General Report

on the Activities of the

European Hospital and Healthcare Federation

2022

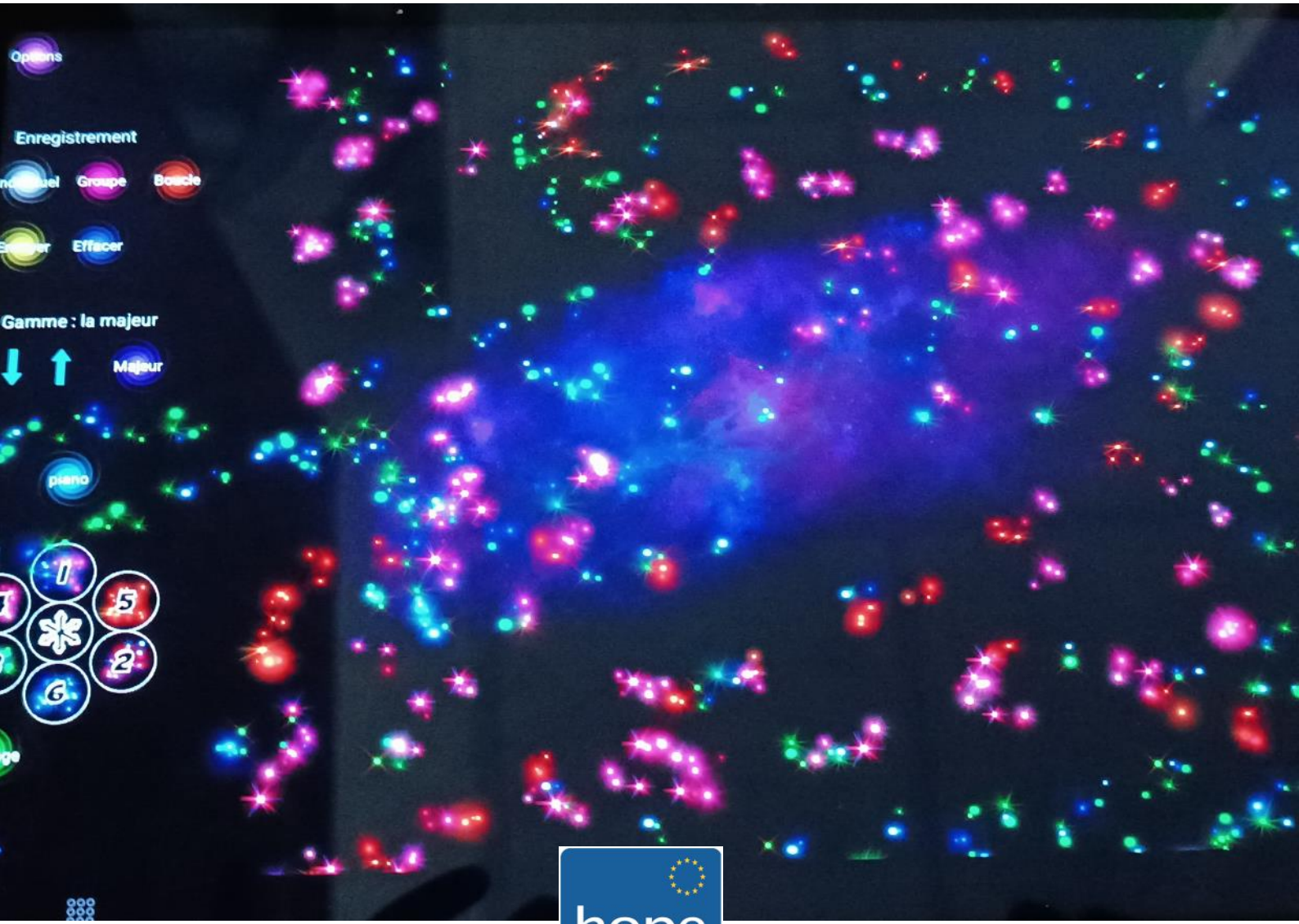

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Illustration Chapter 1: Projection aquarium numérique en Balnéo 2022
Illustration Chapter 2: Illuminart projection chambre 2022
Illustration Chapter 3: Projection Promenade en forêt - salle de détente 2022
Illustration Chapter 4: CCP projection 2022
Back page: Illuminart projection salon des parents

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General Report on the Activities of the European Hospital and Healthcare Federation — 2022

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Introduction

In 2022, health-related issues remained of prime importance in Europe and globally. Russia's invasion of Ukraine, on 24 February 2022, has led to a massive loss of lives and trauma injuries among civilians, the destruction of essential health services – including treatment of chronic conditions, the disruption of medical supply chains, the destruction of health facilities, as well as to 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. A large part of the European Institutions' activity in 2022 was dedicated to responding to this troubled context.

On the EU legislative side, the new EU Health security framework was completed with the adoption of the Emergency Framework Regulation, the new regulation on serious cross-border threats to health, and the new Mandate for the European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC). The new Directive on Cybersecurity (NIS2) and the Data Governance Act were adopted as well as the "Path to a Digital Decade" Policy Programme and the Directive on the Resilience of Critical Entities (CER Directive).

In the meantime, negotiations continued between the European Parliament and the European Council on the legislative proposal on artificial intelligence, on the European Health Data Space and on the ePrivacy Regulation.

HOPE continues monitoring the implementation of the Falsified Medicines Directive and engaging in the discussions on the implementation of the Medical Devices Regulations and of the newly adopted Regulation on Health Technology Assessment. HOPE also continues engaging in the discussions on post-Brexit EU-UK relations, on 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 regulations, such as the Cross-border Healthcare Directive, the European Reference Networks, the Cybersecurity Package, the Blood Tissue and Cells Directive, the

State Aid Package, the Restriction of Hazardous Substances, 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 standardisation, digitalisation, patient safety, pharmaceuticals, antimicrobial resistance, vaccination, cancer, mental health and climate to name but a few.

In 2022, HOPE also contributed to the EU non-legislative agenda through several European projects. The Erasmus + project ALADDIN, tackling the integration of additive manufacturing in the health sector, reached its final stage. H2020 projects TeNDER, RESAMPLE, HosmartAI and PERISCOPE continued to progress in 2022 with HOPE as a partner. Two new projects 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). HOPE is also an advisor in several projects and Joint Actions including a new project on persons with intellectual disability.

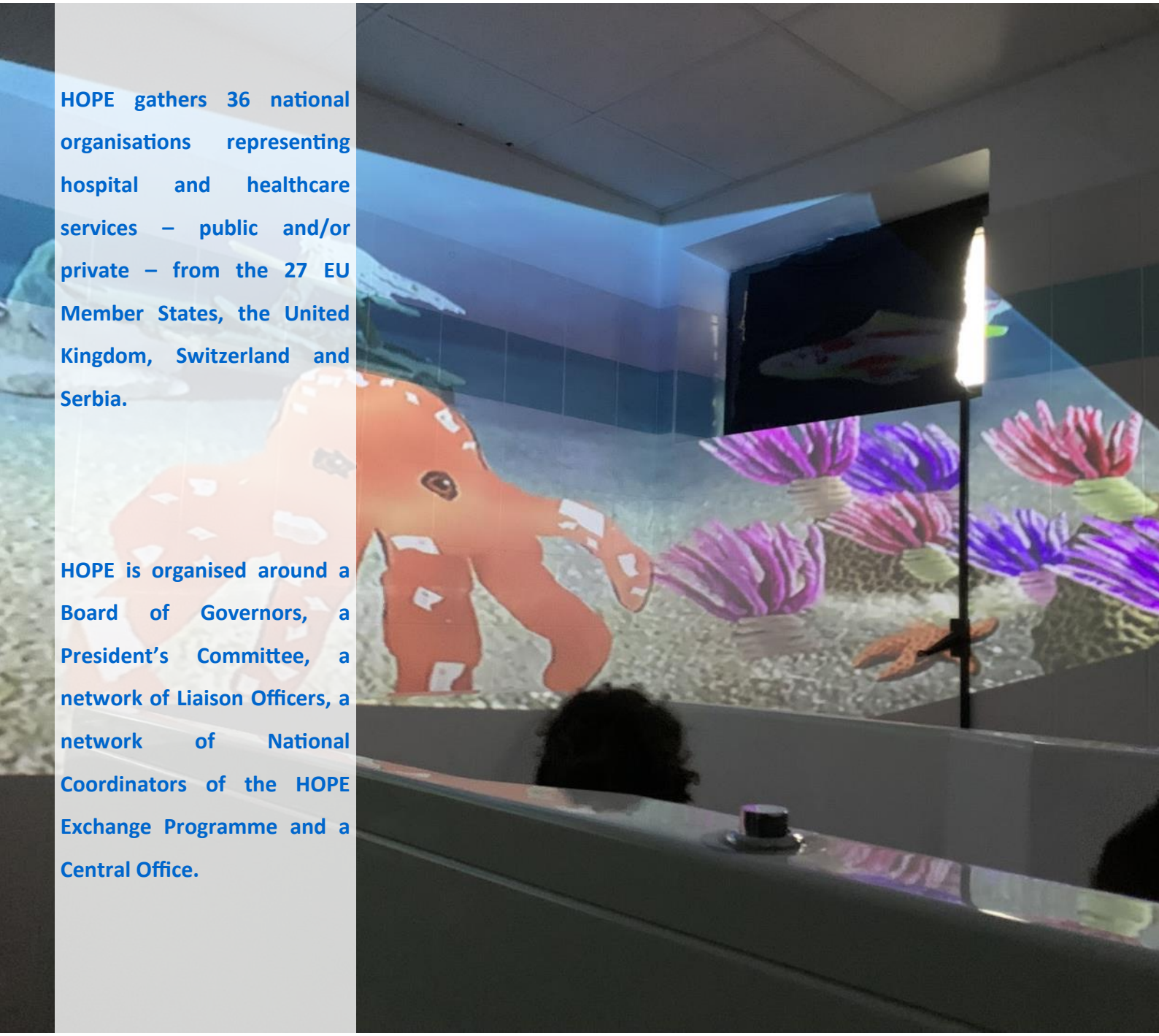
Consistent with HOPE's mission to facilitate the cross-border exchange of good practices among its members and beyond, HOPE staff and representatives participated as speakers or helped organise several European events.

The HOPE Exchange Programme 2022 reopened after two years of absence due to COVID-19 and the HOPE Agora took place on 3 and 4 June 2022 in Brussels, focusing on the theme “Using Evidence in Healthcare Management”.

Lastly, HOPE published the new edition of its annual Hospital Healthcare Europe report in December 2022.

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

HOPE gathers 36 national organisations representing hospital and healthcare services (public and/or private) from 30 countries.

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

The Board of Governors (BoG) is composed of the President, the Governors, one from each 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 2022: on 3 June in Brussels and on 31 October in Riga.

The President's Committee (PsC) consists of the President Dr Urmas Sule, the Vice-President Mr Eamonn Fitzgerald (Governor for Ireland) and three governors: the former President Dr Sara C. Pupato Ferrari (Governor for Spain), then Ms Yolanda Agra Varella (Governor for Spain), Mr Francis De Drée (Governor Belgium), and the former president Ms Eva M. Weinreich-Jensen (Governor for Denmark). One Governor is part of it as co-opted member: Dr Jaroslaw Fedorowski (Governor for Poland). 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 25 April and on 19 September 2022 to discuss the Board of Governors' agenda 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 2022, HOPE Liaison Officers meetings took place: online on 31 March, in Brussels on 3 June, and in Copenhagen on 24 November. At these meetings, Liaison Officers discussed changes related to COVID-19 outbreak management, the latest project developments, major EU health topics of the year and the transposition of EU legislation.

HOPE Board of Governors meeting, Riga, 31 October 2022

The network of National Coordinators of the HOPE Exchange Programme met in Copenhagen on 25 November to prepare the 2023 programme.

Located in Brussels, Belgium, the Central Office is managed by the Chief Executive, Mr Pascal Garel. Ms Laurie Andrieu is part-time EU Policies and Communication Officer replaced by Ms Adèle Le Bihan during her six-month sabbatical. 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. HOPE also welcomed two interns.

GOVERNANCE AT THE END OF 2022

President	Urmas Sule, Estonia
Vice-President	Eamonn Fitzgerald, Ireland
Chief Executive	Pascal Garel

GOVERNORS AND HEADS OF DELEGATION

Austria	Nikolaus Koller
Belgium	Francis De Drée
Bulgaria	Krasimir Grudev
Croatia	Željko Plazonic
Cyprus	Christis Loizides
Czech Republic	Miloslav Ludvik
Denmark	Eva Weinreich-Jensen
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	Yolanda Agra Varella
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 2022, 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, 2022 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 2022, among the major issues regarding EU political activity was still the response to the COVID-19 crisis. Four legislative proposals were adopted: the regulation on serious cross-border threats to health, the regulation establishing the new European Health Emergency Preparedness and Response Authority (HERA), the regulation for the extension of the mandate of The European Centre for Disease Prevention and Control (ECDC) and the regulation for the extension of the mandate of the European Medicines Agency (EMA).

The new Directive on Cybersecurity (NIS2) and the Data Governance Act were adopted as well as the "Path to a Digital Decade" Policy Programme and the Directive on the Resilience of Critical Entities (CER Directive). HOPE continued following the Delegated Act on the safety features appearing on the packaging of medicinal products for human use (the so-call "Falsified Medicines Directive") and the implementation of the Medical Devices Regulations. HOPE also continues engaging in the discussions on post-Brexit EU-UK relations.

Other pieces of legislation that had been adopted in previous years were still on HOPE's agenda, in the implementation process or reviewed by the European Commission: 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 2022, the European Commission proposed four new regulations: a proposal for a Data Act in February, a proposal on a Regulation for a European Health Data Space in May; a proposal to reform the Blood, Tissues and Cells Directives in July and a proposal for a Cyber Resilience Act in September.

In addition, several other initiatives remain on the EU political agenda: the legislative proposal on artificial intelligence released in April 2021 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 ADOPTED

CROSS-BORDER THREATS TO HEALTH

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).

In summary 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

On May 2021, HOPE published a position paper on the proposal for a regulation on serious cross-border threats to health.

On 23 June 2022, the European Parliament and the Council reached a provisional agreement on a draft regulation on serious cross-border threats to health. The text reinforces preparedness, surveillance, risk assessment, early warning and responses at EU and Member State level in the event of cross-border threats to health. On 4 October, the Parliament adopted, with 544 votes in favour, 50 against and 10 abstentions. The texts were endorsed by the Council on 24 October. The final signature took place 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 will establish 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 produc-

tion 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

In May 2021, HOPE published a position paper on the proposal for a regulation to extend the mandate of the European Centre for Disease Prevention and Control (ECDC).

This was adopted with 598 votes in favour, 84 against and 13 abstentions by the European Parliament Plenary on 15 September 2021.

On 4 October 2022, the Parliament endorsed the deal reached with the Council on extending the mandate of the ECDC with 542 votes in favour, 43 against and 9 abstentions. The agency will coordinate the standardisation of data collection procedures, data validation, analysis and dissemination of data at EU level. In addition, it will monitor the ability of national health systems to detect, prevent, respond to and recover from communicable disease outbreaks, identify gaps and provide science-based recommendations. The text was endorsed by the Council on 24 October.

The signature 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.

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
- the reporting of shortages of critical medicines during a crisis
- the coordination of EU/EEA countries to 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 (HERA)

The European Commission adopted the decision establishing the HERA on 16 September 2021. 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.

HERA was established as an internal Commission structure for operational reasons. Its functioning will be reviewed and adapted on an annual basis until 2025, the date of the full review.

On 10 February 2022, HERA presented its first annual work plan with a budget of €1.3 billion in 2022 to prevent, prepare for and rapidly respond to cross-border health emergencies.

On 9 June 2022, the European Commission and the U.S. Department of Health and Human Services signed an arrangement to strengthen cooperation on preparedness and response to public health threats. On the European side, this agreement will be coordinated by HERA.

Selected as a representative stakeholder, HOPE attended on 28 June 2022 the first meeting of the HERA Civil Society Forum. 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 process.

On 19 July 2022, the Commission Health Preparedness and Response Authority (HERA) signed a new joint procurement framework contract for the supply of Veklury (remdesivir), an antiviral treatment for patients with COVID-19, with the pharmaceutical company Gilead. This is the second framework contract for this therapeutic, the first having ended in April 2022. On 2 August 2022, HERA signed a joint procurement framework contract with the company HIPRA HUMAN HEALTH for the supply of their protein COVID-19 vaccine. 14 Member States and countries are participating in this joint procurement, under which they can purchase up to 250 million doses.

On 24 October 2022, the Council adopted the Emergency Framework Regulation to provide extra powers to HERA.

On 30 November 2022, HERA released its first State of Health Preparedness report.

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 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.

On 9 March 2022, the Council agreed on the mandate for the proposed directive and regulation to ensure continued supply of medicines to Northern Ireland, and to Cyprus, Ireland and Malta which entered into force on 20 April. The measures apply retroactively from 1 January 2022.

The aim of the directive is to preserve the uninterrupted supply of medicinal products for human use in Northern Ireland after Brexit, within the Protocol on Ireland/Northern Ireland. It will also, exceptionally and for a transitional period of three years, allow medicinal products from the United Kingdom to be placed on the market in Ireland, Malta and Cyprus under exemptions from the requirement for authorisation holders to be established in the European Union. The regulation is closely linked to the directive and aims to ensure the supply of investigational medicinal products to the same markets.

On 14 March 2022, the Commission approved the disbursement of more than €2 billion under the Brexit Adjustment Reserve to a group of 12 Member States. This decision made available a total of €819.2 million by the end of March 2022 and the rest by April 2023. This funding helps the economies of the Member States in mitigating the adverse impact of Brexit on their economies and regions, through support to regions and economic sectors, small and medium-sized companies as well as job creation and protection, such as short-time work schemes, re-skilling, and training. The Member States may use the funding until 31 December 2023 to cover expenses incurred and paid since 1 January 2020.

On 12 and 13 May 2022, the first meeting of the EU-UK Parliamentary Partnership Assembly (PPA) took place in Brussels. The meeting was organised in two sessions. The first was devoted to discussions on the state of play within the Partnership Council and EU-UK cooperation in relation to the war in Ukraine. The PPA also addressed technical issues. Thus, it adopted its Rules of Procedure and agreed on what type of information to

seek and share with the Partnership Council. The second session focused on the impact of Withdrawal Agreement issues upon the work of the Partnership Council and the importance of building the new multidimensional EU-UK relationship, cooperation in the field of energy and the future work of the assembly. The Co-Chairs, Ms Nathalie Loiseau and Sir Oliver Heald, signed a joint statement.

On 18 October 2022 the European Health Stakeholder Group organised a meeting at HOPE's office to cover several pending issues: Data sharing with the UK data protection reforms and on what they mean for health and health research; Research collaborations with updates on progress for UK and Swiss association to Horizon Europe ; Clinical trials with a review of the current and upcoming risks and challenges for cross-border clinical trials; The future UK-EU relationship with feedback from the NHS Confederation's meeting with MEPs involved in the EU-UK Parliamentary Partnership Assembly; Brexit Health Alliance: update on Alliance for International Health Policy (Brexit Health Alliance) focus on NI Protocol and UK trade deals; Regulation and supply of medicines and medical devices with a review of the current and upcoming risks and challenges for regulation and supply of medicines and medical devices.

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 10 March 2022, the European Commission published the rolling plan for the implementation of the Regulation on HTA. The first meeting of the Member State Coordination Group on Health Technology Assessment (HTACG) was then held on 21 June 2022 in Brussels. The second meeting of the HTACG was held on 28 November 2022 in Brussels. It covered the following points for decision: Rules of procedure of the HTACG; Elections of Chair(s) and Co-Chair(s) of the HTACG; Set up of the subgroup(s) of the HTACG. The HTACG agreed to start the process of establishing the subgroup on the development of methodological and procedural guidance, the subgroup on joint clinical assessments, the subgroup on joint scientific consultations, and the subgroup on the identification of emerging health technologies.

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 2-D barcode and an anti-tampering device on the box of prescription medicines. The pharmacies – including online pharmacies – and hospitals have to 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, so as 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 considerable tension in terms of governance as well.

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 REGULATIONS

HOPE has been a member since 2010 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 aims at discussing issues related with the implementation of the Medical Devices Directive. Additionally, HOPE is part of its Cybersecurity and EUDAMED Working Groups.

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. The aim of both proposals was to address inconsistencies in how Member States interpret the current rules, increase patient safety and transparency, remove obstacles to the internal market and strengthen the rules on traceability. The new Medical Device Regulations introduced the Unique Device Identification system to facilitate traceability of medical devices, allow for better monitoring by relevant authorities, help reduce medical errors and fight against falsified devices. Both texts were adopted and published in the Official Journal in May 2017.

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

The new rule on medical devices was supposed to apply from 26 May 2020 but it was 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. While leaving the date of application unchanged on 26 May 2022, the regulation:

- provides that devices lawfully placed on the market through a certificate issued by a notified body in accordance with the current in vitro diagnostic medical devices directive (Directive 98/79/EC) prior to 26 May 2022 may continue to be placed on the market or put into service until 26 May 2025. This represents a one-year extension;

- introduces tailored transitional periods for devices which have to undergo a conformity assessment involving notified bodies for the first time under the IVDR (but which have a declaration of conformity issued under the IVDD prior to 26 May 2022). The length of the transitional period depends on the risk class of the device concerned. Lower risk devices such as class B and class A sterile devices may be placed on the market or put into service until 26 May 2027, whereas higher risk devices (class D and class C devices) may only be placed on the market or put into service until 26 May 2025 and 26 May 2026 respectively. During these extended transitional periods, the devices must continue to comply with the IVDD. They must not have any significant changes made in their design and intended purpose;

- provides that devices lawfully placed on the market from 26 May 2022 pursuant to point 2 above may continue to be made available on the market, including to be supplied to end users, or put into service until 26 May 2026, 26 May 2027 and 26 May 2028 respectively, depending on the type of device concerned;

- gives additional time to health institutions which manufacture devices for use within their own premises (i.e., so-called “in-house devices”) to meet the conditions set forth in Article 5, IVDR, namely until 26 May 2024 (conditions (b) (c) and (e) to (i)) and 26 May 2028 (condition (d)).

HOPE attended the Medical Devices Coordination Group EUDAMED on 28 April 2022. The Subgroup meetings are not public and are intended for MDCG EUDAMED Subgroup members and selected observers only. The last plenary meeting took place on 9 December 2021 and since then two new releases have been deployed: Production 2.7 with new functionalities for Designating Authorities and the Commission and Playground 3.0 with the first functionalities of the Vigilance and Market Surveillance modules.

On 27 April 2022, the Commission released the report to the European Parliament and the Council on the exercise of the power to adopt delegated acts conferred on the EU Commission pursuant to MDR and IVDR.

On 11 May 2022, harmonised standards under the Medical Devices Regulations were published. Harmonised standards are developed by the European

Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC) on the basis of a Standardisation Request issued by the EU Commission according to Regulation (EU) No 1025/2012 on European standardisation. Once their references are published by the EU Commission in the Official Journal of the European Union, the voluntary use of those standards confers presumption of conformity with the requirements of the regulations they aim to cover. The new standards published in May 2022 were:

- For MDR: Commission Implementing Decision (EU) 2022/757
- For IVDR: Commission Implementing Decision (EU) 2022/729 of 11 May 2022

During their 50th plenary meeting on 3 June 2022 competent authorities for medical devices (CAMD) agreed on a statement concerning the Medical Devices Regulation. CAMD stressed the significant and urgent challenges that remain in ensuring sufficient capacity and a readiness across all stakeholders with an appropriate regulatory infrastructure within time for May 2024. They expressed their commitment to work together, with the European Commission, the Medical Devices Coordination group (MDCG) and CAMD leadership, to seek and consider all potential solutions to mitigate supply disruption and a lack of system readiness.

On 13 July 2022, the Commission published a guidance document endorsed by the Medical Devices Coordination Group on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional. This aims to provide guidance to Member States and other relevant parties on the application of certain IVDR provisions during the absence of EUDAMED.

At the request of the EU Health Ministers, the MDCG adopted on 26 August 2022 a list of actions to enhance notified body capacity, access to notified bodies and manufacturers' preparedness in order to facilitate transition to the MDR and IVDR and to avoid shortage of medical devices. The MDCG will implement and/or support the implementation of the actions listed and call for the commitment of all actors involved, including notified bodies and industry.

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 highlights 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 European Commission has proposed legislative amendments early 2023.

PATH TO THE DIGITAL DECADE

On 15 September 2021, following Ursula von der Leyen's State of the Union address, the European Commission released a proposal for a Path to the Digital Decade, a concrete plan to achieve the digital transformation of the society and economy by 2030. A draft decision proposed by the Commission establishes the Policy Programme 'Path to the Digital Decade' and sets out a monitoring and cooperation mechanism. Regarding health more specifically, a few elements of the proposal can be underlined:

- digitalisation of public services: a. 100% online accessible provision of key public services for EU citizens and businesses; b. 100% of EU citizens have access to their medical records (electronic health records (EHR)); c. at least 80% of EU citizens use a digital identification (ID) solution.
- transparency and public participation: close cooperation and consultation of stakeholders including private and public actors, such as bodies governed by public laws of the educational or health sector.
- access: ensure that democratic life, public services and health and care services are accessible online for everyone, in particular disadvantaged groups including persons with disabilities, offering inclusive, efficient and personalised services and tools with high security and privacy standards.

At the Parliament, the legislative file has been assigned to the Industry, Research and Energy Committee (ITRE). The rapporteur MEP Martina Dlabajová (Renew/CZ), published her draft report on 3 March 2022. It was adopted on 17 May 2022 at the ITRE Committee meeting with 74 votes to 1, with 1 abstention. On 11 May 2022 the Council adopted its position. The trilogues started on 22 June 2022 and an agreement was reached on 13 July 2022. At the Parliament, the text was voted in plenary on 24 November 2022 with 522 votes to 29, with 25 abstentions. The agreement was also adopted by the Council on 8 December 2022. The decision entered into force on the twentieth day following that of its publication in the Official Journal of the European Union on 19 December 2022. It is directly binding on Member States without transposition into national law.

DATA GOVERNANCE

The Data Governance Act (DGA) was the first of a set of measures announced in the 2020 European Strategy for Data.

On 25 November 2020, the European Commission published its draft Data Governance Act. It aims at making more data available to help create new products and innovation, in particular in artificial intelligence. It also aims at increasing trust in data sharing, at creating new EU rules on neutrality of data marketplaces and at facilitating the reuse of certain data held by the public sector e.g. certain health, agricultural or environmental data, which were previously not available under the Open Data Directive.

The European Parliament adopted the final text on 6 April 2022, and the Council adopted it on 16 May 2022. The act was signed by the President of the European Parliament and the President of the Council on 30 Mai 2022 and promulgated in the Official Journal of the European Union on 3 June 2022. It entered into force 20 days after publication and the new rules will apply from 24 September 2023.

CYBERSECURITY

HOPE continued its monitoring of cybersecurity-related EU legislation in 2022 in the face of further disruptive and costly cyberattacks (often deploying ransomware) on hospitals and healthcare facilities in many member states.

As part of the EU Cybersecurity Strategy to boost the cyber and physical resilience of critical entities and networks, in December 2020 the European Commission released proposals for a directive on measures for high common level of cybersecurity across the Union (revised NIS Directive or 'NIS2', replacing cybersecurity rules introduced in 2016), and a directive on the resilience of critical entities (CER Directive). They cover a wide range of sectors and address current and future online and offline risks, from cyberattacks to crime or natural disasters.

Following the Council's adoption of its negotiating position in December 2021, which introduced significant changes to the NIS2 proposal, trialogue interinstitutional negotiations started on 13 January 2022, with the second round of trilogue negotiations taking place on 17 February.

On 13 May, the European Parliament and the Council reached a political agreement on the NIS2 text:

- The directive will formally establish the European Cyber Crises Liaison Organisation Network, EU-CyCLONe, which will support the coordinated management of large-scale cybersecurity incidents. The new NIS2 directive introduces a size-cap rule. This means that all medium-sized and large entities operating within the sectors or providing services covered by the directive will fall within its scope.

- While the agreement between the European Parliament and the Council maintains this general rule, the provisionally agreed text includes additional provisions to ensure proportionality, a higher level of risk management and clear-cut criticality criteria for determining the entities covered.

- As public administrations are also and often targets of cyberattacks, NIS2 will apply to public administration entities at central and regional level. In addition, Member States may decide that it applies to such entities at local level too.

- The European Parliament and the Council have aligned the text with sector-specific legislation, in particular the regulation on digital operational resilience for the financial sector (DORA) and the directive on the resilience of critical entities (CER), to provide legal clarity and ensure coherence between NIS2 and these acts.

- The two co-legislators have also streamlined the reporting obligations in order to avoid causing over-reporting and creating an excessive burden on the entities covered.

The political agreement was adopted by the ITRE committee on 13 July 2022 and by Parliament in its plenary of 10 November with 577 votes in favour, 6 against and 31 abstentions. The proposal was also adopted by the Council on 28 November and signed by both co-legislators on 14 December 2022. After publication in the Official Journal in January 2023, Member States will have 21 months after the entry into force 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 to 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 ones 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 main provisions include:

- Member States would be required to adopt a national strategy for ensuring the resilience of critical entities and to carry out regular risk assessments to identify critical entities;
- Critical entities would have to carry out risk assessments of their own and to take technical and organisational measures to ensure their resilience, as well as to report disruptive incidents;

- A Critical Entities Resilience Group, gathering Member States and the Commission, will evaluate national strategies and facilitate cooperation and exchange of best practices;
- To enforce rules, Member States should enable national authorities to conduct on-site inspections of critical entities, and introduce penalties for non-compliance.
- The Commission would provide support to Member States and critical entities, for instance, by developing a Union-level overview of cross-border and cross-sectoral risks, best practices, methodologies, cross-border training activities and exercises to test the resilience of critical entities.

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.

On 28 June 2022, the Council and the Parliament reached a political agreement on the CER Directive.

The European Parliament and the Council formally approved the text, and the two institutions signed the final act on 14 December 2022. The text will enter 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.

HOPE attended on 14 June 2022 the eighth meeting of the Operators' Forum for the Protection of Public Spaces, taking place as a hybrid meeting. The European Commission presented on that occasion the EU City Pledge Initiative — Cities against Radicalisation and Terrorism Initiative. In the 2020 EU Counter-Terrorism Agenda, the Commission committed to propose an EU Pledge on Urban Security and Resilience, which should be part of this initiative. The EU Counter-Terrorism Agenda mentions cities as the "backbone of urban security".

In a nutshell, this new initiative is meant to support cities in the field of protection of public spaces and prevention of radicalisation, by providing a "glocal" "one-stop-shop" for cities, consisting of two elements:

- The EU Pledge on Urban Security and Resilience (the Pledge);
- The EU Cities against Radicalisation and Terrorism Initiative (the Framework Initiative).

HOPE was invited on 5 December 2022 to the 9th meeting of the Operators' Forum for the Protection of Public Spaces, as part of the implementation of the EU Action Plan for the Protection of Public Spaces, and continuing the work of the Policy Group and Operators' Forum established in 2017. At the last meeting of the Operators' Forum held on 14 June 2022, there were presentations of the RECEDD and PACTESUR projects and the Commission updated on the EU Protective Security Advisory Mission programme, on the EU City Pledge Initiative and about the relevant projects funded under Horizon Europe. The Commission Joint Research Centre gave un update on its work, including on the work on

CROSS-BORDER HEALTHCARE

The Directive 2011/24/EU on Patients' Rights in Cross-Border Healthcare adopted in March 2011 was one of the most controversial pieces of European healthcare legislation in recent years. During the transposition period from 2011 to 2013, HOPE continued to work intensely on the directive and to raise awareness about its content. Since then, HOPE has been monitoring the directive and reports.

On 13 May 2022, the European Commission published its evaluating report on patients' rights under the Cross-Border Healthcare Directive, together with an assessment of its impact ten years after its adoption. The report confirms that the directive has guaranteed equal treatment of all EU patients when treated in another EU country, and that it provides for partial or full reimbursement of the costs of care cross-border healthcare. The report also found that the directive could help reduce the very large backlog of non-emergency routine treatments, which have been postponed due to the COVID-19 pandemic, where unused healthcare capacity may exist on the other side of the border. However, patients continue to face difficulties when seeking treatment abroad, mainly due to the uneven application of the directive by EU countries, heavy administrative procedures, and excess of complex information about the best cross-border healthcare options available.

The evaluation results were presented to the Public Health Working Party in the Council in June 2022. The Member States agreed with the main conclusion of the evaluation that there is currently no need to revise the CBHC Directive.

An awareness-raising event at EU level on patients' rights to cross-border healthcare will be organised by the Commission at the end of 2023.

EUROPEAN REFERENCE NETWORKS

On 1 March 2017, the newly established European Reference Networks (ERNs) were officially launched. HOPE had contributed to this development since the beginning by suggesting it back in 2002. ERNs are virtual networks bringing together healthcare providers across Europe to tackle complex or rare medical conditions that require highly specialised treatment and a concentration of knowledge and resources. They are being set up under the EU Directive on Patients' Rights in Healthcare (2011/24/EU).

Twenty-four thematic ERNs, gathering over 900 highly specialised healthcare units from 26 countries, began working together on a wide range of issues, from bone disorders to haematological diseases, from paediatric cancer to immunodeficiency.

On 26 November 2021, the ERN Board of Member States unanimously approved Implementing Decision 2014/287/EU Article 10 stating that on 1 January 2022, 620 new members would join the European Reference Networks. As a result of the call there are nearly 1,500 ERN units in the 27 Member States and Norway. The highest number of new applicants (43) was accepted to ERN RITA – the European Reference Network that aims to improve the care of patients with rare immunological disorders. Thirty-eight new applicants joined EURACAN – the ERN that connects patients who have rare adult solid cancers, and 36 applicants joined ERN EuroBloodNet – the ERN in Rare Haematological Diseases (RHD). The healthcare units which joined the ERNs rank as follows: Italy (145), Germany (84), Spain (68), Latvia and Slovenia (4), Estonia (3) and Cyprus (2). Greece joined as a new country to have healthcare units in the ERNs – with 18 units.

In December 2022, the Commission launched the evaluation process of the ERNs. It will take about a year, from the appointment of the Independent Evaluation Body to the issue of the final evaluation reports.

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 1,483 million tonnes of oil equivalent (Mtoe) of primary energy or 1,086 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 17 November 2020, the European Commission launched a public consultation on the evaluation of the EU Energy Efficiency Directive, open until 9 February 2021.

On 11 June 2021, the Council approved conclusions on a renovation wave. The renovation wave strategy aims to intensify renovation efforts throughout the EU, in order to make the necessary contribution by the building sector to the 2050 climate neutrality goal and to deliver a fair green transition.

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'.

The Council of the EU discussed the energy efficiency issue extensively in the Working Party on Energy and at COREPER level, and finally agreed a general approach on 27 June 2022. Trilogue negotiations between the Parliament, the Council and the Commission were still ongoing at the end of 2022.

Energy Performance of Building

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 Building 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 Building Directive.

Renewable Energy

On 14 July 2021, the Commission published a proposal to revise the Renewable Energy Directive and set an increased target to produce 40% of energy from renewable sources by 2030. All Member States will contribute to this goal, and specific targets are proposed for renewable energy use in transport, heating and cooling, buildings and industry. To meet both climate and environmental goals, sustainability criteria for the use of bioenergy are strengthened and Member States must design any support schemes for bioenergy in a way that complies with the cascading principle of uses for woody biomass.

EU energy ministers agreed their joint position on the proposal for a revised EU renewable energy directive on 27 June 2022.

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'. A feedback period on the proposition was open from 15 July to 8 November 2021. The proposal is awaiting the Committee decision in the European parliament. 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. This political agreement is provisional, pending formal endorsement.

WORKERS' PROTECTION FROM EXPOSURE TO HAZARDOUS MEDICINAL 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 will be 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. Member States will have two years to transpose the directive after its entering into force.

STAITE 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 an 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).

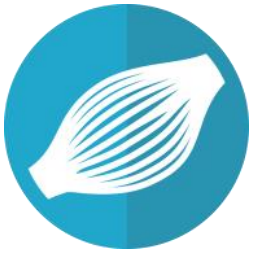
Compensation measures for health and social services – to the extent that they constitute state aid and exceed the (SGEI) de minimis threshold – usually fall under the SGEI Decision, regardless of the aid amounts involved. Thanks to HOPE lobbying, aid granted under the SGEI Decision does not need to 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 a number of 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.

PROPOSED LEGISLATIONS

BLOOD, TISSUES AND CELLS

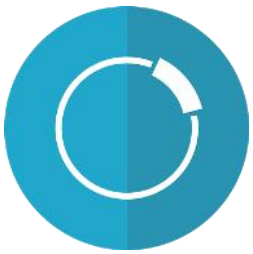


On 11 October 2019, the Commission published its evaluation on the EU Blood, Tissues and Cells Legislation. This was the first evaluation since the adoption of the basic acts in 2002 (blood) and 2004 (tissues and cells).

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 aimed to address the (re-)emergence of communicable diseases, including lessons learnt from the COVID-19 pandemic. It also wanted also 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 aims 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.

During the Czech Presidency, three meetings of the Working Party on Public Health (16 September, 7 October, 14 October 2022) and an informal virtual meeting of members of the Working Party on Public Health (8 November 2022) were dedicated to the proposal. On 9 December 2022, the Czech presidency presented at the EPSCO (Health) Council the state of play of the proposal currently being examined by the EU Member States.

HOPE worked on its position in 2022.

ARTIFICIAL INTELLIGENCE

HOPE's work in the area of artificial intelligence (AI) and robotics has become more ubiquitous in line with increased EU policy engagement.

EU milestones include the 2018 Communication “Artificial Intelligence for Europe”, which first outlined technological, ethical, legal and socio -economic aspects to boost the EU's research and industrial capacity and put AI at the service of European citizens and economy; the creation of a High-Level Expert Group on Artificial Intelligence to support the implementation of the EU Strategy on AI; the Expert Group’s “Ethics Guidelines for Trustworthy AI” and Commission communication, “Building Trust in Human Centric Artificial Intelligence” released in 2019; and the Commission’s “White Paper on Artificial Intelligence: a European approach to excellence and trust” in February 2020, published together with an accompanying report on the safety and liability framework. HOPE provided inputs to the white paper and other AI consultations.

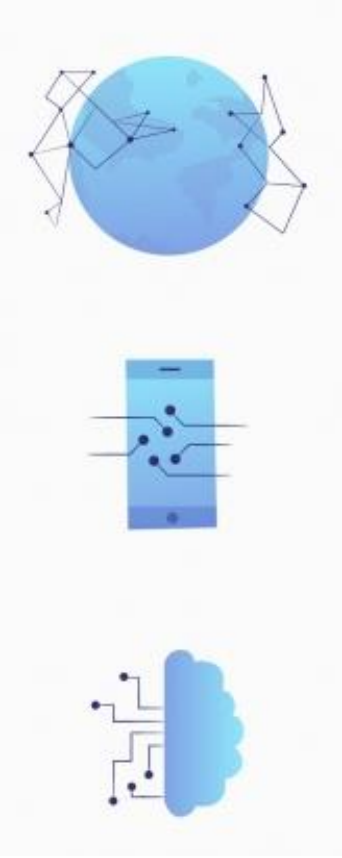
The European Commission finally released an AI regulatory framework in April 2021. The so-called AI Act proposes to enshrine in EU law a technology-neutral definition of AI systems and to adopt different set of rules tailored on a risk-based approach with four levels of risk (minimal, limited, high-risk and unacceptable). At Council level, following progress made by the Slovenian presidency in 2021, EU ministers supported the main objectives of the proposal and took note of the progress report presented by the French presidency in June 2022. In Parliament, the discussions are led by the Committee on Internal Market and Consumer Protection (IMCO; rapporteur: Brando Benifei, S&D, Italy) and the Committee on Civil Liberties, Justice and Home Affairs (LIBE; rapporteur: Dragos Tudorache, Renew, Romania) under a joint committee procedure.

On 9 November 2021, a draft report on the AI regulation was presented to the AIDA committee by the rapporteur Alex Voss. According to the draft, the EU should not regulate AI as a technology; instead, the type, intensity and timing of regulatory intervention should solely depend on the type of risk associated with a particular use of an AI system. The draft report identifies policy options for unlocking the potential of AI in health, environment and climate change, competitiveness, and the labour market. It notes that autonomous AI systems are at odds with the information duties laid down in the EU's General Data Protection Regulation (GDPR), which has led to legal uncertainty and lack of cooperation in the health sector. The draft report also highlights the challenge of reaching a consensus within the global community on minimum standards for the responsible use of AI, and concerns about military research and technological developments into weapon systems without human oversight. On 23 March 2022, AIDA adopted its final recommendations.

The two co-rapporteurs released their draft report in April 2022, sharing the view that AI developed and used in Europe should be human-centric, trustworthy and respect fundamental rights and Union values. At the same time, however, the regulation should support innovation. Agreeing with the risk-based approach, they stated that the obligations introduced by the regulation should only apply to forbidden practices, to high-risk AI systems, and to certain AI systems that require transparency. As such, no AI system should be excluded ex-ante, either from the definition of "artificial intelligence" or by carving out exceptions for certain types including general purpose AI. Where, for objective reasons, providers are unable to fulfil their obligations, they should be able to enter into agreements with users to share responsibilities. Another key element was the alignment of the text with the GDPR. Moreover, they proposed to add practices that amount to "predictive policing" to the list of forbidden practices and to include specific cases on the list of high-risk AI systems (i.e., triage of patients in the healthcare sector, determination of eligibility for health and life insurance).

Other amendments concerned the clarification and rebalancing of the chain of responsibility, as well as governance and enforcement (i.e. expansion of AI Board's role, proposal of a new enforcement mechanism by the EC to be triggered in cases amounting to widespread infringements).

HOPE closely monitored the discussions about the AI Act and updated its position on AI, to be published in 2023.



Civil liability for AI

On 18 October 2021, the European Commission opened a public consultation on "Civil liability – adapting liability rules to the digital age and artificial intelligence". Current rules on products ensure that producers compensate consumers for damage caused by defective products. This initiative proposes to adapt this framework to take account of developments linked to the move towards a circular and digital economy on liability for damage caused by new and refurbished products. The initiative will also address challenges brought about by artificial intelligence. The consultation was closed 10 January 2022.

On 28 September 2022, the Commission adopted two proposals to adapt liability rules to the digital age, circular economy and the impact of global value chains:

- The draft directive on liability for defective products ("Product Liability Directive") aims to modernise and reinforce the existing rules on the strict liability of manufacturers for the compensation of personal injury, damage to property or data loss caused by unsafe products, from smart technology to pharmaceuticals. The purpose is to ensure fair and predictable rules for businesses and consumers alike.
- The draft directive on adapting non-contractual civil liability rules to artificial intelligence ("AI Liability Directive") is intended to establish uniform rules for access to information and alleviation of the burden of proof in relation to damage caused by AI systems, establishing broader protection for victims (whether individuals or companies), and encouraging the AI industry by increasing guarantees. It will harmonise certain rules for compensation claims outside the scope of the Product Liability Directive, in cases where the damage is caused by wrongful conduct.

EUROPEAN HEALTH DATA SPACE

The European Health Data Space (EHDS) is the result of several years of 'preparation work' undertaken by the Commission and the Member States in the digital health realm: in 2014 the eHealth Network was created under the Directive 2011/24/EU on Patients' Rights in Cross-border Healthcare; in 2018, the European eHealth Digital Service Infrastructure (eHDSI) began sharing patient summaries and ePrescriptions securely across borders through the Connecting Europe Facility (CEF); and in 2019 the European Commission adopted a Recommendation on a European Electronic Health Record exchange format. Under the 2019-2024 legislative period, the €7.5 billion Digital Europe Programme was launched to foster investments in high performance computing, artificial intelligence, cybersecurity and trust, advanced digital skills, and the wide use and deployment of digital technologies across the economy and society.

The European Commission released its EHDS Roadmap in December 2020. It led to the establishment of a Joint Action Towards a European Health Data Space (TEHDAS, February 2021 to August 2023) to propose options on governance, infrastructure, data quality and data solidarity and empowering citizens with regards to secondary health data use in the EU. In budgetary terms, in addition to Digital Europe, funds from the EU4Health programme and Horizon Europe will also be channelled into supporting the EHDS while other EU funding was reoriented to include Member State actions accelerating the digital transformation of health and care (Recovery and Resilience Facility, European Regional Development Fund, European Social Fund+, InvestEU).

On 3 May 2022, the Commission published its proposal for a Regulation on a European Health Data Space. The main provisions include:

- Immediate and easy access for citizens to their data in electronic form, free of charge. They will be able to add information, rectify wrong data, restrict access to others and obtain information on how their data are used and for which purpose.
- Member States will ensure that patient summaries, ePrescriptions, images and image reports, laboratory results, discharge reports are issued and accepted in a common European format.
- Interoperability and security will become mandatory requirements. Manufacturers of electronic health record systems will need to certify compliance with these standards.
- All Member States have to appoint digital health authorities. These authorities will participate in the cross-border digital infrastructure (MyHealth@EU) that will support patients in sharing their data across borders.
- Under strict conditions, researchers, innovators, public institutions or industry will have access to large amounts of high-quality health data. The access to such data by researchers, companies or institutions will require a permit from a health data access body, to be set up in all Member States. Access will only be granted if the requested data is used for specific purposes, in closed, secure nvironments and without revealing the identity of the individual. It is also strictly prohibited to use the data for decisions, which are detrimental to citizens such as designing harmful products or services or increasing an insurance premium.
- The health data access bodies will be connected to the new decentralised EU infrastructure for secondary use (HealthData@EU) which will be set up to support cross-border projects.

In May 2022, HOPE took part in a discussion organised by TEHDAS Joint Action to hear first stakeholder reactions to the proposal. This was followed by an exchange of views between national health ministers organised under the French presidency at a meeting of the Employment, Social Policy, Health, and Consumer Affairs Council (Health), which HOPE followed online. The strong consensus message was that the EHDS proposal is welcome and necessary to achieve tangible progress in Europe ongoing digital transformation of health and care, with digital solutions (e.g. digital COVID certificates, telemedicine) having proven their added value during the pandemic and created new expectations. However, the EHDS objectives and benefits needed to be clear and well communicated to build public trust and confidence in data-driven digital healthcare and research.

Priority items mentioned during the debate included, inter alia, ensuring high levels of data protection and privacy given the particularly sensitive nature of health data; upholding the Ethical Principles adopted under the French Presidency; investing in digital skills and inclusion; and offering certain opt-out options for patients. Making "right data available at the right time" was seen as a particular challenge given the current high levels of fragmentation. The effect of the EHDS on national health systems was another important theme: several Member States pointed out the tremendous effort required (in terms of time, costs, and resources) to meet European data space ambitions. Hence the EHDS should be geared to the specificities of health in the Member States, recognise different levels of digital health readiness, and it should ultimately result in levelling up the quality of care across the entire Union. Finally, it will be important to ensure consistency between the EHDS and other pieces of legislation.

In July 2022, HOPE released its initial feedback on the EHDS proposal, followed by discussions with and between civil society partners during the second half of the year to exchange information and identify potential common concerns for future amendments. In December, the European Parliament announced the lead rapporteur of the dossier would be MEP Annalisa Tardino (Italy, ID – ENVI and LIBE Committees) with MEPs Cristian Buşoi (Romania, EPP – ENVI, ITRE, ECON), Andrey Kovatch (Bulgaria, EPP – IMCO) and Tomislav Sokol (Croatia, EPP - IMCO) also drafting opinions on behalf of their respective Committees.

At the end of the year, the Czech presidency released a progress report indicating the proposal's first examination has been concluded, including discussions on its legal basis and governance structure, as well as the interlinkage with other EU legislation such as the GDPR. It also asked the Council Legal Service to provide a written opinion on the legal basis of the text in response to Member States' concerns about the limits of EU powers in the organisation and delivery of national health services and medical care, and the lack of any reference to Article 168 TFEU in the text. The Czech presidency tabled a revised text for Chapters II and III of the proposal (respectively covering the primary use of electronic health data and EHR systems and wellness applications), proposing to align provisions with the GDPR, tackle possible interference with the organisation and delivery of health services and medical care, and make changes as regards implementing acts and delegated acts, including the substitution of an examination procedure by an advisory procedure in all implementing acts.

DATA ACT

In May 2021, the Commission published an Inception Impact Assessments on a Data Act. This legislative initiative aims at facilitating data access and use, and reviews the rules on the legal protection of databases. The Commission conducted a public consultation on its Inception Impact Assessment. Furthermore, the Commission gathered the views of all interested parties to shape the Data Act.

In February 2022, the Commission published the proposal for a Data Act, which includes:

- Measures to allow users of connected devices to gain access to data generated by them and to share such data with third parties to provide aftermarket or other data-driven innovative services.
- Measures to prevent abuse of contractual imbalances in data-sharing contracts.
- Means for public sector bodies to access and use data held by the private sector that is necessary for exceptional circumstances, particularly in case of a public emergency, such as floods and wildfires, or to implement a legal mandate if data are not otherwise available.
- New rules allowing customers to effectively switch between different cloud data-processing services providers and putting in place safeguards against unlawful data transfer.
- Provisions amending certain aspects of the Database Directive (including with respect to databases containing data from internet-of-things (IoT) devices and objects).

In the European Parliament, the Industry, Research and Energy Committee (ITRE) adopted an initiative report on a European strategy for data which calls the European Commission to submit legislation to foster data access and interoperability in the forthcoming data act. MEP Pilar Del Castillo Vera (EPP, Spain) was appointed as a rapporteur in March 2022.

On 14 March 2022, the European Commission opened a feedback period on the Data Act proposal.

On 5 May 2022, the European Data Protection Board and the European Data Protection Supervisor (EDPS) issued a joint opinion on the proposal.

In Council, ministers supported the main objectives of the proposal and took note of the progress report presented by the French presidency in June 2022. The Czech presidency presented compromise texts in September and October 2022. Discussions have focused so far on issues such as the scope of the proposal, the conditions according to for which data would have to be exceptionally provided to a public sector entities, restrictions for gatekeepers and SME exemptions. The Czech presidency presented a progress report in November 2022.

E-PRIVACY

In January 2017, the Commission published an ePrivacy package proposal for a regulation that concerns healthcare providers.

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 aligned the rules for electronic communications with the new world-class standards of the EU's General Data Protection Regulation.

In June 2018 HOPE adopted a position paper on e-Privacy and welcomed the initiative but drew 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; It would be important, concerning Article 13, that emergency services have enough breathing space to be able to do what they need to do to respond to a person in a medical emergency or data.

The Austrian EU presidency adopted a revised text in September 2018. Then the Romanian presidency submitted to Member States a revised text in the first semester 2019. Given the complexity of the subject, a common Council position was not adopted under the Romanian, Croatian, or Finnish presidencies. In July 2020, the German presidency published its first discussion paper. National delegations rejected a revised version of the paper and on 23 November 2020 the German presidency presented its progress report, stating it would 'closely work with the forthcoming Portuguese presidency to facilitate further discussions and to ensure smooth progress on the subject. The

initiative was given utmost priority in the Joint Declaration of the European Parliament, the Council and the European Commission from 17 December 2020.

On 5 January 2021, the Portuguese presidency released a new draft version of the proposed ePrivacy Regulation. On 10 February 2021, the Member States agreed on a mandate for negotiations with the European Parliament and trilogues began on 20 May 2021.

On 10 November 2022, representatives from the European Parliament and EU Council met for a technical discussion on the ePrivacy Regulation. At the core of the discussion was the article defining under which conditions electronic communications data can be processed, namely only insofar as it is strictly necessary for the communication and for the security of the communications networks. As regards the security aspect, the EU policymakers suggested specifying that service providers cannot process data stored in or emitted by the users' devices to detect technical faults and errors, an attempt to compromise with the lawmakers who had deleted this point altogether.

Another critical point for discussion in the ePrivacy Regulation is metadata, information related to who is communicating and how, for instance, in terms of time, location, and IP address. Metadata processing can only be permitted under specific scenarios in the compromise text.

CYBER RESILIENCE ACT

On 16 March 2022 the Commission released a call for evidence and a public consultation initiative on a Cyber Resilience Act (CRA). To address market needs and protect consumers from insecure products and services, this initiative aims to set cybersecurity requirements that manufacturers and vendors of such products shall comply with.

On 15 September 2022, the Commission adopted its proposal for a Cyber Resilience Act (CRA), an EU regulation on horizontal cybersecurity requirements for products with digital elements and amending Regulation (EU) 2019/1020. Stakeholder feedback on the published CRA proposal was also sought, with an extended deadline of 23 January 2023.

The CRA complements the existing EU cybersecurity policy framework, including the recently revised 'NIS2' Directive, as well as other EU legislation relevant to digital products including the Medical Devices / In Vitro Diagnostics Devices Regulations, the Radio Equipment Directive, the proposed Artificial Intelligence Act and European Health Data Space proposal. Its cross-cutting nature means it could be pertinent 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.

In practice, the CRA 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, considering cybersecurity risks during all phases between product conception and exploitation. Put together, the proposed mandatory requirements should enhance the security of many products with digital elements commonly used in hospitals and healthcare, whether generic or tailored, while providing procurers and end users with more transparent information about their cybersecurity properties and safe deployment. Products with digital elements classified as Electronic Health Record (EHR) systems under the proposed EHDS Regulation will also need to demonstrate conformity with CRA requirements.

In 2022, HOPE began working on a revised position paper on the EU cybersecurity framework for release in 2023.

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. EU Environment Commissioner Virginijus Sinkevičius presented the proposal to ENVI Committee members on 7 November 2022. In the Council, the working party on the environment first discussed the proposed directive on 4 November 2022.

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, Pascal Garel, 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 issue. 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.

Soft Law and Other Initiatives

Besides hard law HOPE also closely monitors soft law in areas such as standardisation, digitalisation, patient safety, pharmaceutical strategy, access to medicines, medicine shortages, antimicrobial resistance, vaccines, cancer, mental health, European Pillar of Social Rights, 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.

STANDARDISATION

Standardisation initiatives in the area of healthcare services have increased in number. Healthcare services in hospitals and ambulatory care centres are heavily standardised by private, semi-private and public organisations that can be of national, European and international nature.

In recent years, healthcare services standards have also been developed by the European Committee for Standardisation (CEN) and its members at European and national levels. The CEN technical board decided in March 2016 to establish a Focus Group on Healthcare Services (HSFG) with the aim of exploring how standardisation can support quality, efficiency and safety in complex healthcare services throughout Europe. For two years, HOPE with other stakeholders have fought against this initiative. To raise awareness about the opposition to CEN, it was agreed with the European stakeholders to systematically reach out to other stakeholders, attachés and the Commission. Following this lobbying, the proposal to close down this initiative was discussed by the CEN technical board and then forwarded to the CEN administrative board that adopted it in June 2018. This successfully concluded the work of HOPE with other European key stakeholders.

Since then, HOPE has organised regular meetings with health stakeholders to continue the discussion on standardisation and in particular in 2022 on the European Commission 2022 Work Programme for European Standardisation that is setting out mandates delegated to the European standardisation bodies, including CEN, to develop technical standards to support EU legislation. Several initiatives concerned healthcare.

There is a mandate on COVID-19 vaccines and medicines (n°2) which includes plans to establish a standard set of data to be included in the form detailing the results of COVID-19 tests. It aims to explore the feasibility of establishing standards for single-use items needed for the production of vaccines and therapeutics in order to enhance the interoperability of key production components and minimise the risk of production disruptions in case of shortages of these materials. There is also a mandate on medical devices (n°49) to support the implementation of the legislation, in particular in relation to design and manufacturing, risk management and the obligations on economic operators and sponsors. A further mandate addresses artificial intelligence systems (n°63). Its aim is to develop standards for placing artificial intelligence systems on the market, putting them into service and use in the EU, addressing requirements related to their safety and trustworthiness, including risk management, data quality, transparency, human oversight, accuracy, robustness and cybersecurity. There are also mandates for smart contracts for data spaces (n°8), ambient air quality (n° 14-16), and food safety (n°24-26).

DIGITALISATION

On 19 February 2020, the Commission released the "Shaping Europe's Digital Future" communication for "a digital transformation that works for all" based on three main pillars: technology and innovation, competitive digital economy and the promotion of a sustainable and democratic society.

On 9 June 2020, the Council adopted conclusions on shaping Europe's digital future, addressing a wide range of issues related to the implementation of the EU digital strategy. The areas covered by the conclusions range from connectivity, digital value chains and eHealth to the data economy, artificial intelligence and digital platforms.

Digital rights and principles for a human-centred digital transformation

On 26 January 2022, the European Commission proposed the declaration on digital rights and principles for a human-centred digital transformation. The aim of the declaration is to safeguard the Union values and rights and freedoms of individuals. The declaration will serve as a guide when dealing with new technologies and promote the European approach to digital transformation. It is accompanied by a communication which defines the future steps for monitoring the measures and implementing the declaration in practice. Regarding health, access to public services is mentioned with the commitment to "facilitating and supporting seamless, secure, and interoperable access across the Union to digital health and care services, including health records, designed to meet people's needs." The principles of the declaration are based on the primary and secondary EU law, adapted to the digital environment. They complement existing rights as well as existing legislative proposals; they do not replace them.

The declaration was discussed during interinstitutional trilogue negotiations. The negotiated text gave more weight to the international dimension, working conditions, including the use of the artificial intelligence at the workplace, and protecting people's privacy. The Council adopted the declaration on 5 December 2022.

The text was signed by the Parliament, Council and the Commission in form of a Solemn Declaration 15 December 2022.

1+MG

HOPE is following the 1+MG initiative, which is an initiative, led by Member States, aiming to enable federated access to and analysis of genomic data resources across Europe. The aim of this three-year initiative will be to support the European health data space. A Horizon 2020 project "Beyond 1 million Genomes" (B1MG) provides support and coordination to the implementation of the roadmap.

In November 2022, France and Ireland joined the 1+MG initiative. The genomics initiative has so far been signed by 24 EU Member States, Norway, and the United Kingdom. The next steps in implementing the initiative will focus on establishing a European genomic data infrastructure, 50% of which is co-financed by the European Commission under the Digital Europe Programme.

PATIENT SAFETY

Consistent with HOPE's mission to improve the healthcare of citizens throughout Europe and high standards of hospital care, HOPE's activities have focused on patient safety and quality of care.

These last few years, HOPE and PAQS (the Platform for Continuous Improvement of Quality of Care and Patient Safety) have collaborated on several occasions, e.g. HOPE study tours, presentations at the European Parliament and HOPE Agora. Considering the absence of concrete action by the European Union, both organisations developed a structured network to share quality and safety best practices between European countries. Supported by HOPE members and their respective networks and by the expertise and resources PAQS holds, the creation in 2019 of a "Quality and Safety network" at European level aims at:

- Creating/reinforcing links between different organisations working on quality of care and patient safety in Europe;
- Strengthening the image and visibility of the two organisations;
- Increasing learning opportunities and share best practices;
- In the long run, facilitating the implementation of joint projects in different European countries.

In 2022, four webinars took place:

- 29 March on the quality indicators and public reporting in Flanders;
- 31 May on the healthcare adverse events in France based on the third national incidence survey;
- 18 October on the Critical Incident Reporting Systems in Germany;
- 13 December on the "5 years to save lives" project as a Belgian breakthrough series collaboration.

Quality & Safety network | hope European Hospital and Healthcare Federation | In collaboration with PAQS ASBL

PHARMACEUTICAL STRATEGY

On 25 November 2020, the Commission adopted a Pharmaceutical Strategy for Europe with four main objectives:

- Ensuring access to affordable medicines for patients, and addressing unmet medical needs (e.g. in the areas of antimicrobial resistance, cancer, rare diseases);
- Supporting competitiveness, innovation and sustainability of the EU's pharmaceutical industry and the development of high quality, safe, effective and greener medicines
- Enhancing crisis preparedness and response mechanisms, and addressing security of supply;
- Ensuring a strong EU voice in the world, by promoting a high level of quality, efficacy and safety standards.

Although the strategy 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 a workshop organised on 19 January 2022 by Technopolis Group on the results of its study in support of the European Commission's 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 planned to make it public in March 2023.

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.

MEDICINES SHORTAGE

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. In September 2019, the European Commission invited HOPE together with other European stakeholders for the first meeting on that issue.

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.

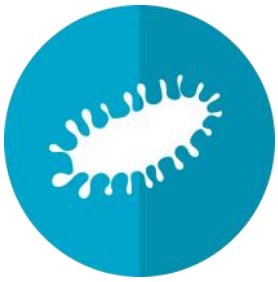
In the Pharmaceutical Strategy for Europe, the European Commission confirmed its willingness to revise the basic pharmaceutical legislation to enhance security of supply and address shortages and to minimising the impact of medicines shortages on patient care thanks to both preventive and mitigating 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 solutions of the Structured Dialogue on the Security of Medicines Supply set up by the Commission and in which HOPE participated. It gathered actors in the pharmaceutical manufacturing value chain, public authorities, patient and health nongovernmental organisations and the research community.

ANTIMICROBIAL RESISTANCE

Since the publication of the EU One Health Action Plan against Antimicrobial Resistance (AMR) by the European Commission in 2017, HOPE has continuously stepped up its work on combatting AMR.

Examples include HOPE's participation in the Joint Action on Antimicrobial Resistance and Healthcare Associated Infections (JAMRAI, Sep 2017 – Feb 2021, to be followed up in 2023) and the endorsement of the Roadmap for Action against AMR of the Stakeholder Network on AMR, led by the European Public Health Alliance (EPHA). This enabled HOPE to join forces with over 80 other partners registered on the Commission's European Health Policy Platform. Inter alia, these joint efforts inspired Council conclusions in June 2019 under the Romanian presidency on the next steps towards making the EU a best practice region in combatting antimicrobial resistance.



In 2022, HOPE continued its collaboration with the European Centre for Disease Prevention and Control (ECDC) by supporting the annual European Antibiotic Awareness Day (EAAD) campaign and World Antibiotic Awareness Week (WAAW) organised by WHO. During the WAAW on 17 November, HOPE presented its views on AMR as a panellist at an event organised by Alliance Healthcare (members of GIRP, the European Healthcare Distribution Association) under the auspices of the Czech presidency. In July, HOPE also participated in an AMR future-proofing study workshop organised by the European Commission's Directorate General for Health and Food Safety (DG SANTE) and a follow-up interview.

In March 2022, HOPE responded to the European Commission's call for evidence for an initiative on "Antimicrobial resistance – recommendation for greater action" aiming at the creation of a proposal for a Council recommendation. The latter would set concrete objectives and activities to strengthen national AMR action , mainly in the area of public health where the EU has limited powers. HOPE's feedback focused on four strategic areas: the need for a clear coordinated EU approach; supporting hospitals and healthcare facilities operationally and financially to set up antimicrobial stewardship teams and infection prevention and control committees; stepping up efforts to identify, share and disseminate good practices; and setting binding measures for the development of new antimicrobials, including via new incentive mechanisms along the development chain and higher public investment in research and development (R&D).

On 19 April 2022, the European Commission proposed a draft list of antimicrobials to be reserved for human health, in response to which HOPE co-signed a joint statement together with 18 other organisations expressing concern, inter alia regarding the absence of vital antimicrobials for human health on the list, including last-resort treatments. The co-signatories argued that, if adopted as proposed, these priority substances will continue to be used in food production to sustain

poor farming practices. HOPE and partners called on the European Commission to review the list and consider the evidence-based advice from civil society organisations to ensure that the list will contribute to protecting human health and animal welfare. We also asked that the European Commission sets a clear timetable for the periodical revision of the list.

In August 2022, HOPE applied to the European Commission call for members of a new Expert Group, the 'AMR One Health Network', for which the selection process is expected to conclude in early 2023. During the second half of 2022, DG SANTE updated its internal structure, including the establishment of a new One Health directorate currently led by Ms Roser Domenech in an acting capacity.

On 14 December 2022, HOPE was invited to participate in an AMR roundtable composed of select stakeholder organisations representing civil society and industry, organised by the UK Special Envoy on AMR and AMR Global Leaders Group Member, Professor Dame Sally Davies at the British Residence in Brussels. The lunch discussion focused on themes including opportunities to promote supply chain security and green manufacturing of antimicrobials; Innovation, stewardship and access; private and public sector collaboration and lessons from COVID-19; and connecting local and global surveillance efforts.

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, combatting 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.

On 14 February 2022, HOPE attended the webinar organised to present the activities and outcomes related to vaccine hesitancy and uptake in the ongoing EU Joint Action on Vaccination (EU-JAV). On 25 April 2022, on the occasion of the European Immunization Week, the Coalition for Vaccination released a position paper calling for easy vaccine access for refugees. On 20 May 2022, HOPE participated in the annual meeting of the Coalition for Vaccination, as an associate member.

On 30 September 2022, the Health Security Committee (HSC) agreed on recommendations for a common EU approach regarding vaccination policies for monkeypox outbreak response. Indeed, this document sets out key elements to be taken into consideration by Member States for their national vaccination strategies, in line with guidance issued so far by the European Centre for Disease Prevention and Control (ECDC) / World Health Organization (WHO) and also bearing in mind their national epidemiological and public health contexts, including the limited number of vaccines currently available.

On 9 December 2022, EU ministers of health approved Council conclusions on vaccination as one of the most effective tools for preventing disease and improving public health. The conclusions focus on combatting vaccine hesitancy and preparing for upcoming challenges through EU cooperation.

The conclusions invite:

- the Commission to establish an expert forum on vaccine hesitancy,
- the Commission to strengthen the coordination between EU policies on vaccination and on fighting disinformation,
- Member States and the Commission to develop training opportunities for health professionals to become more versed in techniques and tools for countering vaccine mis- and disinformation.

In terms of strengthened EU cooperation the conclusions propose additional actions such as:

- exploring the added value and possibilities of overcoming the legal and technical barriers to the interoperability of (sub-)national immunisation information systems,
- developing exchange of information on possible surpluses and shortages of essential vaccines. This would enable a possible resell or donation among member states,
- making use of the possibility for the joint procurement of vaccines.

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.

On 16 February 2022, the European Parliament adopted its final recommendations for a comprehensive and coordinated EU strategy to fight cancer. The report by Parliament's Special Committee on Beating Cancer (BECA) was adopted with 652 votes in favour, 15 against and 27 abstentions. MEPs call for effective prevention measures at national and EU level, based on independent scientific expertise. They also ask for better access to cross-border healthcare and clinical trials for cancer patients, and call for the existing legislative framework to be reformed to allow for mobility and access to highly specialised equipment and care. Lastly, MEPs strongly advocate for extending joint procurement procedures, especially for rare, paediatric and novel cancer medicines and treatments. They also want to diversify the cancer drugs supply chain, monitor shortages more closely and create a strategic stockpile of critical cancer medicines. Other key recommendations in the report included: Guaranteeing the "Right to be Forgotten" to all EU patients ten years after the end of their treatment; Adding other cancers to the new EU-supported Cancer Screening Scheme; Ensuring the pharmaceutical system is more transparent, especially regarding pricing components, reimbursement criteria and net prices of medicines in different European countries.

Cancer is one of the strands of the EU4Health Work Programme for 2023 published in 2022, the full budget for cancer is €187.3 million. The budget is divided into seven 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.

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 screening

HOPE was invited to attend a stakeholder meeting on cancer screening on 20 January 2022. The European Commission's Group of Chief Scientific Advisors was developing a Scientific Opinion with recommendations on the topic of "Cancer screening". As one of the final stages in developing this, the advisors conducted this meeting with stakeholder representatives, in which they presented the main draft elements of the advice under consideration and gather stakeholder views. The call for evidence for the Cancer Screening Recommendation took place from 25 January 2022 to 22 February 2022.

On 20 September 2022, the European Commission put forward its proposal which presents a new approach to support Member States in increasing uptake of cancer screening (especially for breast, colorectal and cervical cancer). This proposal for a Council Recommendation on Strengthening Prevention through Early Detection: a new EU approach on

cancer screening would replace the Council Recommendation 2003/878/EC. The recommendation also considers extending screening to other cancers, notably prostate, lung and gastric cancer.

On 9 December 2022, the Council adopted a new recommendation on cancer screening. Member States agreed to broaden the focus to lung cancer, prostate cancer and gastric cancer. On the basis of information provided by Member States, the Commission will report on the implementation of cancer screening programmes, no later than the end of the fourth year after the date of adoption of this recommendation.

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 on the assessment of the country-specific situation, published at the end of 2022,
- Analytical reports comparing performance at EU level.

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. It was a partner in the Joint Action on Mental health and Well-being, 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).

Mental health and neurological disorders are part of the "Healthier together – EU non-communicable disease initiative" presented in June 2022. In 2022, HOPE joined the thematic network "Mental health in All Policies" led by Mental Health Europe in the EU Health Policy Platform and it attended on 14 November the high-level conference, which was organised by the Czech presidency of the Council of the EU in Brussels to discuss future EU actions regarding mental health.

EUROPEAN PILLAR OF SOCIAL RIGHTS

In 2016, the European Commission launched a public consultation on the European Pillar of Social Rights. It aims to build on, and complement, the EU social "acquis communautaire" in order to guide policies in a number of fields essential for smooth running and fair labour markets and welfare systems. The objectives of the consultation were to assess the present EU social “acquis”, to reflect on new trends in work patterns and societies and to gather views and obtain feedback on the role of the European Pillar of Social Rights.

On 17 November 2017, the European Pillar of Social Rights was proclaimed and signed by the EU institutions during the Gothenburg Social Summit for fair jobs and growth. The social pillar is intended to drive forward a social Europe for all European citizens. It aims at strengthening the social acquis and delivering more effective rights to citizens. It focuses on employment and social aspects and ensures that the European social model is fit for the challenges of the 21st century.

In its contribution, HOPE underlined the link between health and economic development. Indeed, better health is vital to economic progress, as healthy populations live longer, are more productive, and save more.

To support the implementation of the pillar and prepare for the pillar’s action, the Commission launched a broad discussion with all EU countries and regions and with all partners, to which HOPE contributed. The Commission invited all partners to present their views by 30 November 2020 on new policy action or legal initiatives needed on different levels (EU, national, regional, local) and/or pledge concrete commitments as a Member State, region, city or organisation towards implementing the pillar.

On 4 March 2021, the European Commission published a Communication on the European Pillar of Social Rights Action Plan. Building on the 20 key principles of the European Pillar of Social Rights, the action plan presents concrete initiatives and sets 3 targets for 2030: 78% of the population aged 20 to 64 should be in employment by 2024; At least 60% of all adults should participate in training every year; The number of people at risk of poverty or social exclusion should be reduced by at least 15 million by 2030. A review of the action plan is planned for 2025. On 10 December 2021, the European Commission published two proposals for Council recommendations: the first on individual learning accounts and the second on a European approach to micro-credentials for lifelong learning and employability.

European Care Strategy

The European Commission answered on 11 January 2022 the question for written answer E-004836/21 on the follow-up to the Commission Green Paper on Ageing asked by a group of members of the European Parliament (MEPs). The Commission is working to integrate and mainstream aspects related to demography and equality, including age discrimination, in all relevant EU policies, legislation and funding programmes. The Commission will present a European care strategy in 2022 to address both carers and care receivers, from childcare to long-term care.

The European care strategy initiative proposed two Council recommendations, on childcare and on long-term care. The Commission launched a call for evidence running from 1 March to 29 March 2022 to which HOPE replied. On 7 September 2022, the Commission published the European Care Strategy, it includes two proposals for Council Recommendations to be adopted by the Member States. The first one is the revision of the Barcelona targets on early childhood education and care. The second is dedicated to long-term care, based on “integrated person-centred” approach to care as well as focusing on digital transformation and international cooperation as key priorities. On 8 December 2022, the Council adopted the recommendation on affordable high-quality long-term care, along with the recommendation on early childhood education.

CLIMATE

European Climate Law

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.

The European Climate Law 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.

Climate and health

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”.

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.

HOPE closely monitored the 2022 European Semester and regularly reported on it via its monthly newsletter.

On 24 November 2021, the European Commission launched the 2022 European Semester cycle of economic policy coordination. The European Semester Autumn Package includes the Annual Sustainable Growth Survey, opinions on the euro area Draft Budgetary Plans (DBPs) for 2022, policy recommendations for the euro area and the Commission's proposal for a Joint Employment Report. The package draws upon the Autumn 2021 Economic Forecast, which noted that the European economy is moving from recovery to expansion but is now facing new headwinds.

On 17 June 2022, the Council of the EU agreed its Country-Specific Recommendations (CSR) on the Member States' National Reform Programmes of 2022 and its opinions on the updated Stability or Convergence Programmes. This step is part of the 2022 European Semester Programme, which enables Member States to coordinate their economic, employment and fiscal policies. The European Council endorsed the CSR at its meeting on 21 June 2022. On 12 July, the Council adopted conclusions on the 2022 in-depth reviews under the macroeconomic imbalance procedure.

At their meeting on 16 June 2022, EU employment and social affairs ministers presented their national targets to deliver on the European Pillar of Social Rights Action Plan by 2030. The European Pillar of Social Rights Action Plan includes three EU-level social targets to be achieved by 2030:

- At least 78% of people aged 20 to 64 should be in employment.
- At least 60% of all adults should participate in training every year.
- The number of people at risk of poverty or social exclusion should be reduced by at least 15 million, including at least 5 million children, compared to 2019.

The Commission will monitor their implementation in the context of the 2023 cycle of the European Semester, the EU coordination framework for economic and employment policies.

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.

HOPE AS A PARTNER – ONGOING PROJECTS

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 2022, HOPE released four newsletters with the help of partners, in February, April, June and November. Two consortium meetings took place in 2022. The one in March took place on the project's first anniversary. The second, in September, was the first occasion to meet all the partners in person, and to start the preparation of the project's first review. The year 2022 was also the start of the collaboration with two other projects from the same funding stream as RE-SAMPLE: RETENTION and MES-CoBraD. The three projects tackle medical issues with innovative use of real-world data. The three projects held a webinar together to discuss future synergies.

HOSMARTAI

In 2022 HOPE continued as an active member of the HosmartAI - "Hospital Smart development based on AI" consortium led by INTRASOFT International and including 24 partners.

Financed by the European Union's Horizon 2020 programme and involving eight large-scale pilots in five European countries (BE, IT, GR, SI, ES), the 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 (including physicians, nurses, physiotherapists) and hospital / care management and staff. They 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.

HOPE is engaged in three work packages (WP1 – Requirements, Specifications and Reference Architecture, WP 6 – Dissemination, Communication and Ecosystem Building, WP 8 – Social, Ethical and Legal Issues) and participated in two face-to-face plenary meetings of the HosmartAI project consortium, in Athens (June) and at the Philips Healthcare Academy in Best/ Eindhoven (November). Together with WP-6 lead EIT Germany, HOPE co-organised a stakeholder workshop on 24 November (also in Eindhoven), "Bringing AI and Robotics to the Hospital". The purpose of the workshop was to obtain feedback from external AI experts representing industry, hospitals and academia, including individuals identified by HOPE's extensive network of members. In addition to exchanging views on lessons learnt in the development process and providing advice to the pilot leads regarding the feasibility and market potential of their solutions, the experts also engaged in discussions with the winners of two open calls issued during the year. The latter enabled AI start-ups/SMEs to provide additional technologies for the HosmartAI platform and develop new pilots to expand the scope of the project and attract new stakeholders and potential customers.

The year 2022 witnessed the production of a number of deliverables available on the dedicated project website. The second and third newsletters were released by the HosmartAI project in March and September, and HOPE also disseminated and promoted the two open calls and related press releases via its social media and internal communication channels. Throughout the year, HOPE participated in regular work package calls (organised into time-limited 'sprints'), reviewed and co-drafted various communication materials, including brochures and factsheets for the promotion of the stakeholder workshop and further development of a business case for the pilot solutions.

PERISCOPE

PERISCOPE (Pan-European Response to the ImpactS of COVID-19 and future Pandemics and Epidemics) is a Horizon 2020 large-scale research project that brings HOPE together with 31 other European organisations. PERISCOPE is coordinated by the University of Pavia (Italy).

It is formed by a multidisciplinary consortium of experts, including clinical, epidemiologic, socio-economic, political, statistical and technological experts. The project will then combine 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. These will allow new measures to be proposed in order to prepare Europe for future pandemics.

PERISCOPE started on 1 November 2020 and will run until 31 October 2023 to:

- gather 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;
- carry out innovative statistical analysis on the collected data;
- identify best practices that could be applied at pan-European level for a better containment of the pandemic and its related socio-economic impacts;
- develop guidance 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 participates in the dissemination activities, contributes to the analysis of the COVID-19 pandemic effects on health systems, supports the creation of a public engagement platform for decision-making. It will also help to develop training and education for health workers, patients and health authorities.

In April 2022, the project launched a campaign entitled "Meet the PERISCOPE team" to which HOPE participated. Each partner involved in the project made a small video to introduce themselves and their work in the project. On June 1, 2022, HOPE attended the first in-person executive committee meeting, planned just ahead of the CEPS Ideas Lab, organised by CEPS in Brussels. On 4 June 2022, HOPE organised a parallel session during the roundtable session of the AGORA in partnership with POLIMI. The experiment exploited the COCTEAU digital game developed within PERISCOPE for analysing feelings, expectations and visions related to the impact of the pandemic.

On 7 October 2022, HOPE participated in the first session of "PERISCOPE Innovation Challenge", an innovation workshop to ideate novel applications of digital technologies to prepare for and tackle future pandemics. The second and final session took place on 18 November 2022. In this digital workshop, participants:

- Considered future scenarios on emergent socio-economic, cultural and technological forces;
- Explored what possibilities digital technologies will enable in the future;
- Ideated solutions to address future pandemic challenges, based on envisioned scenarios.

Throughout the year, several scientific articles were published; they are all accessible on the PERISCOPE website.

TeNDER

Since 2019, HOPE has been working with TeNDER, an EU research project developing an integrated care system that provides assistive tools and services to elderly people with Alzheimer's, Parkinson's, or cardiovascular diseases.

By combining user-friendly software and devices, the project aims to help improve the quality of life of patients and those who surround them. It is also testing ways to facilitate communication between different health and care providers who treat patients with multi -morbidities.

As the project nears conclusion in 2023, technical partners organised installation workshops with user partners. The third (and final) wave of piloting kicked off in 4 institutions in Spain, Slovenia, and Germany. The Italian pilot experienced some technically related delays and will kick off early January. In each pilot setting, determined by our end-user partners and researchers (i.e., in-hospital acute care, at home, and in day- and full-time nursing homes), patients are monitored with sensors, cameras that capture movement, affective recognition technology, and wristbands that record basic vitals, etc. Meanwhile, TeNDER's technical, legal, and ethical experts evaluate all procedures to ensure that all personal data is protected according to the General Data Protection Regulation (GDPR) and that the approach complies with rigorous ethical guidelines.

HOPE helped lay the groundwork for communication and dissemination: releasing the TeNDER newsletter twice a year packed with news, partner information, and the latest blog posts. HOPE produced recruitment materials for user partners and it ensures that all communication channels remain updated. In addition, HOPE provides content and facilitates inter-project and inter-organisation collaborations.

Besides weekly contributions to communication and dissemination, HOPE also contributes 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 April, which marks the end of the project, HOPE will provide updates, translate results and findings into lay terms, and submit the final project reports on communication and collaboration.

SAFEST

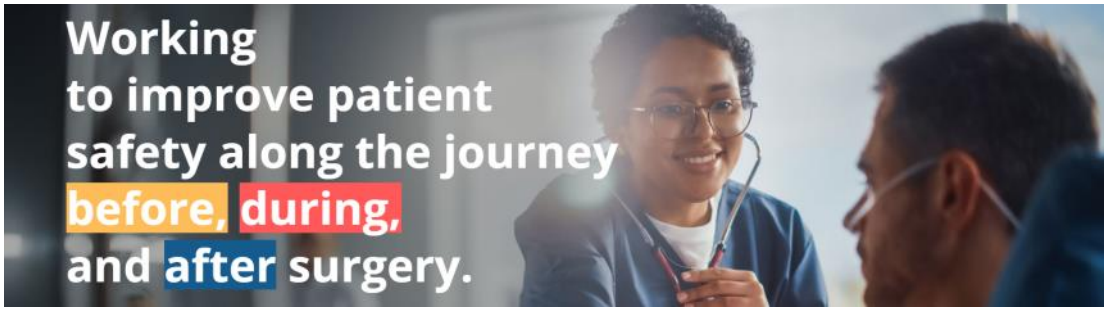
On 1 June 2022, HOPE and consortium partners kicked off SAFEST (Improving quality and patient SAFEty in surgical care through STandardisation and harmonisation of perioperative care in Europe), an ambitious four-year project funded under the new cycle of the EU framework for research and innovation, Horizon Europe. The project is led by Avedis Donabedian Research Institute (FAD) affiliated with the Autonomous University of Barcelona (Spain) and the consortium is composed of nine other partners: SAK- Spojená Akreditační Komise (Czech Republic), SENSAR (Sistema Español de Notificación en Seguridad en Anestesia y Reanimación, Spain), NIVEL (Netherlands Institute for Health Services Research), Radboud University Medical Center (The Netherlands), OptiMedis AG (Germany), National School of Public Health - NOVA University Lisbon (Portugal), Institute of Clinical Medicine – University of Tartu (Estonia), ESAIC (European Society of Anaesthesiology and Intensive Care) and HOPE (Belgium).

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.

The project seeks to play a decisive role in improving patient safety. In this respect it will identify and agree on a unified set of perioperative practices based on evidence. It will also promote their implementation across Europe involving healthcare professionals, patients, and other stakeholders.

The main objectives will be to improve the adherence to evidence-based standardised patient safety practices in perioperative care by 15% and reduce the frequency of surgical complications by 8% after 18 months of a multicomponent intervention.

HOPE is leading tasks on communications. It contributes to other work packages with surveys, and will identify existing perioperative standards as part of a multidisciplinary group. In 2022, HOPE oversaw the creation of the project website and social media accounts, which it now manages. Furthermore, HOPE co-wrote with two project partners the dissemination, communication, and exploitation plan, which will be implemented over the next four years.



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 will be 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 will also identify and scout suppliers and buyers for the matchmaking event (WP3).

HOPE AS AN ADVISOR

PHIRI

Since 2021, HOPE has attended the stakeholder meetings of PHIRI, the Population Health Information Research Infrastructure. PHIRI is a new Health Information project on COVID-19 financed by the European Commission. The project builds on the BRIDGE Health project and the Joint Action Infact.

PHIRI was launched in November 2020 and it includes 41 partners in 30 different countries. PHIRI's vision is to set up a research infrastructure to generate the best available evidence for research on the health and well-being of populations impacted by COVID-19. PHIRI will allow for better coordinated efforts across national and European stakeholders and will generate COVID-19 population health knowledge by enhancing the identification of data sources, access, assessment and reuse of data on COVID-19 determinants, risk setting and outcomes. The meeting focused on the project's scientific activities, presenting PHIRI activities relevant to researchers across Europe.

The "PHIRI Road Show – Mid Project achievements" event took place on 8 April 2022 and presented the outcomes of the project since its start in November 2020 ranging from the launch of the Health Information Portal, a one-stop shop to access health & healthcare data in Europe, to the Rapid Exchange Forum, answering urgent research and policy questions on COVID-19, and much more.

PHIRI contributed to the European Public Health Week (EUPHW) 2022 with three events:

- Monitoring COVID-19-related changes in mental health in Europe - 19 May 2022: As part of PHIRI, different European countries are conducting research through a use case on the COVID-19-related changes in population mental health analysing register data. This webinar, addressing a wide audience of researchers, stakeholders, and decision makers, presented the rationale, implementation process and first results of the use case. It also presented the added value of the federated approach PHIRI is following by bringing together data from different European countries.
- What next for pandemic preparedness in Europe? - 20 May 2022: This webinar explored immediate and long-term aspects of European pandemic preparedness as we stand at crossroads with regard to both the need to adapt COVID-19 strategies to new realities, and to bolster European preparedness against future threats. Speakers explored the role of EU institutions and mechanisms in strengthening joint responses, share learnings from European countries in response to the shifting COVID-19 landscape, and highlighted the role of modelling and forecasting.
- Country visits: interviewing health information system stakeholders - 20 May 2022: Two European projects TEHDAS (Towards the European Health Data Space) and PHIRI zoomed in on health information systems, by conducting semi-structured interviews with stakeholders through country visits. TEHDAS focused on the readiness to join the European Health Data Space, whereas PHIRI maps Health Information Systems accommodating COVID-19. The event presented findings from both projects.

TEHDAS

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 was 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.

HOPE attended the three workshops organised as part of the TEHDAS WP8 on 17, 18 and 19 January 2022.

Following the publication of the communication and proposal for a Regulation on a EHDS by the European Commission, HOPE attended a webinar organised by TEHDAS and led by Finnish innovation Fund Sitra – on 9 May 2022. The purpose of which was to solicit first reactions from different EU stakeholder groups. On 14 June 2022, HOPE attended online the 2022 annual stakeholder forum of TEHDAS, opened to stakeholders of the project, to learn about its results.

HOPE joined on 22 June 2022 the third Project Forum of the TEHDAS Joint Action that brought together online over 120 European health data specialists from 23 countries and representing a wide range of projects and initiatives. The focus was on the newly published Commission proposal on the EHDS, how the project might adapt considering it, and the challenges they anticipate.

EUNETHTA 21 - JOINT ACTION 4

Based on a Service Contract for the Provision of Joint Health Technology Assessment (HTA), signed by the European Health and Digital Executive Agency (HaDEA), an EUnetHTA 21 joint consortium has been created. On 29 September 2021, the heads of 19 European HTA agencies came together and inaugurated a new HTA-focused collaborative network for high-level strategic exchange and discussion.

Organisations that had joined the group included: AEMPS (Spain), AIFA (Italy), AGENAS (Italy), AIHTA (Austria), INFARMED (Portugal), KCE (Belgium), NIPH (Norway), G -BA (Germany), HAS (France), HIQA (Ireland), IQWiG (Germany), FIMEA (Finland), NCPE (Ireland), REDETS (Spain), RER (Italy), RIZIV-INAMI (Belgium), NOMA (Norway), TLV (Sweden) and ZIN (The Netherlands).

For several years, HOPE was part of the stakeholder group "Provider" in the Joint Action for Health Technology Assessment in Europe: EUNetHTA. HOPE participated in the first virtual EUnetHTA 21 Stakeholders' Meeting on 3 December 2021 and in a second on 13 June 2022 and in a third on 18 November 2022.

EUnetHTA Joint Action 3 came to an end in 2022 and the EU is now entering a new phase of European HTA cooperation (see the "Project" section for more information about EUnetHTA 21).

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.

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) will be 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.

COMPLETED PROJECTS

ALADDIN

ALADDIN was an ERASMUS+ project tackling the integration of additive manufacturing (also known as 3D printing) in the health sector. Additive manufacturing is a relatively new technology with a vast potential in the healthcare sector. However, the technology has remained widely unexplored in the sector due to a lack of knowledge, skills and its very complex value chain, requiring the cooperation of actors from different backgrounds.

The project brought together six European organisations under the leadership of AIMPLAS (Technological Institute of Plastics, Spain) from the worlds of research with AMRC (Advanced Manufacturing Research Centre, the UK); innovation with ITEMAS (Medical technology Innovation Platform-Spain) and HIHI (Health Innovation Hub Ireland); healthcare with HOPE (European Hospital and Healthcare Federation) and training with Jobs@skills (Belgian organisation specialised in training programs creation).

ALADDIN developed a specific training programme in hospitals for health professionals working there and engineering students with a future in the health sector. It also included a teaching guide and an e-Learning platform. HOPE led the dissemination and communication activities of the project with the goal of reaching all target audiences and ensuring the proper exploitation of the project's results. HOPE translated the content of the course into French and organised French-speaking pilot courses in June and July 2022. The pilot courses were also delivered in English and Spanish, in Ireland and Spain, throughout the summer. Three multiplier events took place in three different countries (Belgium, Ireland, Spain) during the course of the project to present the training courses and ensure the project reached the target groups.

The project ended in September 2022.

INTERNATIONAL INSTITUTIONS

WHO EUROPE

2020–2025 – 'United Action for Better Health in Europe'

In 2020, the 70th World Health Organization Regional Committee for Europe accredited HOPE to participate in future sessions of the WHO Regional Committee for Europe. As an accredited non-state actor, HOPE will receive an invitation for the annual committee taking place in September to join as an observer, submit written and oral statements, which will also be made available on the WHO/Europe website.

For HOPE, the work with WHO Europe mainly started after 1989 with "East meets West" conferences and a hospital twinning programme between Western Europe/ Central and Eastern Europe. HOPE was involved from the start in the Health Promoting Hospitals network initiative and is part of the scientific committee for the annual conference.

HOPE has been involved in various WHO initiatives: for example, the practical tool for hospital services master planning with a special focus on integrated care; the work on the WHO Global Code of Practice on the International Recruitment of Health Personnel, the consultation by the European Framework for Action on Integrated Health Services Delivery and more recently in the Primary Health Care Advisory Group.

HOPE contributed to the Pan-European Leadership Academy Programme (ELA) launched by WHO-Europe in 2021. It is a key initiative of the WHO Regional Director for Europe to support the delivery of the European Programme of Work (EPW). Participants will be given opportunities to learn about and participate in the regular work of WHO/Europe, including at the Regional Office, country offices and geographically dispersed offices. The overarching goal of the ELA is to support Member States to achieve the objectives of the 13th General Programme of Work and the EPW. This includes supporting national health systems to prepare for potential risks and emergencies, and to deliver universal health coverage that leaves no one behind.

HOPE was invited with its official status of non-state actor to participate to the 72nd session of the WHO Regional Committee for Europe from 12 to 14 September 2022. A particular focus was on the European Programme of work (EPW) contribution to advancing health and well-being at the country level. The meeting provided health stakeholders with a forum to discuss the main challenges for public health in the region, ongoing health emergencies, and opportunities for closer subregional and inter-regional collaboration. The session obtained consensus on actions to be taken in several priority health areas, including empowerment through digital health, health promotion through behavioural and cultural insights, and access to affordable medicines. Several new and updated regional action plans and roadmaps were discussed and put forward for endorsement, on topics including cervical cancer, alcohol use, tuberculosis, HIV, viral hepatitis and sexually transmitted infections.

Quality

The WHO European Centre of Excellence for Quality in Care and Patient Safety was established in April 2021 in Athens, Greece, with a vision to decisively improve the quality of care and patient safety, inspired by the European Programme of Work (EPW) 2020–2025 – 'United Action for Better Health in Europe'.

This sub-regional office will support the implementation of a shared ambition to achieve the highest level of well-being, health and health protection in line with the Sustainable Development Goals (SDG). Its main aim is to support the efforts of Member States to build safe, qualitative, effective and resilient health systems at the core of post-COVID-19 strategies. The WHO office in Athens will contribute to the implementation of the EPW by acting as a centre of excellence for quality of care and patient safety in the WHO European Region with a special focus on the countries bordering the northern shore of the Mediterranean basin.

On 5 October 2022, HOPE participated to the second webinar on quality of care and digital health services from World Health Organization (WHO) webinar series of the Meeting of the Minds (MoM) on Quality of Care. The first MoM meeting was held in Athens in December 2021 and patient experience and engagement was one of the five major themes, with HOPE's CEO as a speaker. The second webinar took forward the discussion of the meeting and explore how to increase the role of patients in decision-making and in the development of a culture of quality and safety.

Ukraine

HOPE participated on 10 May 2022 in the special session of the WHO Regional Committee for Europe (RCSS), which was requested pursuant to Rule 5 of the Rules of Procedure of the Regional Committee for Europe and in furtherance of Article 50(e) of the WHO Constitution.

The invasion of Ukraine, launched on 24 February 2022, has led to a massive loss of lives and trauma injuries among civilians, destruction of essential health services – including treatment of chronic conditions, disruption of medical supply chains, destruction of health facilities, as well as to Europe's largest displacement crisis since the Second World War. The session dealt with the impact of this aggression on the health conditions in Ukraine and its consequences on health matters within the European region as a whole, and on international health matters which have wider than regional significance. It has had a particularly devastating impact on Ukraine's health system, severely restricting access to medicines, facilities and health services for the Ukrainian population. At that point, WHO had confirmed over 160 attacks on healthcare. The invasion has caused huge disruption to vaccination campaigns and efforts to tackle non-communicable diseases and chronic infectious diseases, such as HIV and tuberculosis. The war has uprooted more than 12 million people, including about 5 million who have been forced to flee to neighbouring countries, as well as to countries in other regions, with attendant impact and strain on their health and social support systems. There is also concern over the risk of radiological and chemical events, as well as over the impact of the invasion on international food security, beyond the European region, given the impact of the war on Ukrainian international export capacities.

Non-communicable diseases and cancer

On 17 May 2022, HOPE attended a meeting with other non-state actors organised by WHO in Brussels regarding non-communicable diseases (NCDs) and cancer. This event took place during the WHO NCD mission led by Dr Bente Mikkelsen, Director, Non-Communicable Diseases, WHO and Dr Nino Berdzuli, Director of the Division of Country Health Programmes, WHO/EURO. The meeting's aim was to update participants on the World Health Assembly 75 and to follow up on the political declaration of the third-level meeting of the General Assembly on the prevention and control of NCDs. The WHO Programme of Work in Cancer and the WHO Europe Programme of Work in Cancer were presented.

Rethinking the future of Hospitals in the European Region

HOPE's President and Chief Executive were invited to speak at the first expert meeting organised on 21 and 22 April 2022 in Brussels on "Rethinking the Future of Hospitals in the European Region". As part of the development of the WHO/Europe programme for hospitals by the Health Workforce and Service Delivery Unit, led by Tomas Zapata, a group of internal and external experts in these fields were brought together to help shape the activities and strategic direction of the WHO/Europe in relation to the future of hospitals in the Region.

This meeting was intended to: contribute to thinking about a vision for hospitals and their part in the wider healthcare system; identify areas where further thinking and policy development would be helpful; provide advice about where WHO can positively contribute to this debate; advise on how WHO best can work with Member States, partners and others to adapt the vision to local circumstances and deliver it effectively.

Dr Hans Kluge, Regional Director reminded the group that it was the first WHO/Europe Expert meeting to review the role of hospitals in the broader context of health system since 2009. Dr Natasha Azzopardi-Muscat (Director Country Health Policies & Systems) highlighted the role hospitals played during the pandemic, and the main challenges faced by most countries in continuing provision of routine health services and responding to the crisis. Among the challenges, she mentioned the infrastructure, but also health workforce, the integration and interoperability of multimodality network delivery platforms, and robust supply chains. She pointed to the need to learn from the pandemic to ensure that countries get the recommendations and assistance needed to make their hospitals fit for the present and the future, and to develop strategies that will define the hospital as part of wider systems of healthcare. She also mentioned the following actions, as priorities for CPS Division in 2022: Caring for healthcare workers and making the hospital sector attractive to European youth; announcing that 2022 will be the European Year of Youth; Working on the integration of the IT platforms across healthcare systems.

The discussions between experts revealed a substantive degree of convergence and common ground on a range of issues: opportunities from better integration with the rest of the health system – primary care, mental health and end-of-life care; incorporate the lessons about resilience learnt in the pandemic; improve sustainability, which also links to hospital buildings and the role of the hospital in the wider economy; respond to the challenges of new treatment and diagnostic technology in terms of the cost, workforce impact and potential changes to the models of service provision will be a significant challenge; respond to global shortages in many types of key staff; opportunities for improved coordination, efficiency and safety through digital transformation.

Exchange Programme

HOPE EXCHANGE PROGRAMME 2022– USING EVIDENCE IN HEALTHCARE MANAGEMENT

On 3 and 4 June 2022, HOPE Agora 2022 took place in Brussels focusing on the theme "Using Evidence in Healthcare Management". For more than 30 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. About 150 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. It directly followed and built on the HOPE Agora 2019 which topic was "Evidence-Informed Decision-making in Healthcare Management".

The approach of "evidence-based medicine" was understood as meaning that policy-making and managerial decisions should be based on the best available evidence and not on beliefs nor long-established practices. In increasingly complex health systems, the ability to use all types of available evidence to improve decision-making in healthcare is crucial to ensure that citizens are offered the best care possible.

On 3 June, the HOPE Agora was chaired by HOPE President, Urmas Sule. The first part of the day was dedicated to presentations from the Amsterdam University Medical Centre / University of Amsterdam. Niek Klazinga, also working at the OECD, presented six parameters which drive hospitals for the better during the COVID-19 period. Damir Ivanković, member of the HealthPros network, made a presentation of the "Beyond Hospital Data" Project related to changes in governance and the use of data during COVID-19. His colleague Sofia Carvalho reviewed the impact of COVID-19 on clinical pathways for acute myocardial infarction, cancer, and acute care.

Exchange Programme

Then, a 50-minute panel discussion went on the theme “Sustainability of Changes for the Better”, chaired by Niek Klazinga. Damir Ivanković and Sofia Carvalho were joined by three other panellists: Helle Kruuse-Andersen, Danish HOPE Exchange participant in the Netherlands; Bill O’Reilly, Irish HOPE Exchange participant in Germany; and Antoine Malone, HOPE French National Coordinator. The panel was followed by the first presentations of HOPE Exchange Programme participants who stayed in Austria, Switzerland, Germany, Denmark, and Estonia.

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: Finland, France, Greece, Ireland, Italy, Latvia, Netherlands, Poland, Portugal, Serbia, Spain, United Kingdom. Over the course of the day, a World Café was also organised to allow participants to share their experiences and ideas around different topics. The agora ended with the meetings of participants by country of origin.

Conferences

CONFERENCES, EVENTS AND WEBINARS ORGANISED BY HOPE

EURORDIS BLACK PEARL AWARDS

HOPE helped organise the annual EURORDIS Black Pearl Awards, which takes place every February to celebrate advancements in the field of rare diseases. Since 2012, EURORDIS-Rare Diseases Europe has organised this event to recognise the major achievements and outstanding commitment of patient advocates, patient organisations, policy makers, scientists, companies and media who strive to make a difference for the rare disease community. In 2022, the event's eleventh edition was organised on 8 February in Brussels.

QUALITY AND SAFETY NETWORK WEBINAR – QUALITY INDICATORS AND PUBLIC REPORTING IN FLANDERS

On 29 March 2022, HOPE co-organised with PAQS (Plateforme pour l'Amélioration continue de la Qualité des soins de la Sécurité des patients) the 11th Quality and Safety Network webinar entitled "Quality indicators and public reporting in Flanders".

Svin Deneckere, Director of the VIKZ network, provided an overview of its organisation. Financed by the Flemish government, this organisation has as primary goal to measure, follow up and publicly report quality and safety of care in the Flemish healthcare sector for the purpose of quality improvement.

ICIC 2022: INTERNATIONAL CONFERENCE ON INTEGRATED CARE

HOPE supported the preparation of the 22nd International Conference on Integrated Care that took place in Odense, Denmark, on 23 - 25 May 2022. The conference was a partnership with Healthcare Denmark in cooperation with the Region of Southern Denmark, Odense University Hospital, Municipality of Odense, Campus Odense and Destination FYN. Denmark is among international frontrunners when it comes to integrated healthcare services.

QUALITY AND SAFETY NETWORK WEBINAR – HEALTHCARE ADVERSE EVENTS IN FRANCE: THIRD NATIONAL INCIDENCE SURVEY

On 31 May 2022, HOPE and PAQS (Plateforme pour l'Amélioration continue de la Qualité des soins de la Sécurité des patients) organised the 12th Quality and Safety Network webinar "Healthcare adverse events in France: third national incidence survey".

Philippe Michel, Full Professor in Public Health, Survey Scientific Head, presented the results of the third French national adverse events survey which shows a statistically significant drop in preventable adverse events (AE) and of their severity between 2009 and 2019.

11TH EUROPEAN CONFERENCE ON RARE DISEASES & ORPHAN PRODUCTS (ECRD 2022)

HOPE was an associate partner in the organisation of the 11th European Conference on Rare Diseases & Orphan Products (ECRD 2022), which was held online from 27 June to 1 July 2022. It was organised by EURORDIS-Rare Diseases Europe, a non-profit alliance of over 950 rare disease patient organisations from 74 countries that work together to improve the lives of the 30 million people living with a rare disease in Europe.

Gathering over 1,000 participants, this 11th edition followed a pivotal two-year Rare 2030 Foresight Study, which had been supported by EU bodies that had guided a large scale and multi-stakeholder discussion on rare disease policy in Europe through 2030. Three main topics were addressed throughout this week: good health and well-being, reduced inequalities and industry, innovation & infrastructure.

LAUNCH OF A EUROPEAN HEALTH UNION NETWORK

On 30 June 2022, HOPE CEO spoke at the European Parliament during the launch of the European Health Union Network organised by MEP Istvan Ujhelyi (S&D/HU). This network is intended to establish robust communication between the European Parliament and European healthcare organisations. Alongside HOPE CEO, counterpart healthcare organisations

provided their vision for a European Health Union Network: Sarada Das, Secretary General, Standing Committee of European Doctors (CPME); Sibylle Reichert, Executive Director, International Association of Mutual Benefits Society (AIM); and Kaisa Immonen, Director of Policy, European Patients Forum (EPF).

Other speakers invited were Dr Mihály Kökény, PhD, former Minister for Health of Hungary, and Public Health and MEP Katerina Konečná (the Left/CZ).

QUALITY AND SAFETY NETWORK WEBINAR – CRITICAL INCIDENT REPORTING SYSTEMS IN GERMANY

On 18 October 2022, HOPE co-organised with PAQS (Plateforme pour l'Amélioration continue de la Qualité des soins de la Sécurité des patients) the 13th Quality and Safety Network webinar "Critical Incident Reporting Systems in Germany".

The two speakers — Dr Doris Voit, MBA, Policy Officer at the German Hospital Federation and Dagmar Lüttel, Project Lead of the LüFMS Innovation Project at the German Coalition for Patient Safety — presented the legal framework for cross-facility critical incidents reporting, discussed the results of the LüFMS-project that evaluated the system used and gave an example with the KH-CIRS-Netz Deutschland.

QUALITY AND SAFETY NETWORK WEBINAR – 5 YEARS TO SAVE LIVES: A BELGIAN BREAKTHROUGH SERIES COLLABORATIVE

On 13 December 2022, HOPE co-organised with PAQS (Plateforme pour l'Amélioration continue de la Qualité des soins de la Sécurité des patients) the 14th Quality and Safety Network webinar entitled "5 Years to Save Lives: a Belgian Breakthrough Series Collaborative".

Quentin Schoonvaere, Data & Improvement Officer, Ana Van Innis, Quality and Safety Officer and Mathieu Louiset, Head of Improvement Services, all of them from the PAQS, presented the "5 Years to Save Lives" Pdfroject led by PAQS between 2017 and 2021.

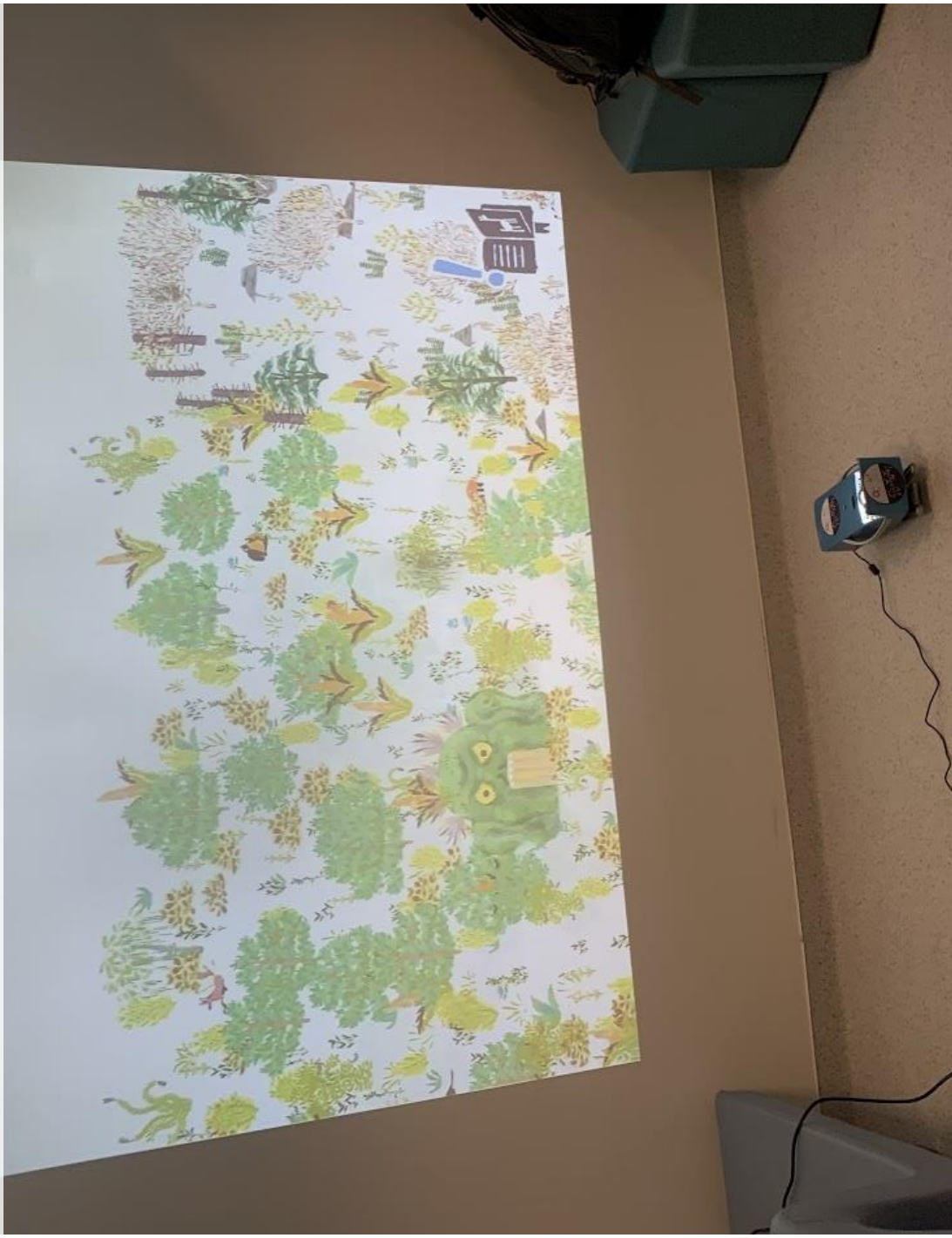
Chapter 4

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

HOSPITAL HEALTHCARE EUROPE 2022

In December 2022, the latest issue of Hospital Healthcare Europe was released online. The first part gives a review of healthcare data before COVID-19 and the second one presents HOPE Governors responses on national COVID programmes and delivery, and the consequences of the pandemic on somatic and mental healthcare provision to non-COVID patients.

Hospital Healthcare Europe represents the essential resource for European hospital healthcare professionals. It is an annual publication containing:

- The HOPE bulletin and in-depth management reviews;
- Informed articles and case studies;
- Individual sections on facilities management, IT and communications, laboratories, radiology and imaging, theatre and surgery, clinical care, nursing and patient care, pharmacy, and therapeutics;
- Expert comment and reports from European Health Ministers, the European Parliament, the European Commission, Council of Ministers, Court of Justice and WHO.

HOPE AGORA REPORT 2022

HOPE released in Autumn 2022 the HOPE Agora 2022 Report.

The HOPE Agora 2022 took place in Brussels and focused on the theme "Using Evidence in Healthcare Management". The report describes the different approaches presented by the guest speakers as well as the insights presented by HOPE Exchange Programme participants during their stay in their host countries.

EU CYBERSECURITY POLICY FRAMEWORK – WHY IT MATTERS FOR HOSPITALS AND HEALTHCARE SERVICES

In May 2022, HOPE wrote a strategic note presenting the EU Cybersecurity Policy Framework.

The European cybersecurity policy framework comprises a number of legislative and non-legislative actions that aim to build resilience to cyber threats. Whereas Directive 2016/1148 on the Security of Network and Information Systems ('NIS Directive') provided the first piece of EU cybersecurity legislation, the new Cybersecurity Strategy, released in December 2020, expands its scope and addresses both cyber and physical resilience of critical entities and networks. It covers the security of essential services (including hospitals) and of connected objects, it also outlines plans for cooperation with global partners and for creating a Joint Cyber Unit at EU level.

REGULATION ON A EUROPEAN HEALTH DATA SPACE: ANALYSIS OF LEGISLATIVE PROPOSALS

In September 2022, HOPE wrote a strategic note analysing the European Health Data Space legislative proposal.

Released in May 2022, the European Commission's proposal for a Regulation on a European Health Data Space (EHDS) envisages the development of a digital health ecosystem in the European Union as a key step for shaping patient-centric and resilient health systems in which digital solutions successfully complement traditional forms of healthcare delivery.

HOPE strategic note draws attention to a number of provisions contained in the legislative proposal that will require further explanation, discussion and elaboration for the EHDS to attain its objectives.

EU4HEALTH – WORK PROGRAMME 2023

In December 2022, HOPE wrote a strategic note presenting the EU4Health Work Programme 2023.

On 24 March 2021, Regulation (EU) 2021/522 of the European Parliament and of the Council was adopted as part of the Multiannual Financial Framework for the 2021-2027 period and within this a programme for the Union's action in the field of health ('the EU4Health Programme'). The EU4Health work programme for 2023 consists of €715 million divided in four overarching 'strands': crisis preparedness with €358.40 million; health promotion & disease prevention €33.54 million; health systems & healthcare workforce €118.42 million; and digital €26.0 million. Cancer is considered as a transversal strand €187.3 million.

POSITION PAPERS

HOPE ANSWER TO THE CONSULTATION ON THE EUROPEAN CARE STRATEGY

In March 2022, HOPE answered the Commission consultation on the initiative for a European care strategy. HOPE welcomed the EU initiative and highlighted the need for coherence and articulation between the hospital and healthcare sector, including long-term care and the social sector. HOPE emphasised the existence of fragmentation and contradictions in these EU policies and thus urged the EU decision makers to avoid handling those issues separately when the population is ageing and will need better coordination between all social and health activities would be a mistake.

HOPE FEEDBACK ON THE CALL FOR EVIDENCE FOR AN INITIATIVE ON "ANTIMICROBIAL RESISTANCE – RECOMMENDATION FOR GREATER ACTION"

From 24 February to 24 March 2022, the European Commission launched a call for evidence on antimicrobial resistance (AMR) aiming at the creation of a proposal for a Council recommendation. This initiative aims to set concrete objectives and activities to strengthen Member States' action against AMR mainly in the area of public health, where the EU has only supporting and complementary competence.

In its feedback, HOPE expressed its involvement in the fight against AMR and emphasised four aspects that should be considered: having a clear coordinated approach through a new "One Health" Action Plan; supporting hospitals and healthcare facilities that are already under financial and staffing pressure; the deployment by the Commission of means to identify, share and develop good practices across the EU; adopting binding measures related to pharmaceuticals as envisaged in the EU Pharmaceutical Strategy and the roadmap for the revision of the EU Pharmaceutical legislation.

HOPE FEEDBACK ON THE EUROPEAN COMMISSION INITIATIVE "BRAIN DRAIN – MITIGATING CHALLENGES ASSOCIATED WITH POPULATION DECLINE (COMMUNICATION)"

From 29 March to 21 June 2022, the European Commission launched a public consultation on for the preparation of a Communication on Brain Drain and Population Decline. HOPE provided feedback.

Nowadays, the emigration of skilled workers, referred to as "brain drain", coupled with ageing, undermines the growth of several regions in the EU. Hence, this initia-

tive aims to investigate the different drivers of brain drain, its long-term consequences for the EU and the potential comprehensive solutions, at European, national, or regional levels, to stop or even reverse it.

JOINT STATEMENT ON THE EUROPEAN COMMISSION DRAFT LIST OF ANTIMICROBIAL MEDICINES RESERVED FOR TREATING HUMANS

In May 2022, HOPE, together with 18 human health and animal welfare organisations, published a joint statement calling on the European Commission to review the draft list of antimicrobials to be reserved for human health adopted on 19 April 2022 and to set a clear timetable for the periodical revision of the list.

Under the 2019/6 Regulation, the Commission is required to draft a list of antimicrobials that will be restricted to human use only to preserve the most critically important drugs for human health. However, the antibiotics proposed by the Commission, based on the European Medicines Agency (EMA)'s Recommendation, are not currently authorised for veterinary use in food production in the EU, so adding these drugs to the list will not change intensive farming practices that rely on antimicrobial use and will not help curb the rising threat of antimicrobial resistance (AMR).

HOPE CONTRIBUTION TO THE EUROPEAN COMMISSION CONSULTATION ON THE REVISION OF THE WASTE FRAMEWORK DIRECTIVE

In July 2022, HOPE released its contribution to the public consultation on the revision of the Waste Framework Directive 2008/98/EC (WFD). Considering the increase of waste generation, the overall objective of the revision is to increase the level of protection of the environment and public health from the impacts of waste management. More specifically, the revision aims to reduce waste generation, increase reuse, and improve separate collection to promote preparations for reuse and quality recycling. The revision is also expected to address waste prevention, including prevention of food waste and lubricant waste oils management.

The consultation was launched by the European Commission on 24 May and was open until 24 August 2022. The Commission's proposal is expected to be adopted in the second quarter of 2023.

INITIAL FEEDBACK ON THE EUROPEAN COMMISSION INITIATIVE "DIGITAL HEALTH DATA AND SERVICES – THE EUROPEAN HEALTH DATA SPACE"

In On 3 May 2022, the European Commission adopted the proposal for a regulation on the European Health Data Space (EHDS).

In July 2022, HOPE released initial feedback highlighting that a number of legal and technical clarifications will be required to comply with the EHDS.

In addition, it will be essential to support hospitals and healthcare facilities in the transition towards the EHDS as the sector is already under economic pressure. The proposed legislation will suppose a high level of interoperability and standardisation to facilitate the meaningful use of personal health data in healthcare and in research, and many Member States would need to introduce legislative changes. Finally, the research realm of the EHDS must safeguard the highest viable levels of personal data protection and fundamental rights, while being subject to strong ethical governance.

HOPE POSITION PAPER ON THE MEDICAL DEVICES REGULATION

The Medical Devices Regulation (MDR) entered into force on 26 May 2021, with new obligations for the placing on the EU market of medical devices. It repeals Directive 93/42/EEC on medical devices and the Directive 90/385/EEC on active implantable medical devices.

In its paper released in November 2022, HOPE warned about the medical device supply situation facing hospitals today and the risks to patients' health. HOPE highlights the shortcomings of the MDR, its insufficient implementation and 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.

General Report on the Activities of the European Hospital and Healthcare Federation 2022

hope
European Hospital and Healthcare Federation