ecosystem to support the adoption of the European Electronic Health Record Exchange (EEHRxF) format (also referred to as "the format") – first recommended by the Commission in 2019 – as a cornerstone of the EHDS for seamless and secure health data exchanges.

It seeks to trigger involvement from all relevant end users – from patient and caregivers to professionals and more – in the EEHRxF implementation and dissemination. Compounding this impact will be the consortium's capacity to ensure the necessary flexibility and openness to manage potential changes and needs that arise from the co-creation process, to ensure real acceptance.

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

Jointly organised by the European Commission and the XpanDH consortium, the first EEHRxF (now more simply referred to as "the format") Summit took place in Brussels on 12 December 2023. Its sessions focused, inter alia, on the format's purpose and value, its utility for the further development of EHDS priority categories, and possibilities for co-creation. The other aim was to take stock of previous and ongoing initiatives undertaken since 2019, when the format was first proposed.

A representative of the European Commission's DG SANTE stated that the format provided a common language vital for enabling interoperability, delivering patient-centric care, providing healthcare professionals with more comprehensive information, and better research and innovation. It would also be a cornerstone for the electronic health record (EHR) certification framework and for the labelling of wellness apps. A new joint action, 'xt-EHR', will establish concrete links between the format and EHR framework. A representative of DG CNECT explained the format's development process, which entailed experimentation via previous joint actions and EU projects, formalisation (eHealth Network guidelines, EHDS Implementing Decisions) and infrastructure/ deployment (MyHealth@EU services).

Among the implementation challenges highlighted by participants were IT issues (e.g., legacy systems, different layers of software, insufficient IT teams), data issues (limited access to patients' records, many different health data sources, enforcing quality management and standard operating procedures) and staff issues (working with different software programmes simultaneously, high administrative burden), which will be tackled by the XpanDH partners during the second year.

Among other activities 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 X-Net discussions, and promoting the project via newsletter articles and social media posts.

# HOPE AS AN 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.

## JOINT ACTION TOWARDS THE EUROPEAN HEALTH DATA SPACE

HOPE was selected in 2021 as a stakeholder in TEHDAS, the Joint Action Towards the European Health Data Space. The purpose of TEHDAS is to create joint European principles for the secondary use of health data. The TEHDAS joint action involves experts from 21 EU Member States and four other European countries.

The project focuses on the following themes:

- a governance model for cross-border cooperation in the secondary use of health data between European countries;
- ensuring the quality of health data and facilitating joint use;
- planning the infrastructure for the cross-border secondary use of health data;
- clarifying the role of the individual.

The key aim of the project is to build a European governance model for the use of health data. The model could include creating a completely new organisation or incorporating the duties into existing EU institutions and organisations.

The results of the TEHDAS project will form the basis of the European Commission legislative proposals and enable member states to harmonise their national legislation, among other things. A current example of legislative preparation in the EU relates to the creation of the European Health Data Space.

The TEHDAS joint project is based on the EU Health Programme 2020, which specifies the objectives and budget of the project. HOPE has been selected to participate as a stakeholder in TEHDAS Joint Action in the Stakeholder Forum and in the WP4 Policy Forum. The aim of the policy forum is to reach out to and engage national and international policy and decision makers, to reflect on their needs and expectations and to explore views on the economic sustainability of the European Health Data Space.

In 2023, TEHDAS organised several workshops and policy fora; this included a stakeholder workshop on health data altruism (in the context of the EHDS, AI Act and Data Governance Act) on 27 April 2023, to which HOPE contributed. The outcomes of the workshop will be formulated into recommendations for policymakers.

HOPE also participated remotely in the TEHDAS Stakeholder Forum organised in Helsinki on 14 June 2023. The event provided an opportunity to assess and discuss the joint action's results. TEHDAS Coordinator Markus Kalliola (Sitra, Finland) described the success factors as being its proximity to the EHDS regulatory proposal, continuous stakeholder engagement from the outset, robust implementation processes, and delivery of quality results (e.g., the EMA framework for EU medicines regulation builds on TEHDAS' work). A new TEHDAS data quality framework – containing 13 recommendations – was released at the end of June, together with three guidelines on data infrastructure, data request processes and secure processing environments. Other main barriers discussed included the necessity to adjust national legislation and to identify role models for best practice. A bottom-up approach allowing for ample citizen involvement was key for building public trust, which is why TEHDAS developed 12 recommendations on how to engage actors in the secondary use of health data.

## 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 2023 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.

# COMPLETED PROJECTS, 2023

## TeNDER

From November 2019 until April 2023, HOPE was part of the TeNDER consortium, an EU research project that worked on a system of assistive tools for elderly people suffering from Alzheimer's, Parkinson's, and cardiovascular diseases.

In each pilot setting (i.e., in-hospital acute care, at home, and in day-care), patients were monitored with sensors, cameras that capture movement, and wristbands that recorded basic vitals, etc. Legal researchers evaluated these procedures to ensure that personal data was protected.

HOPE helped coordinate the communication and dissemination tasks managing all communications channels and producing content. In addition, HOPE facilitated inter-project collaborations, and conducted a gap analysis between use-case scenarios v. actual implementation to help identify areas for potential standardisation.

## PERISCOPE


PERISCOPE (Pan-European Response to the ImpactS of COvid-19 and future Pandemics and Epidemics) was a Horizon 2020 large-scale research project that brought HOPE together with 31 other European organisations.

The multidisciplinary consortium included clinical, epidemiologic, socio-economic, political, statistical and technological experts. The project combined theoretical and experimental research to achieve a deeper understanding of the short and long-term impacts of the pandemic, and the measures adopted to contain it.

From 1 November 2020 to 31 October 2023 PERISCOPE:

- gathered data on the broad impacts of COVID-19 to develop a user-friendly open access COVID-19 Atlas, which will serve as a reference tool for researchers and policymakers;
- carried out innovative statistical analysis on the collected data;
- identified best practices that could be applied at pan-European level for a better containment of the pandemic and its related socio-economic impacts;
- developed guides for policymakers at all levels of government, in order to enhance Europe's preparedness for future similar events and proposed reforms in the multi-level governance of health.

HOPE participated in the dissemination activities, contributed to the analysis of the COVID-19 pandemic effects on health systems, supported the creation of a public engagement platform for decision-making. It also helped to develop training and education for health workers, patients and health authorities.

Throughout the year 2023, several scientific articles were published; they are all accessible on the PERISCOPE website. Besides weekly contributions to communication and dissemination, HOPE also contributed to project standardisation by compiling data emerging from use-case templates and conducting gap analyses, as well as identifying best practices where possible. From the beginning of 2023 until October, which marked the end of the project, HOPE provided updates, translated results and findings into lay terms, and submitted the final project reports on communication and collaboration.

# INTERNATIONAL INSTITUTIONS

## WHO EUROPE

### Fit-for purpose hospitals

HOPE was invited to speak at the "Fit-for-purpose hospitals" conference on "Prioritising quality and sustainability to meet the demands of modern healthcare" held in Baku, Azerbaijan, from 5 to 7 June 2023.

This was the first time the WHO regional office for Europe had organised a ministerial conference devoted to hospitals. It built on the expert workshop organised in April 2022 which HOPE President and CEO attended.

The first plenary presented the evolving landscape of European hospitals: challenges and opportunities, in particular on quality and patient safety with Mina Gaga (Alternate Minister of Health of Greece); financing with Dragoș Garofil (Personal Counsellor of the Minister of Health, Romania); emergency management with Ala Nemerenco (Minister of Health of Moldova), staff focus with Inga Cechanovičienė (Head of the Specialised Health Care Division, Personal Health Care Department, Ministry of Health of Lithuania).

The second session focused on "Embracing the future: a transformative vision for hospitals". Following an introduction to the vision of WHO Regional Office for Europe, the session, moderated by Natasha Azzopardi Muscat (Director, Division of Country Health Policies and Systems, WHO Regional Office for Europe), was an opportunity for HOPE CEO to present the importance of recognising very different starting points but also the fact that the future for some is already the present or even the past for others. He conveyed positive messages taking the example of the good practices presented during the HOPE Agora 2023. In a conference during which hospital bashing was frequent, it was important to strike a balance also showing good examples of coordinated care, integrated care and population health initiative. The WHO tends to oppose hospitals and other healthcare services, in particular primary care.

A total of ten plenaries were organised, on topics including: Climate resilient, environmentally sustainable hospitals; Driving the hospital change agenda; Strategic hospital planning: aligning investments and policies for optimal impact; Driving sustainable hospital quality improvement: cross-sectoral collaboration and innovative approaches; Accelerating hospital transformation in the broader picture; Regional framework to support and guide hospital transformation towards primary healthcare-oriented systems.

A first series of parallel technical sessions ("Bridging the gap") addressed: Integrating hospitals, primary healthcare and communities for a unified vision; Financing and payment systems: catalysts for change; People-centred care models and home-based

solutions. A second group of parallel technical sessions addressed: "The triple imperative: digital transformation, human resources and governance and management."


## Emergency Medical Teams initiative

HOPE participated to the sixth pre-RC73 side event "The Emergency Medical Teams Initiative in the WHO European Region: taking the Global 2030 Strategy to the regional, subregional and national levels" on 9 October 2023.

This event updated Member States and stakeholders on the progress of the Emergency Medical Teams (EMT) Initiative in the WHO European Region and provided an opportunity to discuss the creation of a Regional EMT Action Plan for 2024-2030 that will reinforce health systems' preparedness, response, and resilience by integrating EMT capacities into national frameworks.

## Regional Committee

HOPE was invited to join the 73rd session of the WHO Regional Committee for Europe (RC73) from 24 to 26 October 2023. Health ministers and high-level delegates from the 53 Member States of the WHO European Region, as well as representatives of partner organisations and civil society, met in Astana, Kazakhstan.

In 2023, WHO marked its 75th anniversary, 45 years since the signing of the historic Alma-Ata Declaration on primary health care (PHC), and the mid-point of the European Programme of Work (EPW) 2020–2025 – "United Action for Better Health in Europe". RC73 was therefore an opportunity for delegates to reflect on the current state of health and well-being across the region, take stock of progress in delivering the EPW, celebrate public health milestones over the past 75 years, and discuss what is needed to address current and future challenges.

Several public health plans were considered and put forward for endorsement during the proceedings, including an action plan for refugee and migrant health for 2023-–2030, a framework for action on the health and care workforce for 2023–2028, and a roadmap on antimicrobial resistance for 2023–2030.

During the session, delegates were provided with an update on health emergencies in the region and consulted on the development of the Preparedness 2.0 Strategy and action plan, as well as a regional action plan to strengthen the Emergency Medical Teams initiative.

On 23 October 2023, prior to the Regional Committee session, WHO/Europe, the Government of Kazakhstan and the United Nations Children's Fund (UNICEF) hosted the international meeting "Primary health care policy and practice: implementing for better results". Marking the 45th anniversary of the Declaration of Alma-Ata (1978) and the 5th anniversary of the Declaration of Astana (2018), the meeting brought together global

partners to take stock of progress in advancing PHC and consider key policies and practices needed in the coming decade to build PHC-led health systems.

## World Health Organization

HOPE participated in the workshop on "Making hospitals fit-for-purpose: a triple imperative for people, health systems, and sustainable development" held from 31 October to 2 November 2023 in Geneva, Switzerland.

The key objectives of this workshop were to: align on a shared vision for hospitals roles and position in a PHC-oriented health system; review and enhance guidance on hospital sector policies; establish an informal community of practice for hospital improvement and transformation; inform WHO country support on hospital-related topics.

The workshop was an opportunity to review and enhance draft technical briefs on topics related to hospital reforms, foster an informal community of practice among experts and stakeholders, and inform future work on hospitals, to make them fit-for-purpose.

# Exchange Programme

## HOPE EXCHANGE PROGRAMME 2023

### CLIMATE & ENVIRONMENT: CHALLENGES FOR HOSPITALS & HEALTHCARE SERVICES

From 2 to 4 June 2023, the HOPE Agora 2023 took place in Brussels and focused on the topic "Climate and environment: challenges for hospitals and healthcare services." For more than 40 years, HOPE has organised at the end of its annual Exchange Programme an evaluation meeting renamed more recently agora.

Participants spend four weeks in a European country to learn about how similar healthcare issues are tackled differently. Almost 200 participants were present at the agora this year to share good practices related to evidence in healthcare management that they had identified during their stay in the host country.

Climate and environment changes have profound impacts on human health due to increasing air pollution, reduced food and water supply and quality, and more frequent and extreme weather events. Hospitals and healthcare services are strongly affected by these changes and must develop resilience by making adaptational changes. HOPE The Agora 2023 focused on the other side of the coin: the impact hospitals and healthcare services have on the climate and the environment. This may stem from different sources such as pharmaceuticals, medical devices, medical chemicals and gases, buildings, transports, textiles, food, and energy.


National coordinators

# Exchange Programme


Opening remarks by Urmas Sule

On 3 June, the HOPE Agora was chaired by HOPE President, Urmas Sule. After a video message by Mr Virginijus Sinkevičius, European Commissioner for the Environment, Oceans and Fisheries, the first part of the day was dedicated to presentations of different approaches at local, regional and national level.

The vision of European doctors was presented by Sarada Das, Secretary General, CPME (Standing Committee of European Doctors). She highlighted the work of CPME on air quality and health-related climate change and how doctors can lead by example on the matter. Rudy Chouvel, from the French Hospital Federation, presented the vision of a national federation and focused on how to support public hospital initiatives and foster proper involvement for ecological transition. Marc Schreiner, from the Berlin Hospitals Association, presented the vision of a regional federation: "Moving forward in Berlin – climate protection strategy for the German capital". He stressed the need for action in various areas such as emissions and consumption of resources. Mehreen Kassam, from NHS England, presented the vision of a National Health Service and various areas for action: buildings, energy, inhalers, water, and waste.

This was followed by audience participation through live polling. Participants were asked several questions. They were the starting point of a 30-minute panel discussion with the previously mentioned speakers and chaired by Eva Weinreich -Jensen, former HOPE past-President. The panel was followed by the first presentations of HOPE Exchange Programme participants who had stayed in Malta, The Netherlands, Poland, Latvia, Belgium, and France.

# Exchange Programme

World Café discussions

On 4 June, the agora was chaired by HOPE Vice-President, Eamonn Fitzgerald. This second day was dedicated to other presentations by HOPE Exchange Programme participants regarding good practices identified in their host countries: Italy, Switzerland, Germany Denmark, Estonia, Sweden, Austria, United Kingdom, Greece, Ireland, Spain, and Portugal. Over the course of the day, a World Café was also organised to allow participants to share their experiences and ideas around different topics and to discover two EU-funded projects in which HOPE is a partner: SAFEST and PERISCOPE. The agora ended with the meetings of participants by country of origin.


HOPE Exchange participants 2023

# Conferences

## CONFERENCES, EVENTS, AND WEBINARS ORGANISED BY HOPE

### QUALITY AND SAFETY NETWORK WEBINAR

The "Quality & safety in Denmark: 7 years after the end of accreditation" webinar took place on 31 January 2023. Speakers and participants discussed the Danish experience of improving quality and patient safety since 2015. The webinar examined (1) how Denmark enables quality improvement without accreditation; (2) the patient safety and learning system in Denmark: (3) the cluster-based improvement model for general practices; (4) results.


### ICIC 2023: INTERNATIONAL CONFERENCE ON INTEGRATED CARE

The 23rd International Conference on Integrated Care (ICIC23) in partnership with the Flanders Agency for Health and Care and Visit Flanders took place at Flanders Meeting & Convention Centre in Antwerp from 22 to 24 May 2023 in hybrid form. The year's theme was "Care in action: how to work together, a participatory approach," and it brought together leaders, researchers, clinicians, managers, citizens, patients, and caregivers from around the world who are engaged in the design and delivery of integrated health and social care.


### INNOFACILITATOR WEBINAR

On 30 May 2023, InnoFacilitator, one of HOPE's projects, organised its first online workshop on "The Process of Public Procurement of Innovation." The aim was to help stakeholders understand the factors that impact the design of a PPI system, for instance, facilitators and inhibitors, technological maturity levels and their relationship to PPI typologies, recommended award procedure for each type of PPI, and the stages of the PPI process.

## INTERNATIONAL CONFERENCE ON HEALTH PROMOTING HOSPITALS AND HEALTH SERVICES


The 29th International Conference on Health Promoting Hospitals and Health Services took place this year in hybrid format in Vienna, Austria, from 20 to 22 September 2023. The conference focused on "Contributions of Health Promotion to Well-being-oriented Healthcare" in reference to the WHO Geneva Charter for Well-Being.

## SAFEST WEBINAR


As project partner, HOPE helped organise SAFEST's first webinar on "Patient involvement in quality and safety research" on 26 September 2023. The webinar lined up with WHO's World Day for Patient Safety. The consortia of the projects funded under the Horizon Europe call topic "Enhancing quality of care and patient safety" aimed to underscore the vital role of patients in shaping quality and patient safety research.

# Chapter 4

# PUBLICATIONS

In 2022, the new edition of Hospital Healthcare Europe was released online. HOPE answered consultations on the European Care Strategy, Antimicrobial Resistance, Brain Drain, Waste Framework Directive and released Position Papers, and press releases on other topics such as: Medical Devices Regulation, European Health Data Space and antimicrobial medicines reserved for treating humans. HOPE also provided members with three Strategic Notes on European Health Data Space, Cybersecurity and EU4Health Work Programme.

# Publications

## HOPE REPORT ON HEALTH IN ENVIRONMENT & CLIMATE ADAPTATION POLICIES


In October 2023, HOPE released a report on health in environment and climate adaptation policies. This document compiled information from regional and national level initiatives aiming to adapt our systems to the changing climate.

The healthcare sector's environmental footprint has become an important question since the pandemic, partly because of the terms of EU Resilience funding. The information in this report comes from the Climate ADAPT platform, and from a narrative review. Some data was also shared by the national liaison officers of HOPE.

In national plans concerning climate adaptation, the sections concerning health in these documents are uneven. However, some topics come back frequently: concerns overheat waves, droughts, infectious diseases, pollen allergies/air pollution. The healthcare sector is not often directly mentioned, but is linked to other actions such as emergency services, building adaptation, etc. However, this was not compiled.

When the adaptation plans do not have any mention of health issues, they were excluded. The plans are not uniform and are not always action plans, some only have recommendations. Other strategies or documents were added as national health plans or national/regional healthcare sector strategies on climate adaptation/response. The study of the impact of the healthcare sector itself on the environment is very marginal. The country with the most information regarding this is the United Kingdom (UK) followed by France.

## HOPE AGORA REPORT

From 2 to 3 June 2023, HOPE held its annual Agora Conference. The HOPE Agora report summarises the proceedings of the event. Dr. Urmas Sule, HOPE President and Chairman of the Board of the Estonian Hospitals Association, inaugurated the conference and marked the 40th edition of the HOPE Exchange Programme.

During the month of May 2023, 109 nurses, doctors, physiotherapists, and hospital managers among other healthcare professionals, participated in a 4-week hospital exchange across 20 countries in Europe. This intensive exchange culminated in Brussels. During the two-day Agora conference, HOPE welcomed 170 people, including the national coordinators who made the exchange happen.

In keeping with previous themes, which reflect the most pressing challenges hospitals and healthcare providers face in Europe, this year's topic was "Climate and Environment: Challenges for Hospitals and Healthcare Services." Participants observed green practices in different hospitals, identified the best, and shared them at the conference. Presenters focused on the impact the sector has on the climate and the environment, and vice versa. The challenges are enormous, but there is reason for hope given the actions, commitment, and strategies observed and showcased by each exchange team.

## STRATEGIC NOTE ON MENTAL HEALTH

On 7 June 2023, the European Commission presented a "Communication on a comprehensive approach to mental health" (COM (2023) 298 final). The strategic note provides a short description of the communication, focused on the hospital and healthcare services angle.

The initiative is part of the Commission's priority 'Promoting our European way of life'. The Commission mentions that this is also responding to the call for action from the European Parliament following its resolution from 2022 on mental health in the digital world of work, which calls on the EU institutions and Member States to recognise the scale of work-related mental health problems in the EU and to act accordingly.

The communication is considered by the Commission as the beginning of a new strategic approach to mental health, cross-sectoral in nature, going beyond health policy. It focuses on how to bring relief to people suffering from mental health and on prevention policies. It draws on three guiding principles that should apply to every EU citizen: to have access to adequate and effective prevention, to have access to high quality and affordable mental healthcare and treatment, and to be able to reintegrate society after recovery.

However, the communication is not a strategy as it does not lay down a plan for the European Union to work on a long-term plan nor on the development of long-term action on mental health. It proposes no new initiative or funding but presents existing allocations and financial resources related to mental health.

# POSITION PAPERS

## HOPE POSITION ON THE CYBER RESILIENCE ACT

It is well known that the hospital sector's digital infrastructure has been particularly vulnerable to malicious and costly ransomware and other types of cyberattacks in recent years, which have caused a high degree of operational disruption to administration and care while compromising patient safety. Such attacks also threaten the delivery of integrated care strategies comprising multiple health and social interventions to meet complex needs. The proliferation of connected IoT tools in care and domestic settings, and the increased blurring between healthcare and consumer products, further increase the risk of cyberattacks.

From this perspective, the CRA provides a missing link in the expanding EU cybersecurity legislative framework including the recently revised NIHS 2 Directive. It contains harmonised rules for placing connected hard- and software products on the market and for vulnerability handling during the entire product life cycle, coupled with essential cybersecurity requirements for the design and development of products with digital elements. The obligations manufacturers and other supply chain actors will need to comply with are comprehensive and stringent, and they take into account cybersecurity risks during all phases between product conception and exploitation.

However, HOPE feels that further clarification is needed regarding the scope of the CRA and its relevance to everyday hospital and healthcare functions, its relationship with other EU legislation (e.g., to avoid duplication of procedures, but also to ensure that hospitals can continue to work with in-house solutions where necessary), as well as how it relates to developments such as cloud services and open-source software.

## HOPE POSITION ON THE EUROPEAN HEALTH DATA SPACE

The European Commission's proposal for a Regulation on a European Health Data Space (EHDS) envisages the development and implementation of a digital health ecosystem in the EU as a key step for shaping more patient-centric, integrated, and resilient health systems. The envisioned primary uses of electronic health data contribute to improved patient health outcomes by facilitating easy access to, sharing and portability of electronic health data, while supporting healthcare professionals' tasks and administration. In parallel, the secondary uses are meant to advance health research, decision-making and innovation, while strengthening public health.

As hospitals and healthcare institutions are critically important settings in which data-driven technologies shape all spheres of activity, a prerequisite for the successful development of the EHDS will be good governance and transparency. Dialogue is crucial to ensure that the EHDS becomes an accessible, inclusive space that respects different structures of healthcare provision, safeguards patient safety and fundamental rights, and meets the needs of the beneficiaries it aims to empower.

This position paper draws attention to provisions of the legislative proposal where HOPE considers that further clarification, discussion, and elaboration is required for the EHDS to attain its objectives.

## HOPE CONTRIBUTION TO THE EUROPEAN COMMISSION CALL FOR EVIDENCE ON "A COMPREHENSIVE APPROACH TO MENTAL HEALTH"

HOPE welcomes the initiative of the European Commission and its overall aim of a comprehensive EU approach to mental health.

It makes sense to improve mental health by integrating it into all relevant EU policies and to maximise the added value of EU policies in national and local efforts. Mental health is indeed a determining factor in the effectiveness of EU policies as well as in the health, stability and prosperity of our societies. It is therefore essential to ensure that the EU adds maximum value to the coordinated efforts undertaken by Member States and others to help promote mental health, prevent poor mental health, treat mental health problems and deal effectively with the consequences. This is clearly rightly in line with the Council conclusions on the Economy of Well-being adopted in 2019 stating the importance of making "greater efforts to promote good mental health and to advance […] prevention."

HOPE is particularly pleased that the initiative seeks to promote a comprehensive, prevention-oriented approach to mental health as a public health issue and to mainstream mental health into EU policies. It is important to set out possible future work streams, focusing on clearly defined EU added value to facilitate the work of Member States and those on the frontline.

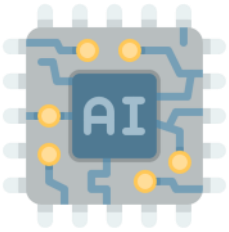
## JOINT STATEMENT ON THE EUROPEAN HEALTH DATA SPACE PROPOSAL

In March 2023, HOPE and five other not-for-profit organisations – representing patients, healthcare professionals, hospital pharmacists, payers, and healthcare institutions – called on European policymakers to ensure a more coherent, fair, and society-centred approach to the European Health Data Space (EHDS).

The statement specifically called for the following elements:

- Not to support strengthened provisions for IP rights and trade secrets.
- To include provisions on public return on data investment.
- To incorporate a wider range of civil society representatives into EHDS governance.

To plan sufficient time to develop and implement the EHDS.




## JOINT STATEMENT ON THE IMPACT OF ARTIFICIAL INTELLIGENCE ON HEALTH OUTCOMES FOR KEY POPULATIONS

In June 2023, HOPE joined 32 organisations to issue a statement focusing on actions needed to benefit from the potential of AI in health while protecting key populations from the risk of harmful effects. The main objective should be to prevent AI algorithmic tools from deepening health inequalities in the EU while reinforcing patterns of bias and discrimination.

Simultaneously, the joint statement, in its recommendations, aims to direct the use of AI in health in responsible, participatory, ethical, and equitable ways, exploring how its use and deployment could have the potential to close the chasm of health inequalities for key populations.

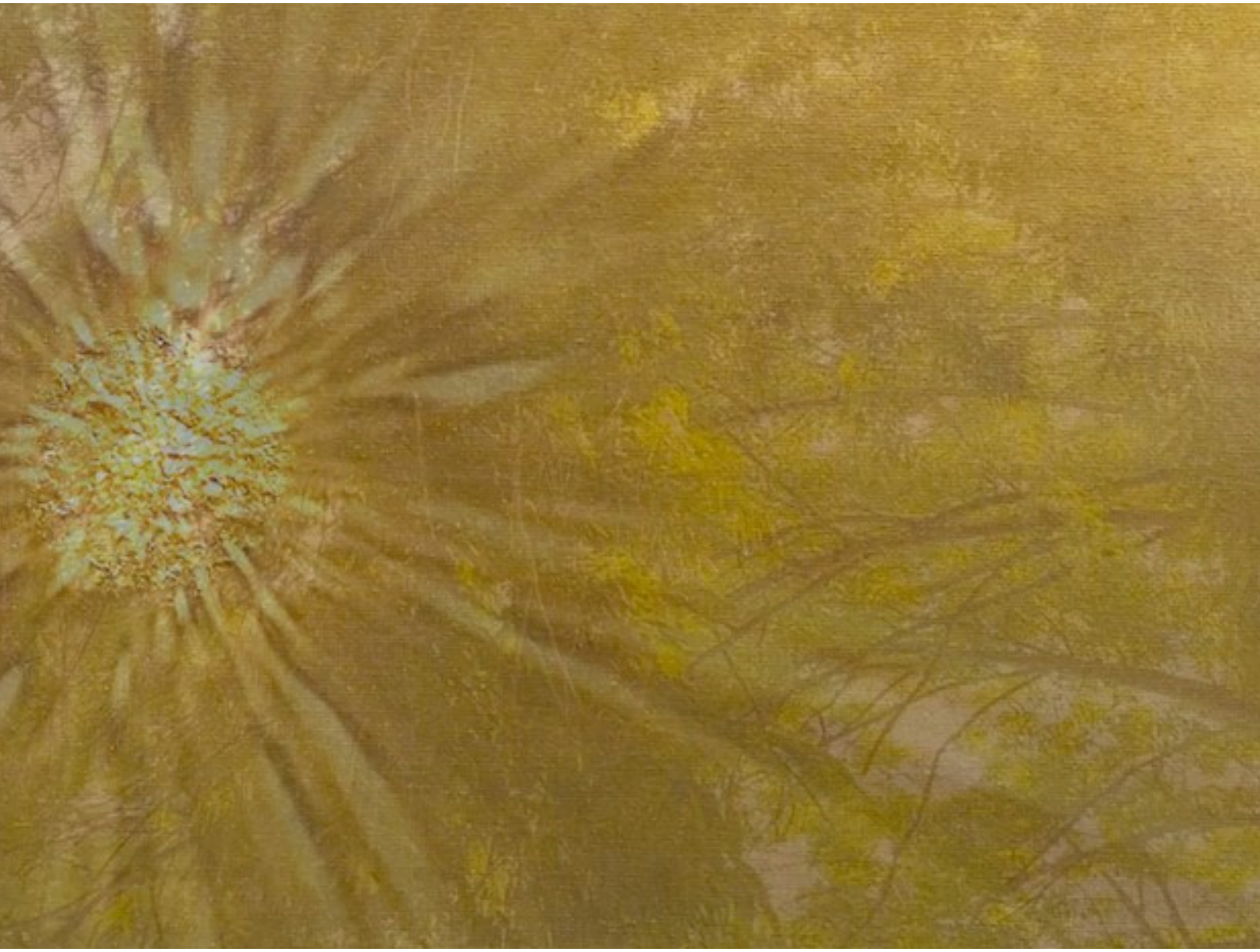
## HOPE POSITION ON THE EU CYBERSECURITY FRAMEWORK

The evolving EU legislative framework for cybersecurity is of paramount importance to hospitals and healthcare institutions in the context of increased data exchanges facilitated by an ever-growing array of connected, interoperable digital systems, devices and applications accessed across different locations.

Day-to-day hospital operations and healthcare provision relies increasingly on connected digital technologies, which must be forcefully protected from the disruptive, burdensome, immensely costly, and potentially harmful effects of cyberattacks. Given that international hacking networks are increasingly bold in their intentions and cause major damage, both economically and societally, the expansion of the EU cybersecurity framework reflects a mounting awareness that joining forces and expertise to tackle vulnerabilities in the digital realm is as important as ensuring an adequate military defence capacity.

Taking a holistic approach, this position paper outlines HOPE's perspective on the EU cybersecurity framework considering the growing threat affecting hospitals and healthcare institutions, including its practical implications and potential gaps.

All things considered, within the overall EU strategy, it is particularly important to develop comprehensive strategies in the sector, build up leadership and skills, ensure proper integration between cybersecurity and other digital policies (including health data sharing, data protection, privacy, fundamental rights), and to earmark sufficient and flexible resources. At the same time, it is important that cybersecurity measures match users' needs and competences, and that they fit into everyday workflows without compromising care provision.



# General Report on the Activities of the European Hospital and Healthcare Federation 2023

hope
European Hospital and Healthcare Federation