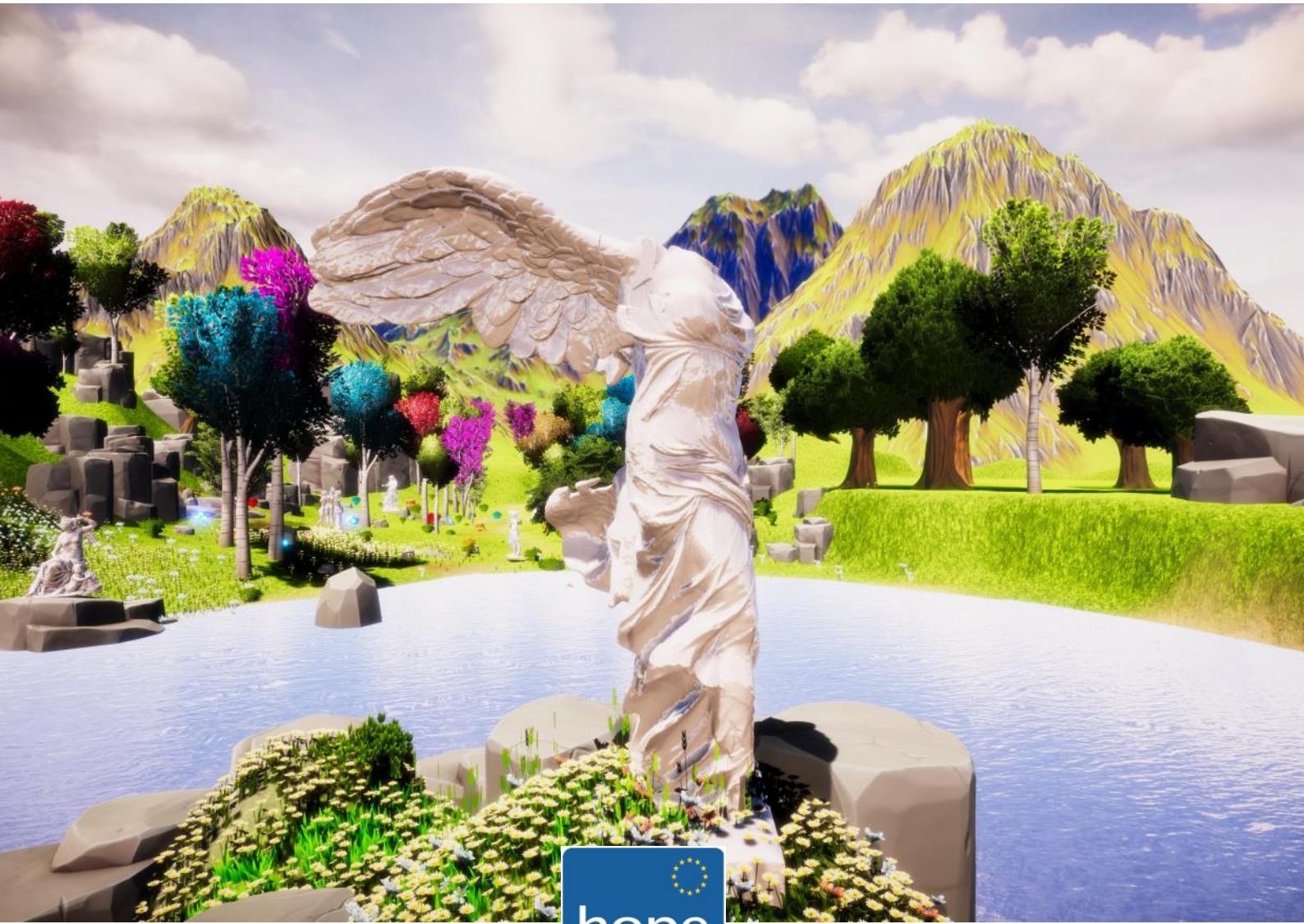
General Report

on the Activities of the

European Hospital and Healthcare Federation

2021



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General Report on the Activities of the European Hospital and Healthcare Federation — 2021

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

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Chapter 4

Introduction

The year 2021 was very intense in Europe and globally regarding health-related issues. The COVID-19 pandemic that arose in 2020 strongly impacted European health systems, economies, and daily life, the consequences of which were felt throughout 2021. European hospital and healthcare services were and still are at the forefront of the battle against COVID-19. A large part of the European Institutions' activity in 2021 was dedicated to fighting the pandemic and its adverse effects but not only.

Following the COVID-19 outbreak, several legislative proposals were released to improve the European response to health emergencies: a proposal for a regulation on serious cross-border threats to health, a proposal establishing the new European Health Emergency Preparedness and Response Authority (HERA), a proposal for the extension of the mandate of The European Centre for Disease Prevention and Control (ECDC) and a proposal for the extension of the mandate of the European Medicines Agency (EMA).

In 2021, European politics were also strongly marked by the end of the Brexit transition period negotiations. After the agreement was finally reached on 24 December 2020, some discussion remained intense on trade measures and research.

On the legislative side, the Health Technology Assessment (HTA) was finally adopted while negotiations started between the European Parliament and the European Council on the legislative proposal on Artificial Intelligence released in April 2021. A legislative proposal on Critical Entities Infrastructure was also released and the European Climate Law was adopted.

Some past topics found themselves back on the agenda due to the evaluation of existing legislation, such as the Cross-border Healthcare Directive including the European Reference Networks, the Blood Tissue and Cells Directive, the GDPR, the Cybersecurity Package, the Orphan Drugs Regulation, the State Aid Package, the Restriction of Hazardous Substances, the Public Procurement rules as well environment-related topics: Energy Efficiency Directive and the Energy Performance of Buildings Directive, Emission Trading Schemes and Water Pollution.

Introduction

Several other initiatives gained momentum on the European political agenda. HOPE closely monitored developments and joined discussions about several topics, including the implementation of the Falsified Medicines Directive and of the Medical Devices Regulation, the revision of the Cybersecurity Directive (NIS2), Digitalisation and in particular the European Health Data Space, the Pharmaceutical Strategy and the preparation of the revision of the legislation, Cancer Antimicrobial Resistance, Vaccination, Farm-to-Fork Strategy or Climate and health, Child Guarantee, Ageing and Mental Health to name but a few.

In 2021, HOPE also contributed to the EU non-legislative agenda through several European projects. The Joint Actions JAMRAI on antimicrobial resistance and iPAAC on cancer reached their final stages. H2020 projects TeNDER and PERISCOPE as well as Erasmus + project ALADDIN further developed their activities in 2021 with HOPE as a partner. Two new projects kicked off in November 2021: HosmartAI “Hospital Smart development based on AI” and RE-SAMPLE which develops a revolutionary tailor-made care for complex chronic conditions. A new Joint Action Toward a European Health Data Space (TEHDAS) started as did a new Joint Action on Health Technology Assessment (EUnetHTA 21).

Consistent with HOPE's mission to facilitate cross-border exchange of good practices among its members and beyond, HOPE staff and representatives participated as speakers or helped organise several European online events. And despite being postponed, the HOPE Exchange Programme for healthcare professionals (and subsequently the HOPE Agora) kept momentum by taking the form of questionnaires and two subsequent webinars.

Chapter 1

LIFE AND GOVERNANCE

HOPE gathers 36 national organisations representing hospital and healthcare services – public and 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, 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 2021: on 4 June online and on 9 November in Paris and online.

The President's Committee (PsC) consisted of the President Dr Urmas Sule, the Vice-President Mr. Eamonn Fitzgerald (Governor for Ireland) and four Governors: the three former Presidents Dr Sara C. Pupato Ferrari (Governor for Spain), Mr. Georg Baum (Governor for Germany until end of March 2021), Mrs. Eva M. Weinreich-Jensen (Governor for Denmark) and Mr. Simon Vrhunec (Governor for Slovenia). 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 26 April and on 4 October 2021 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 2021, HOPE Liaison Officers meetings took place four times online: on 29 January, 25 February, 22 March, 12 May and in Berlin on 25 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, Paris, November 2021

The network of National Coordinators of the HOPE Exchange Programme met in Berlin on 26 November to prepare the 2022 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, and Ms. Ana Sofia Carbonell is part-time EU Project Officer. Ms. Lucia Gonzalez, who was Comparative Activities Officer, left HOPE and Marie Nabbe joined the team as EU Affairs Officer. HOPE also welcomed two interns through the year: Ms. Adèle Le Bihan (FR), Mr. Damir Ivankovic (HR).

GOVERNANCE IN 2021

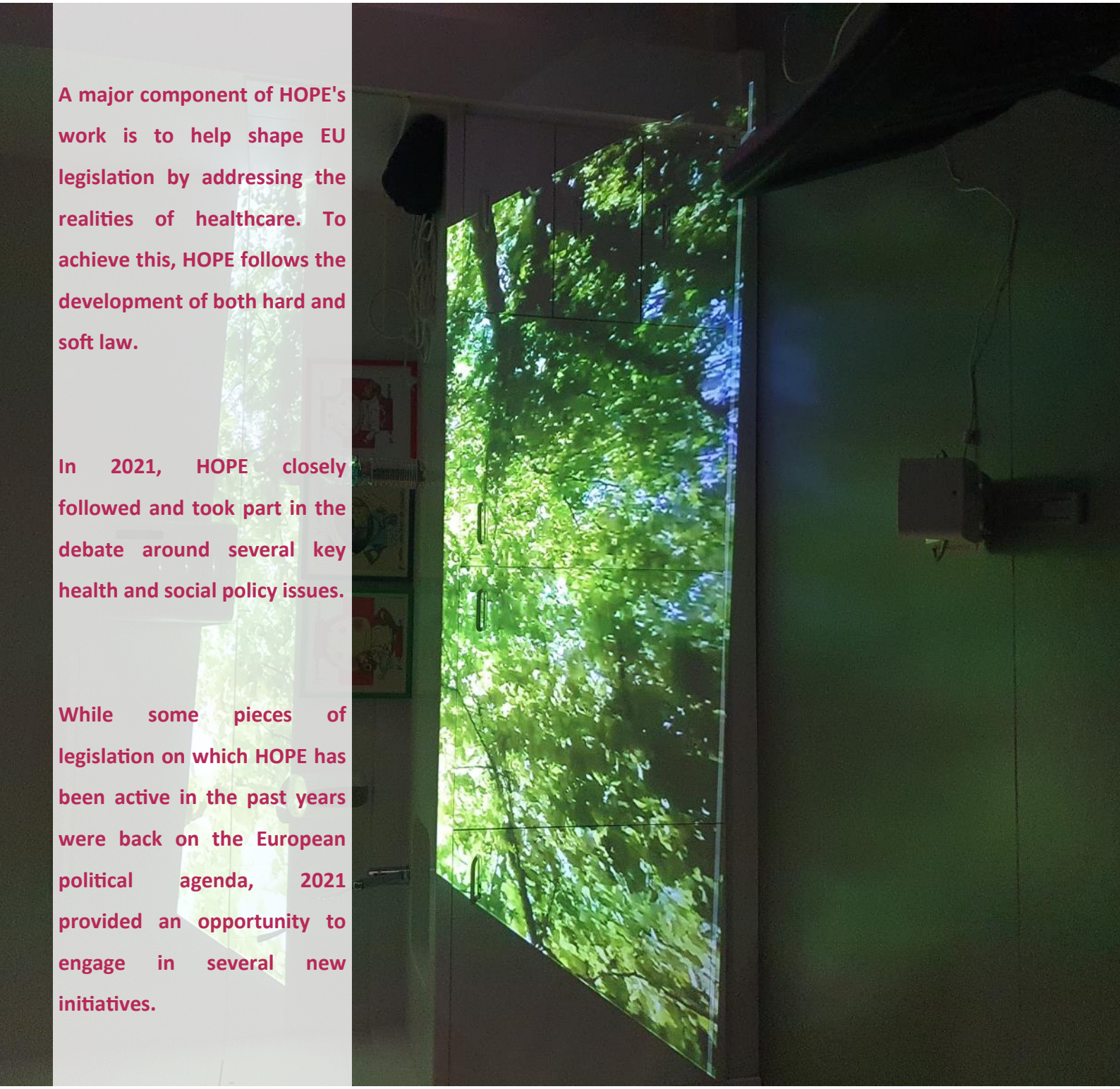
President	Urmas Sule, Estonia
Vice-President	Eamonn Fitzgerald, Ireland
Chief Executive	Mr. Pascal Garel

GOVERNORS AND HEADS OF DELEGATION

Austria	Nikolaus Koller
Belgium	Francis De Drée
Bulgaria	Krasimir Grudev
Croatia	Željko Plazonic
Cyprus	Christis Loizides
Czech Republic	Roman Zdarek
Denmark	Eva M. Weinreich-Jensen
Finland	Sari Raassina
France	Zaynad Riet
Germany	Georg Baum (March 2021); Gerald Gaß (April 2021)
Greece	Yannis Skalkidis
Hungary	György Velkey
Italy	Domenico Mantoan
Latvia	Jevgenijs Kalejs
Lithuania	Dalis Vaiginas
Luxembourg	Marc Hastert
Malta	Denis Vella Baldacchino
The Netherlands	Sander Gerritsen
Poland	Jaroslaw Fedorowski
Portugal	Carlos Pereira Alves
Serbia	Georgios Konstantinidis
Slovakia	Marián Bencat
Slovenia	Radivoj Nardin
Spain	Sara Pupato Ferrari
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 2021, 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, 2021 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 2021, the major issue regarding EU political activity was, of course, the response to the COVID-19 crisis. Funds were allocated to emergency measures but also to projects, research, and long-term recovery. New legislative proposals were released: a proposal for a regulation on serious cross-border threats to health, a proposal establishing the new European Health Emergency Preparedness and Response Authority (HERA), a proposal for the extension of the mandate of The European Centre For Disease Prevention And Control (ECDC) and a proposal for the extension of the mandate of the European Medicines Agency (EMA). Some legislation was adjusted, such as the In Vitro Diagnostics Regulation, which came into force and was rolled out.

Another important issue on the legislative agenda was the EU-UK relations after the agreement was finally reached on 24 December 2020. Discussions continued, especially on trade, research and medicines supplies. The Health Technology Assessment legislation was finally adopted. 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. The European Climate Law was also adopted.

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 Cybersecurity Package; the General Data Protection Regulation; the Blood, Tissues and Cells Directives; the Cross-border Healthcare Directive and the European Reference Networks; the Orphan Drugs Regulation; the Water Directive; the Energy Efficiency Directive; the Emission Trading Schemes; the Fluorinated Greenhouse Gases; the State Aid Package; the Restriction of Hazardous Substances; and Public Procurement rules.

In addition, several other initiatives remain on the EU political agenda: the European Pillars of Social Rights and the ePrivacy Package. A legislative proposal on Critical Infrastructure Protection was released in December 2020 and a legislative proposal on Artificial Intelligence was released in April 2021. 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

EU-UK RELATIONS

On 7 December 2017, HOPE (with the support of its NHS Confederation member) and a group of European organisations representing patients, healthcare professionals and the health care industry -the European Health Stakeholder Group- had called on the EU and UK to prioritise patients in the Brexit negotiations. The action 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 due to last until 31 December 2020. This transition period aimed to provide time for citizens and businesses to adapt and for leaders to agree on mutual relations at the end of the transition period. During this period, the UK continued to apply Union law but it was no longer represented in EU institutions. After intense negotiations until the very end of the year 2020, the EU and UK negotiators in Brussels reached an agreement on 24 December 2020. The EU and UK signed the agreement on 30 December 2020.

HOPE had been following those episodes, working at all stages – and will continue – to identify the possible consequences for its members.

On 27 April 2021, the European Parliament voted with a large majority in favour of the agreement setting the rules of the future EU-UK relationship. The consent decision was adopted by 660 votes for, five against and 32 abstentions, while the accompanying resolution, setting out Parliament's evaluation of and expectations from the deal, passed by 578 votes, with 51 against and 68 abstentions. On 24 December 2020, EU and UK negotiators had agreed on the Trade and Cooperation Agreement establishing the terms for future EU-UK cooperation. To minimise disruption, the agreement has been provisionally applied since 1 January 2021. The European Parliament's consent was necessary for the agreement to enter into force permanently before its lapse on 30 April 2021. In the resolution prepared by the UK Coordination Group and the Conference of Presidents, the Parliament strongly welcomed the conclusion of the EU-UK Trade and Cooperation Agreement. However, MEPs called on the UK government to fully implement the terms of the agreements including the Protocol on Ireland and Northern Ireland and to apply them based on a timetable jointly set up with the European Commission.

On 29 April 2021, the Council adopted a decision on the conclusion of the EU-UK trade and cooperation agreement and the security of information agreement. This was the last step for the EU in their ratification. The UK was notified of the finalisation of the internal EU procedures. Following this, the agreements and accompanying texts were published in the Official Journal of the EU. On 1 May 2021, both agreements entered into force.

On 6 May 2021 the European Health Stakeholder Group organised a webinar titled "EU-UK data transfers, implications for the European healthcare sector" which tackled the challenge of international transfers of personal health data between the EU and the UK. The session focused on the importance EU-UK data transfers for the European healthcare sector, considered the likelihood of the UK being awarded adequacy, and raised awareness of additional steps health organisations will need to consider if adequacy is denied.

On 8 December 2021, the European Health Stakeholders Group released a position paper on Horizon Europe in which the group called for the UK association to Horizon Europe to be formalised as soon as possible.

On 17 December 2021, the Commission put forward proposals to ensure the continued long-term supply of medicines from Great Britain to Northern Ireland and to address outstanding supply concerns in Cyprus, Ireland and Malta. In the context of the Protocol on Ireland/Northern Ireland, this means that the same medicines will continue to be available in Northern Ireland at the same time as in the rest of the UK, while specific conditions ensure that UK-authorised medicines do not enter the Single Market.

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 29 March 2017, the European Commission Unit on "Medical products: safety, quality, innovation" (B4) published the preliminary results of the public consultation on Health Technology Assessment (HTA), which had been launched in October 2016. HOPE submitted a position to this consultation. The results of the public consultation informed the Commission on future initiative to undertake to improve collaboration on HTA in the EU Member States.

On 31 January 2018 the Commission put forward a proposal for a Regulation on Health Technology Assessment (HTA). The discussion then started at Council and European Parliament levels. HOPE released a position in June 2018.

A Presidency compromise text of 22 December 2020 was prepared by the outgoing German Presidency in cooperation with the incoming Portuguese Presidency. In March 2021, the latter garnered enough support on its compromise proposal to move the Health Technology Assessment file to COREPER. On 24 March 2021, after three years of discussions in the Council, COREPER agreed on a mandate for negotiations with the Parliament. ENVI approved the decision to enter into interinstitutional negotiations on 16 April 2021. The committee decision was announced in plenary on 26 April 2021.

On 22 June 2021, the European Parliament and the Council reached an informal agreement on the text. The deal leans towards the position of the Council: it requires Member States "to give consideration to" and not anymore to "use" future joint assessments. Member States will effectively be able to ignore the assessments. The European Parliament succeeded, however, to reduce the phase-in period for the Regulation from 8 to 5 years and secured simple majority voting on non-political decisions (the scientific and technical decisions).

COREPER confirmed the provisional agreement from interinstitutional negotiations on 30 June 2021. ENVI voted on the provisional agreement on 13 July 2021 (58 votes in favour, 14 against and 6 abstentions).

On 9 November 2021, the Council adopted by vote its position at first reading. On 13 December 2021, the Regulation on Health Technology Assessment (HTA) was adopted by the European Parliament and the Council.

The Regulation provides for a delayed application of three years, during which the Commission will:

- set up the Coordination Group. The Commission will soon invite Member States to nominate their members and the first meetings of the Coordination Group is tentatively scheduled for mid-2022;
- 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 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. In the coming period, the Heads of Agencies Group will focus on:

- supporting the development of the basis for joint work on all HTA activities at the EU level within the model of EU cooperation anticipated by the Regulation on HTA.
- supporting the preparation of national systems and capacities for the adoption of the HTA Regulation.
- supporting the joint work performed at the technical and scientific levels by HTA bodies across Europe.
- advising policymakers and relevant EU and national institutions on matters regarding HTA, particularly cooperation in HTA.

Organisations that have joined the group so far include 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).

HOPE was part for several years of the stakeholder group “Provider” in the Joint Action for Health Technology Assessment in Europe: EUNetHTA. EUnetHTA Joint Action 3 came to an end and the EU is now entering a new phase of European HTA cooperation (see the “Project” section for more information about EUnetHTA 21). HOPE was invited to the first virtual EUnetHTA 21 Stakeholder Meeting on 3 December 2021.

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 those bases, the Delegated Regulation 2016/161, laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use, had been 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 on-line pharmacies – and hospitals have to check the authenticity of medicines before dispensing to patients.

Medicines produced before 9 February 2019 without safety features may also remain on the market until their expiry date. But the new end-to-end verification system will require authorised persons (and in particular pharmacists and hospitals) to verify, throughout the supply chain, the authenticity of the products.

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 Regulation 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.

To facilitate compliance with the Regulation by 2019, HOPE conducted a mapping exercise of hospital representation within the National Medicines Verification Systems in the Member States in 2016. Moreover, 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 hospital on-boarding monitoring.

Since 2019 HOPE together with EAHP has been pushing for aggregation and led EMVO to start recognising it as a topic for discussion end of 2019. During the 36th EMVO stakeholder meeting in December 2019, under the item "EMVO 4/5 years Roadmap for EMVS upgrade", EMVO stakeholders acknowledged the need to have an "aligned vision on the topic of aggregation", in order to be ready when the Commission triggers that discussion again. A decision was taken to organise a workshop in February 2020, before the General Assembly and the Board Meeting of March and aside from the Stakeholders and the Commission. During the 37th EMVO stakeholder meeting on 22 January 2020, the minutes again mention this point. EMVO relayed that a communication from the COM was expected on this, as pressure from the member states is increasing, and EMVO wanted to seek EMVO stakeholders' alignment in order to prepare an extended discussion at the EMVO Statutory General Assembly of 6 March 2020.

On 11 and 12 February 2020 "Aggregation" meetings took place. As a conclusion, it was agreed to do surveys to clarify which aggregation is requested in order to then be able to make a cost analysis. The objective was to understand the benefits and challenges of implementing the concepts of aggregation and consolidation within the medicinal supply chain and specifically in association with the EMVS and FMD project. The issue was also on the agenda of the General Assembly of the European Medicines Verification Organisation that took place on 6 March 2020.

In September 2020, the questionnaire on aggregation was finalised and HOPE joined the European Association of Hospital Pharmacists in disseminating it to solve some of the issues identified in European hospitals. The results were presented to the EMVO stakeholders' meeting and sent to Liaison officers and experts. The next step was to further analyse the results of the workshop focused in three countries that have developed aggregation, but this point was not further discussed due to the lack of support of industry members within EMVO. HOPE has however integrated this request in the answer to the consultation of the revision of the pharmaceutical legislation end of 2021.

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 are important tensions in terms of governance as well. This may lead some stakeholders to propose elements to revise the FMD legislation in 2022.

HOPE informs Liaison officers and experts identified by Liaison officers on a regular basis. Since the creation of EMVO, meetings are taking place on a regular basis (usually monthly): Board of EMVO, stakeholders' meetings, project managers' meetings and EFPIA-Medicines for Europe project managers' meeting. In 2021 on a monthly basis HOPE office kept informed Liaison officers (and the experts they have identified) about the FMD implementation through the EMVO reports.

MEDICAL DEVICES REGULATIONS

HOPE is a member since 2010 of the European Commission Expert Group on Medical Devices (MDEG), now called 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 re-use 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 has been 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.

On 24 July 2020 HOPE was selected as an observer of the EUDAMED subgroup of the Medical Devices Coordination Group for a period of five years starting from 1 September 2020. This working group assists and advises the MDCG on policy and technical matters related to the establishment, management and maintenance of the European Database on Medical Devices (EUDAMED), including the implementation and application of the relevant provisions of the MDR and IVDR. In doing so, the Subgroup supports the development process of the necessary specifications and technical functionalities related to EUDAMED.

On 16 April 2021, the European Commission's Medical Device Coordinating Group (MDCG) issued new guidance on the role of safety and performance standards under current Medical Device Directives as well as the upcoming Medical Devices Regulation (MDR) and In-vitro Medical Devices Directive (IVDR).

On 27 April 2021, the European Commission released a Draft Implementing Act on medical devices, open for feedback until 25 May 2021. To ensure the smooth implementation of the new regulatory framework for medical devices (Regulation (EU) 207/2012), economic operators are now allowed to provide online manuals instead of paper instructions for certain device categories. The new implementing regulation expands the scope of the Regulation to include medical device software.

As of 26 May 2021, new EU rules on medical devices (MDR) came into force. In summary, the Medical Devices Regulation:

- imposes tighter controls on high-risk devices such as implants and requires the consultation of a pool of EU level experts before placing medical devices on the market. Clinical evaluations, investigations and the notified bodies that approve the certification of medical devices will be subject to tighter controls.

- requires manufacturers to collect data about the devices' performance once they are available on the market. EU countries will closely coordinate their vigilance and market surveillance.

- implements the use of the European database of medical devices (EUDAMED), which contains information about each medical device on the market, including economic operators and certificates issued by notified bodies. Each device will have a unique device identifier so that it can be found in EUDAMED. Implant patients will receive an implant card with all the essential information

On 17 May 2021, the European Commission launched a new helpdesk to support economic operators in implementing the obligations and requirements introduced by the new UDI system.

On 4 June 2021, the EU Commission released a FAQ document on the European Medical Device Nomenclature (EMDN). The EMDN aims at supporting the functioning of the European database on medical devices (EUDAMED). Among its various uses, it will allow manufacturers to register medical devices in EUDAMED, where it will be associated to each Unique Device Identifier - Device Identifier (UDI-DI).

During the Medical Devices Coordination Group that took place on 18 October 2021, the European Commission informed stakeholders that from 22 December 2023, the ban on octylphenol ethoxylate (Triton-X-100) will be applicable to medical devices and in vitro diagnostic medical devices for diagnosis, treatment or prevention of COVID-19.

⇒ **IVDs Regulation**

Concerning the IVDs Regulation, on 15 September 2020, HOPE released a Position on In Vitro Diagnostics Regulation. In this paper, HOPE expresses concern on 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.

On 7 June 2021, the EU Commission released a Joint Implementation and Preparedness Plan on the In Vitro Diagnostic Medical Devices Regulation. This Joint Implementation Plan was the result of review by the Medical Devices Coordination Group (MDCG), including the relevant sub-groups, with input from stakeholders. It was endorsed in principle in the MDCG meeting of 28 May 2021. In addition to setting the priorities, the Plan will serve as a living document to monitor their implementation.

On 14 October 2021, the European Commission proposed a progressive roll-out 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 Regulation does not change any requirements of the original In Vitro Diagnostic (IVD) Regulation of 2017. It only changes the dates of application of some of these requirements for certain medical devices. For higher risk devices, such as HIV or hepatitis tests (class D), the new requirements will apply as from May 2025. For devices of the lower risk class C, such as certain influenza tests, the date of application is extended until May 2026, whilst for lower risk class devices (class B and A sterile), the application starts in May 2027. Moreover, the application of certain requirements for devices manufactured and used in the same health institution (so-called 'in-house devices') is delayed by two years until May 2024. If, however, the health institutions prove the unavailability of an equivalent device on the market, the transitional periods will end in May 2028

CYBERSECURITY

A Directive on the security of network and information systems (the NIS Directive) was adopted by the European Parliament on 6 July 2016 and came into force in August 2016. Member States had 21 months to transpose the Directive into their national laws and 6 months more to identify operators of essential services. The NIS Directive was the first piece of EU-wide legislation on cybersecurity. It provides legal measures to boost the overall level of cybersecurity in the EU. As hospitals were targeted in cyberattacks in 2018, HOPE is now closely monitoring the EU legislation in this field.

On 26 March 2018, the Commission published an impact assessment to consult stakeholders on a proposal to create a cybersecurity competence network with a European Cybersecurity Research and Competence Centre. The Council agreed on 8 June 2018 its general approach to the proposal, known as the Cybersecurity Act. On 12 September 2018, the Parliament approved in a plenary session the mandate of the EU Cybersecurity Agency (ENISA) and the Cybersecurity Act. The deal was signed by the European Parliament and the Council on 17 April 2019. The regulation was published in the official journal of 7 June 2019 and entered into force on 27 June 2019. Cybersecurity remains a priority in the years to come under the new political guidelines for the European Commission 2019-2024.

The European Commission's work programme 2020 mentioned the policy objective “Increasing cybersecurity”: “review of the Directive on security of networks and information systems (NIS Directive). A consultation process took place ending on 2 October 2020.

On 14 May 2020, the Council adopted a decision extending, by one more year, to 18 May 2021, the restrictive measures framework against cyber-attacks which threaten the EU or its member states.

On 2 December 2020, the Council approved conclusions that acknowledge the increased use of consumer products and industrial devices connected to the internet and the related new risks for privacy, information security and cybersecurity. The conclusions underline the importance of assessing the need for cross-cutting legislation in the long term to address all relevant aspects of the cybersecurity of connected devices, such as availability, integrity and confidentiality. The conclusions invited the Commission to consider a request for candidate cybersecurity certification schemes for connected devices and related services.

On 16 December 2020, the Commission and the High Representative of the Union for Foreign Affairs and Security Policy presented a new EU Cybersecurity Strategy. The Commission made proposals to address both cyber and physical resilience of critical entities and networks: a Directive on measures for high common level of cybersecurity across the Union (revised NIS Directive or ‘NIS 2'), and a new Directive on the resilience of critical entities. They cover a wide range of sectors and aim to address current and future online and offline risks, from cyberattacks to crime or natural disasters.

A consultation on the NIS2 proposal was launched and was open until 11 February 2021. The new Commission proposal aimed to:

- expands the scope of the current NIS Directive by adding new sectors based on their criticality for the economy and society, and by introducing a clear size cap – meaning that all medium and large companies in selected sectors will come under its scope. At the same time, it leaves some flexibility for Member States to identify smaller entities with a high security risk profile.
- eliminates the distinction between operators of essential services and digital service providers. Entities would be classified based on their importance, and divided respectively into essential and important categories with the consequence of being subjected to different supervisory regimes.
- strengthens security requirements for companies, by imposing a risk management approach which provides a minimum list of basic security requirements. The proposal introduces more precise provisions on the process for incident reporting, content of the reports and timelines.
- addresses security of supply chains and supplier relationships by requiring individual companies to address cybersecurity risks in supply chains and supplier relationships.
- enhances the role of the Cooperation Group in shaping strategic policy decisions on emerging technologies and new trends, and increases information sharing and cooperation between Member State authorities. It also enhances operational cooperation including on cyber crisis management.
- establishes a basic framework with key actors on coordinated vulnerability disclosure for newly discovered vulnerabilities across the EU and creates an EU registry on that will be operated by the European Union Agency for Cybersecurity (ENISA).

On 18 January 2021, the European Union Agency for Cybersecurity (ENISA) published the Cloud Security for Healthcare Services report. It builds on ENISA's procurement guidelines for cybersecurity in hospitals published in 2020 and offers good practices for their secure integration into the European healthcare sector.

ENISA released an online tool on 7 April 2021 to support the healthcare sector in identifying procurement good practices to meet cybersecurity objectives when procuring products or services.

On 23 June 2021, the Commission reported on the Security Union and presented the first implementation report under the Cybersecurity Strategy, as requested by the European Council.

On 28 October 2021, the European Parliament's Committee on Industry, Research and Energy (ITRE) adopted its report on NIS2 with 70 votes in favour, 3 against and 1 abstention. MEPs also voted to open negotiations with the Council with 71 votes in favour, 2 against, and 1 abstention. According to the ITRE Committee's position, Member States would have to meet stricter supervisory and enforcement measures, and harmonise their sanctions regimes. The report was adopted by the European Parliament in its plenary of 22 November 2021 together with the decision to enter into interinstitutional negotiations.

The Council adopted its negotiating position on 3 December 2021. Compared to the initial proposal for NIS2, the Council has introduced a number of significant changes. For instance, it has introduced additional criteria to determine the entities to be covered by NIS2, excluding from this scope those entities operating in defence or national security, public security, law enforcement and the judiciary, as well as parliaments and central banks. It has aligned the text with other related proposed legislation, such as the Directive on the resilience of critical entities (CER Directive) and the proposed Regulation on digital operational resilience for the financial sector (DORA). It has also simplified the incident reporting obligations to avoid over-reporting; and has extended the period for Member States to transpose NIS2 into national law to two years, instead of 18 months.

⇒ Cybersecurity package

In a resolution adopted on 10 June 2021, the European Parliament called for connected products and associated services, including supply chains, to be made secure-by-design, resilient to cyber incidents, and quickly patched if vulnerabilities are discovered. The text also demanded legislation imposing cybersecurity requirements for apps, software, embedded software (that control various devices and machines that are not computers) and operating systems (software that runs a computer's basic functions) by 2023. The resolution, adopted with 670 votes to 4, with 12 abstentions, comes in response to the EU's Cybersecurity Strategy for the Digital Decade.

During the State of the Union speech on 15 September 2021, the President of the European Commission announced an initiative to create a European Cyber Defence Policy, including legislation on common standards under a new European Cyber Resilience Act.

According to the European Commission work programme for 2022, released on 19 October 2021, a proposal on a European cybersecurity resilience act (legislative) will be published in Q3 2022. The aim is to establish common standardisation standards for cybersecurity products.

⇒ EU Joint cyber unit

On 7 October 2021, MEPs adopted a draft report by 591 votes in favour, 65 against and 26 abstentions calling for the creation of a Joint Cyber Unit to tackle the lack of information sharing among EU institutions, bodies and agencies and to foster a secure and rapid information network. The report also calls for joint and coordinated responses to cyberattacks, which also need to include NATO so that these responses can lead to sanctions against hostile actors threatening Euro-Atlantic security interests.

On 19 October 2021, the Council adopted conclusions inviting the EU and Member States to further develop the EU cybersecurity crisis management framework, including by exploring the potential of a joint cyber unit.

DATA PROTECTION REGULATION

The General Data Protection Regulation (GDPR), adopted in April 2016, has been in full force since 25 May 2018. The rules aim to protect all EU citizens from privacy and data breaches in an increasingly data-driven world, while creating a clearer and more consistent framework for businesses. It gives consumers more power over their digital presence, including the right to information about how their data is used, and to delete content they no longer want visible online.

It provides new rights for citizens:

- a citizen has to give their "clear and affirmative consent" for their data to be processed;
- the right to receive clear and understandable information about who is processing the data, what data and why;
- the right to be forgotten: a citizen can ask for his/her data to be deleted;
- the right to transfer data to another service provider (e.g. when switching from one social network to another);
- the right to know when data has been hacked.

Once the Regulation had been adopted, HOPE collaborated with the NHS European Office to share information about its impact on the daily work of hospitals and other healthcare organisations. As a result, the briefing “Protecting and managing personal data: changes on the horizon for hospitals and other health and care organisations” was released in May 2017. It provides recommendations for national and EU implementers on how to prepare for a smooth transition to the new law.

The end of May 2019 marked the first year since the GDPR's full application. Besides several initiatives organised, the Commission also published the results of a Eurobarometer and a Communication at the end of July 2019, taking stock of the first year of application of the GDPR: the assessment is overall positive, but it also states that further progress is needed. Although the regulation is directly applicable, Member States have to adapt their current laws in line with the GDPR.

Finally, on 11 December 2019 the European Data Protection Board (EDPB) opened a survey on Guidelines 5/2019 on the criteria of the Right to be Forgotten in the search engine cases under the GDPR, which ran until 5 February 2020. Every year, in accordance with Article 71 GDPR, the EDPB is

required to draw up an annual report on the protection of natural persons, with regard to data processing, in the European Union and, where relevant, in third countries and international organisations. The report is made public and sent to the European Parliament, the European Council and the European Commission.

The Health Work Programme 2020 mentioned a joint action on the application of the GDPR. It aims to iron out differences in national GDPR implementation in the health sector — the development of a code of conduct for data processing (Article 40 GDPR).

In 2020 a consultation to contribute to the guidance of the GDPR was launched by the European Data Protection Board (the new independent body with decision-making powers and legal personality created by the Regulation) in which HOPE was involved.

On 25 November 2020, the European Commission proposed new rules on data governance. The Regulation aims to facilitate data sharing across the EU and between sectors to create wealth for society, increase control and trust of both citizens and companies regarding their data, and offer an alternative European model to the data handling practices of major tech platforms.

On 12 February 2021, the Commission published a study on the "Assessment of the EU Member States' rules on health data in the light of GDPR". The study finds that while the General Data Protection Regulation (GDPR) lays down directly applicable cross-cutting rules in all Member States, there remains variation in the range of national-level legislation linked to its implementation in the area of health. This, the study suggests, has led to a fragmented approach in the way that health data processing for health and research is conducted in the Member States. This can negatively impact cross-border cooperation for care provision, healthcare system administration, public health or research.

On 16 March 2021, the Civil Liberties Committee adopted the draft resolution evaluating the GDPR and called for effective enforcement and adequate resources for supervisory authorities. The resolution was adopted in Plenary on 25 March 2021 with 483 votes to 96 and 108 abstentions.

HOPE participated in the European Data Protection Board Stakeholder Event on processing of personal data for scientific research purposes that took place on 30 April 2021.

In its 2021 Work Programme the European Commission mentions a legislative data package: a Data Act and the Review of the Database Directive.

⇒ Data Act

In May 2021, the Commission published its Inception Impact Assessments on the forthcoming Data Act. This legislative initiative aims at facilitating data access and use, and reviews the rules on the legal protection of databases. The initiative is about ensuring fairness in the allocation of data value among actors of the data economy, including in business-to-business and business-to-government situations. 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 up to 3 September 2021. Feedback will be taken into account for further development and fine tuning of the initiative to be tabled at the beginning of 2022.

⇒ Data Governance Act

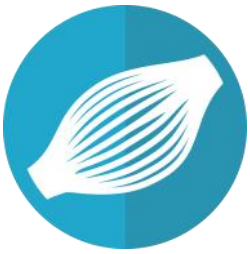
In parallel, the Data Governance Act (DGA) was the first of a set of measures announced in the 2020 European Strategy for Data. On 25 November 2020, the European Commission published its draft Data Governance Act. It aims at making more data available to help create new products and innovation, in particular 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. A public consultation on the draft act was opened from 25 November 2020 to 08 February 2021.

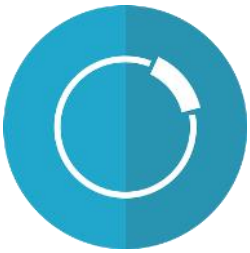
In the European Parliament (EP), the file was assigned to the Industry, Research and Energy Committee (ITRE) and MEP Angelika Niebler (Germany, EPP) was appointed as rapporteur on 17 December 2020. The Committee adopted its report on 22 July 2021. On 24 September 2021, the Council adopted its position and the proposal is now under negotiation in trilogues.

The text mentions health data specifically: “certain datasets held by actors in the public health system, such as public hospitals, could be identified as highly sensitive. In order to ensure harmonised practices across the Union, such types of highly sensitive non-personal public data should be defined by Union law, for example in the context of the European Health Data Space or other sectoral legislation. The conditions attached to the transfer of such data to third countries should be laid down in delegated acts. Conditions should be proportionate, non-discriminatory and necessary to protect legitimate public policy objectives identified, such as the protection of public health".

⇒ Free flow of non-personal data

On 30 June 2021, HOPE was contacted by Deloitte Belgium mandated by the European Commission (DG CNECT) to circulate a study on the evaluation of Regulation (EU) 2018/1807 on the free flow of non-personal data (“FFDR”). As part of the study, Deloitte is reaching out to stakeholders, including organisations using data storage and processing services (cloud services) in all sectors of the economy, in order to gather their opinion and data on the areas governed by the FFDR.





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). It was conducted in line with the Commission's Better Regulation Guidelines and assessed whether the legislation achieved its original objectives and whether it is still fit for purpose. The evaluation consisted of several steps, starting with the publication of a Roadmap in 2017 and an online public consultation which received about 200 answers from individuals and organisations.

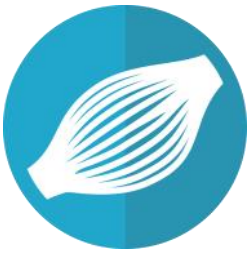
Following the publication of the evaluation, the European Commission organised on 28 October 2019 a conference to present the findings and give stakeholders, including HOPE, an opportunity to discuss them.

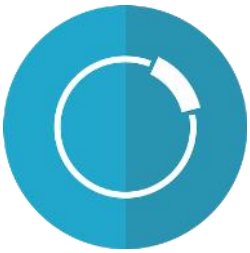
In January 2020 the summary of the 2018 annual reporting of serious adverse reactions and events for tissues and cells and for blood and blood components was published.

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 aims to update the current legislation to allow for more flexible alignment to scientific and technological developments. It aims to address the (re-)emergence of communicable diseases, including lessons learnt from the COVID-19 pandemic. It will also address increasing commercialisation and globalisation in the sector. The revision aims at the removal from legislation of many technical provisions, which will allow faster updating of standards. Also, the revision would allow the possibility to merge the basic acts into a single instrument. The Inception Impact Assessment on the "Revision of the Union legislation on blood, tissues and cells" was also published on the Have Your Say portal of the European Commission and open for feedback until 14 December 2020.

From 21 January 2021 to 15 April 2021, an online public consultation on the revision of this framework opened on the Have Your Say portal of the European Commission. In parallel to this, a targeted consultation was also launched. This consultation was targeted at organisations that are directly involved in, or impacted by, the BTC legislation and that are familiar with the legal framework.

HOPE had been 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.





HOPE attended the workshop with Stakeholders Tissue and Cell of the Competent Authorities Substances of Human Origin Expert Group (CASoHO E01718) on 5 May 2021. The workshop topic was "Regulating for Sufficiency – Tissues and Cells". The current legislation has not achieved an objective to support sufficiency of supply – routinely or in crisis situations. The workshop explored legislative measures that might support Member States in safeguarding sufficiency of supply. This included rules regarding activity reporting for improved monitoring of supply. Proposals and recommendations for mandatory reporting from an EDQM project (tissues and cells) were evaluated. Delegates also discussed potential EU-level measures to increase collection and provide guidance on utilisation, indication, or use, while strengthening the Member State measures to control the flow of substances, monitor their volumes, and report these at the EU-level. The delegates were from tissue and cell competent authorities, EDQM, ECDC, key tissue and cell professional stakeholders, donor and patient representatives.

On 28 June 2021, HOPE was contacted to answer a survey conducted by ICF consulting, launched on behalf of DG SANTE of the European Commission, to contribute to the assessment of proposed reforms to EU legislation on blood, tissues and cells (BTC). It ran from 28 June to 24 July.

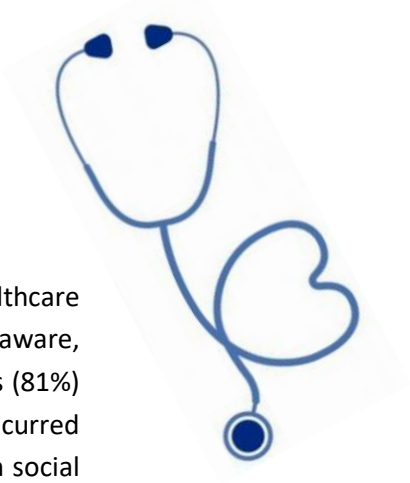
CROSS-BORDER HEALTHCARE

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.

The Commission Work Programme 2021 included the evaluation of the Directive 2011/24/EU on the application on patient rights in cross-border healthcare. The evaluation aimed at looking into the approaches implemented by Member States in practice, how well these work and what areas still act as barriers to patients seeking healthcare across borders.

On 15 January 2021, the Commission published the Roadmap on the Evaluation of Patients' Rights in Cross-border Healthcare, open until 11 February 2021. On 4 May 2021, a public consultation was opened by the European Commission for 12 weeks (until 27 July 2021).

On 8 October 2021, the European Commission published the outcome of the consultation which received 193 responses.



The main findings are the following:

- Seven in ten respondents said that they were aware of their rights to seek healthcare in another EU country. However, only 15% responded that they were fully aware, indicating that information gaps remain. The vast majority of the respondents (81%) also indicated that they were aware that patients can get healthcare costs incurred in another EU country reimbursed under the Directive and/or the EU rules on social security coordination. Nevertheless, 71% of respondents also indicated that they were aware of problems resulting from both EU schemes. Respondents were also of the opinion that the EU schemes for reimbursement do not fully meet patients' needs on accessing healthcare in another EU country, and that gaps persist.
- Respondents were also asked to provide their views on reasons for seeking healthcare abroad. The main reasons mentioned were: healthcare services and treatment needed unavailable in home country (selected by 60% of respondents); better quality of treatment (45%); long waiting times for treatment in the home country (29%); and the closest healthcare provider being in the neighbouring country (22%) .
- More than half of respondents agree that there are barriers to cross-border healthcare either completely (13%) or to a great extent (40%). The main barriers experienced in accessing healthcare abroad are: patients have to pay upfront for treatment and then seek reimbursement from their own health insurer, lack of information on patients' rights to healthcare abroad, and language barriers.
- Nearly two thirds of respondents were aware of the existence of ERNs and their purpose (63%), while 37% were not.
- Contributors were asked to identify to what extent the Directive has supported cross border cooperation in healthcare between neighbouring countries and in the border regions over the past 5 years. Six in ten respondents believe that the Directive did support the sharing of information good practices. Less than half believed that the Directive supported agreements in cooperation in healthcare provision.
- Among the barriers facing hospitals, health authorities and health insurers in cooperation across border regions, respondents pointed to the differences in health systems and resources as the most common ones.

On 9 November 2021, HOPE took part in a virtual stakeholder workshop organised by the European Commission and Tetra Tech to discuss and gather feedback on the results of the evaluation of the Directive on patients' rights in cross-border healthcare. Tetra Tech presented the findings of the study and discussed them with about 90 stakeholders. Among the main findings, the barriers to access cross border healthcare and to use ERNs were underlined: language, lack of information, red tape, and lack of interoperability. The future needs of patients were also stressed and particularly the challenges of telemedicine and how it should be reimbursed. The output of the discussions will feed into the conclusions and recommendations that Tetra Tech delivered to the Commission in December 2021.

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 this back in 2002. European Reference Networks (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), which also makes it easier for patients to access information on healthcare and thus increase their treatment options.

24 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. Joining up the EU's best expertise on this scale should benefit, every year, thousands of patients with conditions requiring a rare and highly specialised care.

In September 2018, the Expert Panel on Effective Ways of Investing in Health released a draft opinion, to which HOPE contributed, on the “Application of the ERN model in European cross-border healthcare cooperation outside the rare diseases area.”

On 26 July 2019, the Commission adopted the Commission Implementing Decision (EU) 2019/1269 amending Decision 2014/287/EU and it launched the call for new members. It aims to:

- clarify the role of the Board of Member States in steering the ERNs,
- modify the procedure concerning the application for membership of existing European Reference Networks (ERN); and
- add provisions concerning the establishment of the Clinical Patient Management System (CPMS) and clarify the applicable data protection rules, in compliance with the General Data Protection Regulation (GDPR).

In July 2019, two statements on ERNs integration into the national health systems and cooperation with industry were adopted by the ERN Board of Member States, thus marking a significant step forward in the consolidation of the ERNs

On 1 October 2019, the European Commission launched the first call for new healthcare providers (HCPs) to join the existing 24 European Reference Networks (ERNs) as full members. 841 new clinical units in hospitals across Europe asked to become members of the European Reference Networks. The call closed on 30 November 2019.

On 17 April 2020, the Commission announced that the examination of membership applications for existing ERNs would be suspended from 1 April 2020 to 31 August 2020 due to the COVID-19 outbreak.

On 9 November 2021, HOPE took part in a virtual stakeholder workshop organised by the European Commission and Tetra Tech to discuss and gather feedback on the results of the evaluation of the Directive on patients' rights in cross-border healthcare. A session was dedicated in discussing European Reference Networks.

The study revealed that more than 1.6 million patients are currently treated by the ERN members (in the Clinical Patient Management System CPMS). Some barriers for healthcare providers were mentioned: non-interoperable IT facilities, red tape, insufficient integration of ERNs in the national health systems, lack of awareness or knowledge on how to access the ERNs, especially for healthcare professionals outside the rare diseases field. Virtual consultations have been under-used as the system has been found to be complicated for some tasks and not always fit for purpose. Another issue mentioned is the resources required to set up and maintain the ERN infrastructure (many have been spent on coordinating the networks and developing tools to support he network instead of treating patients) and the healthcare professionals' time is also used in administrative tasks (identifying and applying for funding) instead of patient-related work. It was mentioned that there is a need to develop a sustainable reimbursement model. Indeed, under the current model, hospitals are often not reimbursed by other Member States for the time spent by their experts in virtual consultations about the cases of foreign patients. Overall, the main issue is the lack of awareness on ERN by doctors and patients alike; there is a need to strengthen cooperation and the role of National Contact Points in providing information to patient and doctors.

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 will join the European Reference Networks). As a result of the current call there will be nearly 1,500 ERN units in 27 Member States and Norway. This milestone extends the geographical scope of the ERNs, and the possibility of patients with rare and low prevalence as well as complex diseases and conditions to access highly specialised healthcare.

The new 620 healthcare units will join the Networks in 24 EU Member States and Norway (except Bulgaria, Malta and Luxembourg). The highest number of new applicants (43) has been accepted to ERN RITA – the European Reference Network that aims to improve the care of patients with Rare Immunological Disorders. 38 new applicants will join EURACAN – the ERN that connects patients who have rare adult solid cancers, and 36 applicants will join ERN EuroBloodNet – the ERN in Rare Hematological Diseases (RHD). The healthcare units set to join the ERNs rank as follows: Italy (145), Germany (84),Spain (68), Latvia and Slovenia (4), Estonia (3) and Cyprus (2). Greece joins as a new country to have healthcare units in the ERNs – with 18 units.

ORPHAN DRUGS

On 11 August 2020, the European Commission published its evaluation on the legislation for medicines for rare diseases and for children. This is the first comprehensive evaluation of the two regulations since their adoption in 2000 and 2006 respectively. They are evaluated together, given that the majority of rare diseases may appear already in children and many children's diseases are also rare.

For some rare diseases the market has started to look more similar to 'standard' medicines. Hence, in such cases it could be questionable whether a 10-year market exclusivity is justified. The Orphan Regulation allows for a shortening of the market exclusivity period once a medicine becomes commercially successful but, in practice, Member States do not trigger the procedure because it is too difficult to provide the necessary evidence. The evaluation has also shown that the medicines developed thanks to the two regulations are not accessible by patients equally in all Member States.

On 25 November 2020, the European Commission launched a Roadmap to revise the rules on medicines for children and rare diseases.

On 7 May 2021, the Commission launched a public consultation on the revision of the legislation on medicines for children and rare diseases (medicines for special populations). It ran until 30 July 2021.

It aims to support the Commission in assessing the impact of possible amendments to EU rules for these medical areas which builds on the recent evaluation published in summer 2020. This evaluation showed that the regulations have stimulated research and development of medicines to treat rare diseases and of medicines for children. However, 95% of rare diseases still have no treatment option and the evaluation also revealed shortcomings in the current system concerning in particular the development of medicines in areas of high unmet need for patients and their accessibility to all EU patients across the Member States.

This revision aims to address these shortcomings to ensure that:

- products for the specific needs of children and patients with rare diseases are developed
- these groups have timely access to medicines
- there are efficient assessment & authorisation procedures

On 28 June 2021, HOPE was contacted to answer the study "Supporting the Impact Assessment of the Revision of the EU Legislation on Medicines for Children and Rare Diseases" led by PPMI Group (PPMI), the Fondazione per la Ricerca Farmacologica Gianni Benzi Onlus (FGB), and Asklepios which have been contracted by DG SANTE, European Commission, to carry out this project. The purpose of this study, which ran until 18 July 2021, was to support the Impact Assessment by refining policy options for the review of the Paediatric and Orphan Regulations and assessing the impact of the options selected.

This topic is also part of the consultation launched by the Commission with a deadline on 21 December 2021.

WATER DIRECTIVE

- PHARMACEUTICALS IN THE ENVIRONMENT

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 toward 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, incentivise “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. Despite improvements in the protection of water bodies and flood risk management, the evaluation points to insufficient levels of implementation by Member States and by sectors with a heavy impact on water such as agriculture, energy and transport. The fact that the WFD objectives have not yet been fully reached is largely due to insufficient funding, slow implementation and insufficient integration of environmental objectives in sectoral policies, rather than deficiencies in the legislation. Assessing whether it is future-proof, this fitness check finds that the Water Framework Directive is sufficiently flexible to accommodate emerging challenges such as climate change, water scarcity and pollutants of emerging concern (e.g. micro-plastics and pharmaceuticals). Chemicals is a key area where there is room for improvement.

This issue was covered in the discussion between HOPE and the Commissioner for the Environment in May 2020. Later, on 21 July 2020, the European Commission launched a Roadmap on the revision of the Directive on ‘Water pollution – EU rules on urban wastewater treatment’. The objective is to make sure that urban wastewater is clean and safe to protect public health and the environment. This key part of EU water policy is covered by the Urban Wastewater Treatment Directive. One of the issues to address is the presence of pharmaceuticals in wastewater.

The European Commission published on 25 November 2020 an overview of the progress made in implementing the actions of the Strategic Approach to Pharmaceuticals in the Environment. Findings show that overall, good progress has been made so far, and some actions presented in the strategy are already well advanced or have even been completed. Several European Green Deal initiatives, as well

as the Pharmaceutical Strategy adopted on the same day, will help to achieve the remaining actions. These Green Deal initiatives include actions that will play a role in reducing the environmental footprint of pharmaceuticals, especially the Chemicals Strategy for Sustainability, the From Farm to Fork target on reducing the EU sale of antimicrobials for farmed animals and in aquaculture, and the forthcoming Zero Pollution Action Plan. The overview shows that implementation of some actions is already quite advanced.

From 28 April 2021 to 21 July 2021, the European Commission held a public consultation on the revision of the Directive on 'Water Pollution – EU Rules on Urban Wastewater Treatment'. This key part of EU water policy is covered by the Urban Wastewater Treatment Directive. This will revise the Directive after a recent evaluation identified certain shortcomings and new societal needs that must be addressed. One of the issues that need to be addressed is the presence of pharmaceuticals in wastewater. HOPE participated in the consultation in May 2021.

ENERGY

⇒ Energy Efficiency Directive

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

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

On 3 August 2020 the European Commission released a Roadmap on the EU energy efficiency directive (EED) to proceed to its evaluation and review. The review aims to provide insights into how the EED could be revised to:

- achieve a higher level of greenhouse gas reduction by 2030
- contribute to other European Green Deal initiatives.

On 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 and just 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'.

⇒ Energy Performance of Building

On 22 February 2021, the European Commission released a Roadmap on a revision of the Energy Performance of Buildings Directive. It was followed by an open public consultation (30 March – 22 June 2021).

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'.

⇒ 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 our 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 our 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.

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 from January 2005 to December 2007, the second from January 2008 to December 2012, coinciding with the first commitment period of the Kyoto Protocol, the third from January 2013 to 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 revised EU Emission Trading System State Aid Guidelines in the context of the system for greenhouse gas emission allowance trading post-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 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 opened from 15 July to 8 November 2021. The proposal is awaiting the Committee decision in the European parliament.

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 learned.

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 Chief Executive, Pascal Garel, reiterated that HOPE used to work on 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). He also stressed the importance of the affordability and accessibility of an alternative treatment if a change should occur in the next years.

After the consultation (15 September 2020 – 29 December 2020), the Commission's adoption was expected for the fourth quarter of 2021. It is now in the Commission's work programme 2022.

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.

On 21 April 2021, the Council's and the European Parliament's negotiators reached a provisional political agreement setting into law the objective of a climate-neutral EU by 2050, and a collective, net greenhouse gas emissions reduction target (emissions after deduction of removals) of at least 55% by 2030 compared to 1990.

On 28 June 2021, the Council adopted its position at first reading on the European climate law, ending the adoption procedure and setting into legislation the objective of a climate-neutral EU by 2050. This follows a political agreement reached with the European Parliament on 21 April and the Parliament's adoption of its position at first reading on 24 June.

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.

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.

On June-July 2019, the Commission opened a Roadmap consultation. The purpose of the evaluation 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 open until December 2019. 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. This study will feed into the Commission's evaluation of the 2012 Services of General Economic Interest ('SGEI') Package insofar this package is applicable to health and social

services. As part of this evaluation, EY has launched an e-survey questionnaire to national stakeholders in 10 EU Member States as well as EU umbrellas organisations.

The Commission work programme 2021 mentions the evaluation of State aid rules for health and social services of general economic interest. The Commission's adoption of a new proposal had been planned for first quarter 2021 and has now been postponed to 2022.

In September 2021, the Commission published an external study on market trends in healthcare and social housing and EU State aid implications. It aims to provide the Commission with factual data regarding the interplay between the 2012 Service of General Economic Interest (SGEI) Package and the changes in the healthcare and social housing sectors in 10 Member States: France, Ireland, Germany, the Czech Republic, Latvia, Portugal, Romania, Croatia, Sweden, and the Netherlands. The Study provides: an overview of sector and market trends since 2012; an analysis of how competition on the market has evolved since 2012; an analysis of how aware Member States are of possible State aid implications of policy and market trends; and an assessment of the effectiveness, efficiency, relevance and EU added value of the SGEI Package in so far as healthcare and social housing are concerned. The Study is 'backward-looking', focusing on the period following the entry into force of the 2012 SGEI Package up to 2020.

WORKERS' PROTECTION FROM EXPOSURE TO HAZARDOUS MEDICINAL PRODUCTS — SAFETY AT WORK

On 24 and 25 September 2020, HOPE attended the conference on workers' protection from exposure to hazardous medicinal products (HMP) organised by the European Commission. The conference was held as part of the study referred to as "Study supporting the assessment of different options concerning the protection of workers from exposure to hazardous medicinal products, including cytotoxic medicinal products".

On 13 October 2020, several organisations (professional organisations, trade unions and patient groups) launched the campaign 'Stop Cancer at Work' to ensure that the current fourth revision of the Carcinogens and Mutagens Directive (CMD) includes groups of carcinogenic and mutagenic hazardous drugs, which cause cancer, and that have not been included by the European Commission in its proposal published on 22 September 2020.

On 29 October 2020, the European Commission launched a Roadmap on an Initiative for an EU Strategic Framework for Health and Safety at Work (2021-2027). The Roadmap was open for comment until 26 November and a Public Consultation took place in December 2020. The objective was to address new risks, such as those resulting from new ways of working, new technologies and digitalisation and COVID-19 pandemic alongside the more traditional ones, such as exposure to dangerous substances and risk of accidents at work. As the previous EU Occupational Safety and Health (OSH) Strategies 2007-20122 and 2014-20203 did, it is also expected for this new Strategic Framework to trigger the adoption or revision of national OSH strategies helping to stimulate coordinated action of Member States, social partners and other key stakeholders to promote actions at the different levels.

The revision of the Carcinogens and Mutagens Directive (CMD) started under the title "Protection of Workers from the Risks Related to Exposure to Carcinogens or Mutagens at Work". The ENVI Committee decision to enter into interinstitutional negotiations was confirmed by plenary on 28 April 2021.

On 28 June 2021, the EU Commission adopted the EU strategic framework on health and safety at work 2021-2027. It sets out the key actions needed to improve workers' health and safety over the coming years. The strategic framework focuses on three key objectives for the coming years:

- anticipate and manage change in the new world of work
- improve prevention of work-related diseases and accidents
- increase preparedness for possible future health threats.

On 16 December 2021, the Council and the European Parliament reached a provisional agreement on the fourth revision of the carcinogens and mutagens directive. 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).

Additionally, it was established that workers who deal with hazardous medicinal products (HMP's) will receive sufficient and appropriate training, with a view to better protect workers in the healthcare sector. The Commission will, after the consultation of stakeholders, prepare Union guidelines and standards of practice for the preparation, administration, and disposal of hazardous medicinal products at the workplace.

PUBLIC PROCUREMENT

The EU public procurement rules govern the way in which public bodies purchase goods, services and works, and seek to guarantee equal access to and fair competition for public contracts within the EU market.

The revised public procurement Directive (2014/24/EU) was adopted on 26 February 2014 and came into force on 17 April 2014. Member States had 24 months to transpose it into national legislation. Since the publication of the proposal in 2011, HOPE has advocated clear and simple rules with less detail and greater reliance upon the general principles of transparency, equal treatment and non-discrimination.

The European Commission's public procurement strategy focuses on six strategic policy priorities that were set out in the 2017 communication 'Making public procurement work in and for Europe'. It aims to improve EU public procurement practices in a collaborative manner by working with public authorities and other stakeholders.

The Health work programme 2020 mentions a joint action on Healthcare public procurement in the EU. The objectives are to map initiatives, procedures and the organisation of public procurement in the health sector, including the procurement of medicinal products, medical devices and services and to analyse available data in existing formats (e.g. Tenders Electronic Daily data as available through the EU open data repository).

In the context of the COVID-19 outbreak, joint procurement related to healthcare products has been at the core of the response strategy.

The voluntary Joint Procurement Agreement for Medical Countermeasures (JPA), approved by the Commission on 10 April 2014, enabled the joint purchase of personal protective equipment, medical ventilators, testing kits for the fight against COVID-19. In April 2020, six more countries – Liechtenstein, Albania, Montenegro, North Macedonia, Serbia and Bosnia and Herzegovina – signed the Joint Procurement Agreement to procure medical countermeasures, bringing the total number of the signatories to 37. It will now cover around 537 million people, including all the EU and EEA population, the UK, as well as almost all candidate countries and potential candidates.

In 2020, the Commission launched seven calls for tenders for the supply of medical countermeasures on 28 February (gloves and coveralls), 17 March (goggles, face shields and masks, as well as ventilators), 19 March (laboratory equipment, including testing kits), 17 June (Intensive Care Unit medicines), 11 September (therapeutic remdesivir – veklury) and 28 September (medical equipment for COVID-19 vaccination) – with participation of up to 36 countries.

On 1 April 2020, the European Commission published guidance on using the public procurement framework, providing an overview of the tendering procedures available to public buyers, applicable deadlines, examples of how public buyers could find alternative solutions and ways of engaging with the market.

Since late October 2020, the Commission has signed over 70 joint procurement contracts for 19 medicines (analgesics, antibiotics, muscle relaxers, anaesthetics, resuscitation), including dexamethasone, to treat more severe COVID-19 cases in Intensive Care Units.

In May 2021, the Commission launched the EU Strategy for the development and availability of therapeutics which included "Joint procurement

and financing: a) Launch new contracts for the purchase of authorised therapeutics by the end of the year; b) Secure faster access to medicines with shorter administrative deadlines."

In June 2021, the Commission identified a portfolio of five promising therapeutics under the EU COVID-19 Therapeutics Strategy.

Joint procurement was progressively signed: with Roche for the product REGN-COV2, a combination of Casirivimab and Imdevimab, on 31 March 2021 and with Glaxo Smith Kline on 27 July 2021 for the supply of sotrovimab (VIR-7831), developed in collaboration with VIR biotechnology. On 21 September 2021, the Commission signed a joint procurement framework contract with the pharmaceutical company Eli Lilly for the supply of a monoclonal antibody treatment (combination of two monoclonal antibodies (bamlanivimab and etesevimab)

On 22 October 2021, the Commission identified a portfolio of 10 promising treatments for COVID-19.

On 3 February 2021 HOPE attended the webinar organised by the European Commission Expert Panel on effective ways of investing in health. The Expert Panel was asked by the Commission to consider the public procurement challenges within healthcare systems. This includes discussion on award criteria other than price or cost that could be used introduced into tenders for different medical supplies, and recommendations on what type of subject matter are more apt for centralised procurement and how to support procurement of innovation.

PROPOSED LEGISLATIONS

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).

It then published the inception impact assessment of a European Health Emergency Response Agency on 27 January 2021. In summary the Commission aims 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);
- ECDC to make policy recommendations;
- EMA to manage shortages of medicines and medical devices.

The three regulations were discussed by the European Parliament and the European Council. The Parliament's Committee on the Environment, Public Health and Food Safety (ENVI) is responsible for this question. In the Council, work was undertaken by the working party on pharmaceuticals and medical devices.

⇒ **Cross-border threats**

The rapporteur, Véronique Trillet-Lenoir (Renew Europe, France) presented her draft report to ENVI on 22 April 2021. Two further sets of amendments to the Commission's proposal were tabled on 29 April 2021. It advocates, among other things, promoting health solidarity in the EU and beyond, and supporting the development of an international treaty on pandemics. In the Council, work is ongoing in the working party on pharmaceuticals and medical devices.

On May 2021, HOPE published a Position Paper on the Proposal for a regulation on serious cross-border threats to health.

On 23 July, the Council agreed on a common position on the draft proposal enabling a mandate to start negotiations with the European Parliament. On 14 September, the Parliament accepted amendments to the proposal by 594 votes to 85 with 16 abstentions.

Among other things, the main amendments adopted in the plenary state that the regulation should apply to:

- threats of biological origin including communicable diseases and those of zoonotic origin,
- epidemiological surveillance of communicable diseases and
- monitoring of the impact of these diseases on major non-communicable diseases and on health problems such as mental health.

Changes to the Health Security Committee (HSC) were mentioned with the suggested presence of representatives of the relevant agencies as observers. Other topics adopted dealt with the EU and nationals' prevention, preparedness and response plans, joint procurement and the early warning and response system. The matter was referred back to the ENVI committee responsible for interinstitutional negotiations.

On 11 November 2021, the Parliament voted again on amendments on the proposal, which will be incorporated into the position originally adopted by the Parliament. Some of the amendments include references to the European Health Emergency Response and Preparedness Authority (HERA), which was launched by the Commission on 16 September 2021, two days after the first vote of Parliament.

Interinstitutional negotiations are ongoing. The first meeting took place on 18 November 2021. The next one is expected early 2022, under the French presidency of the Council of the EU.

⇒ European Centre of Disease Prevention and Control mandate

The rapporteur, Joanna Kopcińska (ECR, Poland) presented her draft report at the ENVI committee meeting of 23 March 2021. In addition to a number of technical adaptations, the rapporteur proposes several amendments highlighting the fact that the organisation and delivery of healthcare is a Member State competence. Among other things, the draft report proposes that participation by Member States in the network of national blood and transplant services, to be set up by the ECDC, should initially be voluntary. Further amendments to the Commission proposal were tabled on 13 April 2021.

In May 2021, HOPE published a Position Paper on the Proposal for a regulation to extend the mandate of the ECDC.

On 29 June 2021, the Committee on the Environment, Public Health and Food Safety (ENVI) adopted its position and proposed that, alongside communicable diseases, the ECDC's mandate should also cover major non-communicable diseases, such as cardiovascular and respiratory diseases, cancer, diabetes and mental illness. The Centre should be tasked with assessing the impact infectious diseases have on health systems in general and the effect of these comorbidities, as observed during the COVID-19 pandemic.

On 23 July 2021, the Council agreed on a common position on the draft proposal enabling a mandate to start negotiations with the European Parliament. On 14 September, the Parliament accepted amendments to the proposal by 598 votes to 84 with 13 abstentions. The main amendments adopted address the extension of the ECDC's mission and tasks to cover major non-communicable diseases. The adopted amendments specify that the Centre should take full account of the responsibilities and competences of the other actors (Member States, Commission, other agencies, WHO). The matter was referred back to the ENVI Committee for interinstitutional negotiations.

The proposal to extend the mandate of the European Centre for Disease Prevention and Control (ECDC) was adopted with 598 votes in favour, 84 against and 13 abstentions by the European Parliament Plenary on 15 September 2021.

On 29 November 2021, the European Parliament and the Council reached an agreement on a stronger role for the ECDC.

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

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

The regulation has to be formally adopted before coming into force.

⇒ European Medicines Agency mandate

The draft report by rapporteur Nicolás González Casares (S&D, Spain) proposes various amendments to the Commission's proposal. Among other things, it stresses the need to reinforce the application of the 'one health' approach in the EU. It also advocates the adoption by the EMA of a list of essential medicines, based on the WHO model list of essential medicinal products, which may contain different categories with different priority levels. Moreover, it puts forward the development of a preparedness and response plan against the risks of shortages of the medicinal products included on the essential medicines list ('shortage risk mitigation plan'), and proposes the creation of an electronic platform to detect and prevent shortages of medicines ('European medicines supply database'). The draft report was discussed at ENVI on 15 April 2021.

On 15 June 2021, the Council reached an agreement on draft rules to reinforce the role of the European Medicines Agency (EMA) in crisis preparedness and management for medicinal products and medical devices. The European Parliament's Committee on the Environment, Public Health and Food Safety adopted its report on 22 June 2021.

On 8 July 2021, the European Parliament adopted, by 587 votes to 28 with 81 abstentions, amendments to the proposal. The main adopted amendments addressed lessons from the COVID-19 pandemic, the framework and means of the EMA, the Executive Steering Group on Shortages and Safety of Medicinal Products, the emergency task force, the European medicines supply database and the information obligations.

On 28 October 2021, a provisional agreement was reached between the Council and the European Parliament. The negotiators agreed on what constitutes a major event and how one can be recognised. They agreed to ensure solid funding from the Union budget for the work of the steering groups, task forces, working parties and expert panels that are to be established. And they also agreed to improve the data protection provisions, so as to ensure that transfers of personal data in the new EMA mandate will be subject to data protection rules, including the GDPR. The objective of the updated mandate is to:

- monitor and mitigate potential and actual shortages of medicinal products and medical devices considered to be critical for addressing public health emergencies;
- ensure timely development of high-quality, safe and efficacious medicinal products, with a particular focus on addressing public health emergencies;
- provide a structure for the functioning of expert panels that assess high-risk medical devices and provide essential advice on crisis preparedness and management.

As a next step, the provisional political agreement has now to be approved by both institutions before the formal adoption procedure is launched.

⇒ Health Emergency Preparedness and Response Authority (HERA)

After a public consultation (31 March 2021 – 12 May 2021), the European Commission adopted the decision establishing 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. It aims at being fully operational by early 2022. Its functioning will be reviewed and adapted on an annual basis until 2025, the date of the full review.

The 2021 Work Programme already presents "preparatory actions" for HERA (60 million EUR) concerning for example flexible manufacturing, AMR and intelligence gathering, mapping of medical countermeasures. For the 2022 Work Programme, HERA actions will reach €275 million and other crisis preparedness actions €100 million.

On 11 November 2021, the European Parliament agreed to align the functioning of the HERA with the future regulation on cross-border health threats. The European Parliament's update mandate calls for transparency, close cooperation and an in-depth review of HERA operations.

On 20 December 2021, the Council reached a political agreement on a new law that would facilitate the purchase of medicines, vaccines and raw materials, activate emergency funding and enable the monitoring of production facilities when another health crisis hits. The Council regulation will establish a Health Crisis Board to coordinate and integrate actions related to medical countermeasures at EU level. The regulation sets up monitoring mechanisms and enables the procurement and purchase of countermeasures. It stipulates how to activate EU FAB facilities – a network of ever warm production capacities for vaccines and medicines manufacturing – as well as emergency research.

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 which proposed amendments seeking to address delegations' concerns and requests for a more flexible regulation.

Then the Romanian presidency submitted to Member States a revised text in the first semester 2019. In particular, amendments focused on: the impact of ePrivacy rules on new technologies, the need for flexible rules taking into account latest developments in areas like Artificial Intelligence or Internet of Things, on metadata, on permitted processing of e-communications data for the purposes of child protection (Art 6.1-a(d)), on supervisory authorities' power and on the exclusion

of national security and defence from the scope of ePrivacy rules. As for the cookies, the amendments included the possibility that users give consent to several providers appearing in white lists. Proposed amendments also relate to the scope of the regulation, proposing the exclusion of: e-communications services which are not publicly available (home Wi-Fi network) as well as of content or metadata processed by the end users 'after receipt', or by a third party entrusted by them to store or otherwise process them.

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.

ARTIFICIAL INTELLIGENCE

In April 2018, the European Commission put forward a European approach to Artificial Intelligence and Robotics. It dealt with technological, ethical, legal and socio-economic aspects to boost the EU's research and industrial capacity and to put AI at the service of European citizens and economy.

In June 2018, following an open selection process, the Commission appointed 52 experts to a High-Level Expert Group on Artificial Intelligence, comprising representatives from academia, civil society, as well as industry. The High-Level Expert Group on Artificial Intelligence (AI HLEG) has as a general objective to support the implementation of the European Strategy on Artificial Intelligence. This includes setting out recommendations on future-related policy development and on ethical, legal and societal issues related to AI, including socio-economic challenges.

On 8 April 2019, the High-Level Expert Group on AI (AI HLEG) released its Ethics Guidelines for Trustworthy AI. The European Commission welcomed the document through a Communication on "Building Trust in Human Centric Artificial Intelligence". HOPE contributed with feedback on the Guidelines first draft, and the AI HLEG published a summary to indicate how the contributor's comments were taken into account.

In June 2019, the European Commission launched the pilot phase of the ethics guidelines for trustworthy AI, as the High-Level Expert Group on Artificial Intelligence released its policy recommendations.

The Commission presented on 7 December 2019 a coordinated plan prepared with Member States to foster the development and use of Artificial Intelligence in Europe.

On 19 February 2020, the Commission presented its White Paper on Artificial Intelligence (AI), "A European approach to excellence and trust", together with an accompanying report on the safety and liability framework. The White Paper's purpose was to initiate a stakeholder consultation to prepare the ground for legislative proposals (including in the fields of safety, liability, fundamental rights and data). The European Commission ran a public consultation between February and June 2020. HOPE contributed to the consultation on this White Paper in May 2020.

Furthermore, a special committee on artificial intelligence in a digital age was set up in June 2020 to analyse the future impact of AI in the digital age, investigate the challenge of deploying AI, analyse the approach of third countries and submit to Parliament's responsible standing committees an evaluation defining common EU objectives in this matter.

On 20 October 2020, MEPs adopted the three proposals on how the EU can best regulate Artificial Intelligence (AI): the draft report on AI civil liability (rapporteur Axel Voss, EPP, Germany), the draft report on AI ethical framework (rapporteur Ibán García del Blanco, S&D, Spain) and the draft report on intellectual property rights for the development of artificial intelligence technologies (rapporteur Stéphane Séjourné, Renew, France).

On 21 October 2020, the Council of the EU Presidency issued Conclusions on ensuring respect for fundamental rights in the development of Artificial intelligence.

On 29 October 2020, HOPE was contacted by Deloitte Belgium to take part in a study mandated by the European Commission on liability for artificial intelligence (outside of product liability). The study's aim was to assess whether the current national civil liability rules were appropriate for the future development of AI applications and ensure adequate incentives for organisations that (plan to) operate AI technologies. These include AI-enabled medical devices used in treatment to patients.

The European Commission released a new EU regulatory framework on AI in April 2021. It 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 risks:

- Unacceptable risk AI. Harmful uses of AI that contravene EU values (such as social scoring by governments) will be banned because of the unacceptable risk they create;
- High-risk AI. A number of AI systems (listed in an Annex) that create adverse impact on people's safety or their fundamental rights are considered to be high-risk. In order to ensure trust and a consistently high level of protection of safety and fundamental rights, a range of legal requirements (including a conformity assessment) would apply to all high-risks systems;
- Limited risk AI. Some AI systems will be subject to a limited set of obligations (e.g. transparency);
- Minimal risk AI. All other AI systems can be developed and used in the EU without additional legal obligations than existing legislation.

Feedback on the proposal was open from 26 April to 6 August 2021

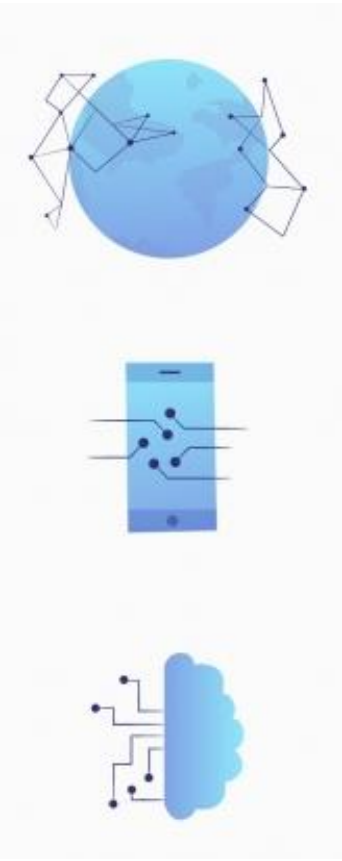
In Parliament, the matter was provisionally assigned to the Committee on Internal Market and Consumer Protection (IMCO). On 9 June 2021, Brando Benifei (S&D, IT) was appointed as Rapporteur for the proposal.

In the Council, negotiations between Member States have started to find a common position. The Portuguese presidency circulated a progress report in June 2021. While the Member States generally support the proposal's overall objectives, questions arose as to the definition of AI system, the scope of the draft regulation and the requirements for high-risk AI systems. In November 2021, the Slovenian presidency presented a progress report (draft compromise).

Telecommunications ministers held their first in-depth policy debate on the proposed AI Act on 14 October 2021. They welcomed the risk-based approach of the proposal, but indicated that many issues require further discussion, regarding the

scope of the Act, law enforcement aspects and definitions of key terms.

On 9 November 2021, a draft report on 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.

The draft report (and any amendments) will be put to a committee vote in March 2022, followed by a plenary debate and vote in May.

⇒ **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.

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 well-functioning and fair labour markets and welfare systems. The objectives of the consultation were to make an assessment of the present EU social "acquis", to reflect on new rends 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.

In her political guidelines and her mission letters to Commissioner Nicola Schmit (Jobs and Social Rights) and Executive Vice-President Valdis Dombrovskis (An Economy that Works for People), Commission President Ursula von der Leyen in September 2019 the creation of an Action Plan for the implementation of the social pillar.

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 7 and 8 May 2021, EU leaders met in Porto for their informal summit and adopted the Porto declaration on social issues. The EU leaders discussed how to ensure an inclusive recovery, with education and skills at the heart of the EU's political action. They also discussed the implementation of the European pillar of social rights at EU and national level, as established by the EU strategic agenda 2019-2024. The action plan presented by the Commission in March 2021 provides guidance on the implementation of the European Pillar of Social Rights, including in the areas of employment, skills and social protection. The action plan also sets three main targets to be achieved throughout the European Union by 2030:

- an employment rate of at least 78% in the EU;
- at least 60% of adults attending training courses every year;
- a reduction by at least 15 million in the number of people at risk of social exclusion or poverty.

On 23 August 2021, as announced in the European Pillar of Social Rights Action Plan, the European Commission set up a high-level expert group on the future of social protection and of the welfare state in the EU. It will study the future of the welfare state, its financing and interconnections with the changing world of work and will present a report and recommendations by the end of 2022. The main aim of the high-level expert group is to reflect on how to make social protection systems and the welfare state fit for the future.

On 10 December 2021, the European Commission published 2 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.

SAFETY OF PUBLIC PLACES

On 18 October 2017, the European Commission adopted an Action Plan, which proposes new measures to help protect EU citizens against terrorist attacks in public spaces. The guidance includes technical "security by design" solutions to make public spaces more secure while preserving their open and public nature. 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 took part to several meetings every year since.

The annex to the European Commission's Adjusted 2020 Work Programme released on 27 May 2020 envisages a "proposal for additional An external study was launched by the Commission's Directorate-General for Migration and Home Affairs (DG HOME) following the evaluation of the European Critical Infrastructure (ECI) Directive.

At the same time, Member States have exercised their margin of discretion by implementing existing legislation in different ways. Operators providing essential services in different Member States have to comply with different reporting regimes. The Commission was looking into whether new frameworks for both physical and digital infrastructures could bring more consistency and a more coherent approach to ensuring the reliable provision of essential services. This framework needs to be accompanied by sector-specific initiatives to tackle the specific risks faced by critical infrastructures such as in transport, space, energy, finance and health.

On 9 December 2020, the European Commission adopted a Counter-Terrorism Agenda for the EU. In the face of recurring terrorist attacks across Europe, the agenda sets the way forward for action to counter terrorism at EU level, looking at better anticipating, preventing, protecting and responding to the terrorist threat. It states that the Commission will increase efforts at EU level to promote security by-design solutions, which build security into public spaces (buildings and infrastructures) from the beginning of the design and urban planning processes and the renovation of existing public spaces.

It also stated that the Commission was committed to enhancing the EU Forum on the protection of public spaces. It will support the EU Pledge on Urban Security and Resilience, and will use targeted funding to help improving the protection of public spaces. The Commission will also explore the possibility of setting minimum obligations for those that are responsible for guaranteeing the security of public spaces to clarify what can be expected from the operators of public spaces. Among the key actions listed, the Commission intends to propose measures to enhance the resilience of critical infrastructure, as critical infrastructure, including transport hubs, power stations, health care infrastructures and water treatment facilities, can be terrorist targets.

On 16 December 2020 the Commission presented a proposal for a directive on the resilience of critical entities that underpin services fundamental for societal or economic activities in many vital sectors. It aims to support Member States in ensuring that critical entities are able to prevent, resist, absorb and recover from disruptive incidents (natural hazards, accidents, terrorism, insider threats, or public health emergencies). The proposal covers ten sectors: energy, transport, banking, financial market infrastructures, health, drinking water, wastewater, digital infrastructure, public administration and space. The proposal was open for feedback for until 11 February 2021. The main provisions include:

- Member States would be required to adopt a national strategy for ensuring the resilience of critical entities and carry out regular risk assessments in order 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.

Within the European Parliament, the proposal has been assigned to the Civil Liberties, Justice and Home Affairs Committee (LIBE), and the rapporteur is Michal ŠIMEČKA, Renew Europe, Slovakia. On 12 October 2021, the LIBE Committee adopted its report (by 57 votes in favour and 6 against) and the negotiating mandate with a view of reaching a first-reading agreement with the Council (approved in plenary on 20 October 2021). MEPs proposed to extend the definition of ‘essential services’ to include protecting the environment, public health and safety, and the rule of law, as well as to ensure greater coherence between the rules under the CER and the NIS2 directives and to enhance incident reporting mechanisms.

In the Council, the examination of the proposal is carried out in a specific formation of the Working Party on Civil Protection, dedicated to the CER Directive.

In its opinion on 'Cybersecurity and Resilience of Critical Entities' of 27 April 2021, covering both the NIS2 and the CER proposals, the European Economic and Social Committee (EESC) suggests considering the possibility of combining the two proposals into a single text for the sake of simplicity and to streamline the interpretation and implementation process. It takes the view that given the relevance and sensitivity of the objectives pursued by the two proposals, a regulation would have been preferable to a directive.

The Council also decided to request the optional opinion of the Committee of the Regions (CoR). The CoR adopted its opinion on 1 July 2021, welcoming the extended scope of the proposed act and suggesting further extending the number of sectors to be covered to the distribution chains of essential items, and in particular to the food production, processing and distribution sector.

The European Data Protection Supervisor issued its formal comments on the proposal in August 2021.

The Council approved on 7 June 2021 conclusions on the protection of public spaces. In these conclusions the Council invites the Commission to explore further opportunities to support projects and initiatives to improve the protection of public spaces and community resilience. It also encourages Member States to support the development and implementation of security-by-design concepts in public spaces. The Council urges Europol to continue exploring digital technologies and countermeasures to put in place against terrorist attacks in public spaces. The focus of this research could be directed at developing explosives detection techniques, protection against drones and serious cybercrime, and the use of artificial intelligence to process large data sets. The Council also recommends that Member States examine their national legal frameworks with a view to restricting the non-legitimate carrying of bladed weapons in public spaces and at major events. They should also consider developing specific protection measures with regard to places of worship.

HOPE attended the 5th EU Operators' Forum on the Protection of Public Spaces on 28 January 2021, which was chaired by the Head of the DG HOME's Counter-terrorism Unit Martin Schieffer. It gathered over 80 representatives from the Commission, EU Member States, operators from the public and private sectors, and faith associations representing the Jewish, Muslim, and Christian communities. DG HOME gave an update on recent policy initiatives, notably the new EU Counter-Terrorism Agenda and key initiatives announced therein, including the EU Protective Security Advisors programme.

HOPE attended the 6th EU Operators' Forum on the Protection of Public Spaces that took place on 24 June 2021. The event allowed operators and Member States to reflect on the impact of COVID-19 on security concepts and measures. A coordinator of the Urban Agenda Partnership on security in public spaces presented the Action Plan that has been published with six concrete actions, inter alia on artificial intelligence, security by design and social cohesion to improve urban security with a holistic and local approach.

HOPE was invited to attend the EU Digital Autumn School on Protection of Public Spaces 2021 on 23 September 2021. In line with the new Counter-Terrorism Agenda for the EU, the European Commission organised a series of webinars for national, regional and urban authorities and operators of public spaces.

HOPE was invited to the 7th virtual Operators' Forum for the Protection of Public Spaces on 2 December 2021. The thematic focus was the implementation of the EU Counter Terrorism Agenda, the EU Protective Security Advisory Mission programme, work on detection standards and the Commission's proposal on Artificial Intelligence. The Commission then covered the EU Vulnerability Assessment Checklist Application, an EU update on work related to voluntary detection standards and update on EU-funded projects related to the Protection of Public Spaces (PERICLES).

Soft Law and Other Initiatives

Besides hard law HOPE also closely monitors soft law in areas such as standardisation, patient safety, pharmaceutical strategy, access to medicines, medicine shortages, digitalisation and European Health Data Space, European Semester, environment, farm to fork, climate and health, antimicrobial resistance, vaccines, cancer, ageing, child guarantee, health workforce and mental health.

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. International examples include the Joint Commission International (JCI) and Health Standards Organization (HSO). Other standardisation bodies in this field include associations of hospitals or medical doctors, quality institutes or private consortia. 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.

HOPE organised with health stakeholders a meeting with DG GROW on 21 October 2020 to continue the discussion on standardisation, which had started in 2018. The opportunity was linked to several previous declarations and publications.

The Council's conclusions on the single market of 21 September 2020 make one reference to standardisation on page 15 but also call ‘that the Single Market should be further deepened and strengthened, with particular emphasis on the development of a service economy and on mainstreaming digital services, removing remaining unjustified barriers, and avoiding creating new ones.’

The European Parliament report on Single Market (INI 2020/2020 Free movement of services – LØKKEGAARD with a plenary vote expected on 18 January 2021) is also very supportive of further services liberalisation.

There is also the opinion of the European Economic and Social Committee on the annual work programme CEN-CENELEC, in which it:

- Agrees with the Commission that standardisation is crucial to the strategy for the single market and that it should be constantly updated;
- Considers that there is an urgent need to modernise the European standardisation system to meet global challenges with an innovative process of cooperation, with a view to the timely development of standards in a fast-changing technological climate;
- Agrees on the importance of AI for the single market, and considers that the current rules on safety and security should be updated;
- Calls for minimum environmental criteria to be made mandatory in public procurement, and for the use of secondary raw materials to be included among the criteria to be encouraged;
- Welcomes the possibility of a new standardisation request on the Internet of things, and rules on cybersecurity, security, privacy and connectivity;
- Advocates for an inclusive approach to standardisation that includes objectives on employability, social rights, and respect for biodiversity and the environment.

A new European Standard, titled EN 17398:2020 'Patient involvement in health care - Minimum requirements for person-centred care', was published in November 2020. This document specifies minimum requirements for patient involvement in health care services with the aim to create favourable structural conditions for person-centred care. It is applicable for use before, during and after the actual care that is provided by the care personnel. This document is also applicable to strategic quality assurance and quality improvement, procurement, educational and supervisory purposes and as a guiding document for research and development projects in the field of intervention and implementation of person-centred care.

Two standards establishing an International Patient Summary, EN 17269:2019 and CEN/TS 17288:2020, were developed in February 2021 by CEN/TC 251 'Health informatics'. These standards cover the requirements for exchanging a core, essential dataset of healthcare data to support the continuity of care for a patient, whenever and wherever it is needed.

In February 2021, CEN and CENELEC released the report "Lessons Learned During the COVID-19 Pandemic". The report presents a series of insights gathered by CEN and CENELEC Members during the outbreak of the COVID-19 pandemic in 2020.

In March 2021, CEN and CENELEC established the new CEN-CENELEC Joint Technical Committee 21 'Artificial Intelligence'. This group brings together experts that will implement and lead the recommendations available in CEN and CENELEC's response to the EC White Paper on AI and CEN and CENELEC's Roadmap on AI. The Joint Technical Committee, whose Secretariat is held by DS, the Danish Standardization Body, is responsible for the development and adoption of standards for AI and related data, as well as for providing guidance to other Technical Committees concerned with AI.

On 28 June 2021, the European Commission released a Roadmap of the "European Strategy for Standardization" open for feedback until 9 August 2021. This initiative addresses the challenges facing the European standardisation system arising from the green and digital transformation of the EU's industrial ecosystem.

On 19-20 July 2021, the first references of harmonised European standards in support of the Medical Devices Regulation (EU) 2017/745 and the In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 were published in the Official Journal of the European Union (OJEU). These very first publications contain 5 and 4 references of EN ISO harmonised standards, to confer a presumption of conformity with the legal requirements of the Regulations covered by those standards. They will be regularly broadened and updated, according to the development of the standardisation work at international and European levels, and according to the new proposals by CEN and Cenelec, usually every three months.

On 30 August 2021, CEN published new guidelines on health and wellness apps.

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 more and more on the topic of 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, the two 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 2021, five webinars were organised: on 26 January on the Dutch Hospital Patient Safety Programme, on 20 April on the evaluation of the Spanish Patient Safety Strategy implemented since 2005, on 15 June on lessons learned from the Portuguese Patient Safety Culture Assessment, on 12 October on quality management system as a basis for patient safety in Estonia and on 14 December on how the Patient Reported Incident Measure (PRIM) can help capture the patients' voices to improve patient safety.

PHARMACEUTICAL STRATEGY

A Pharmaceutical Strategy for Europe was mentioned in the Commission's work programme 2020. The Health work programme 2020 also mentions that it will finance the OECD for work on pharmaceutical innovation and access to medicines.

The OECD has undertaken, with the financial support of the EU Health Programme, several projects to further identify avenues to increase pharmaceutical expenditure efficiency and better prepare to changes in the market.

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

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

The 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 marks 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, but also some aspects of medical devices. It creates synergies with the Green Deal and EU actions under the EU Strategic approach of pharmaceuticals in the environment to reduce their environmental risk, address pollution from pharmaceutical residues and promote greener manufacturing, use and disposal. It is also linked to the action plan on Intellectual Property.

On 26 November 2020, Health Commissioner Stella Kyriakides presented the Pharma Strategy at the European Parliament plenary session where MEPs stressed the need to ensure access to safe and affordable medicines and support EU pharmaceutical innovation.

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.

On 26 April, the Committee on the Environment, Public Health and Food Safety (ENVI), the lead committee in Parliament for the Pharmaceutical Strategy file, published a draft own initiative report. The Committee on Industry, Research and Energy (ITRE) is the associated committee.

The report was adopted by ENVI Committee on 12 October 2021 with 62 votes in favour, 8 against and 8 abstentions. MEPs highlighted the need for increasing the affordability and availability of medicines by addressing the root causes of shortages, increasing transparency on prices and public R&D funding, promoting collective price negotiations, and introducing measures to support a

greater market presence for generic and biosimilar medicines. MEPs insisted that the Commission, Member States and the European Medicines Agency should develop an early warning system for medicine shortages, based on a transparent and centralised digital European platform. Other recommendations include:

- introducing an EU therapeutic guide for antimicrobials and coordinated awareness
- campaigns on antimicrobial resistance (AMR);
- promoting "Made in Europe" pharmaceuticals by strengthening EU manufacturing and supply resilience;
- developing adequate capacity for the sustainable production of active substances, raw materials and medicines which reduce dependence on external sources;
- facilitating the launch of large clinical trials coordinated at the European level; Setting up a wider political High Level Pharmaceutical Forum.

On 24 November 2021, the European Parliament adopted the report in plenary session with 527 votes in favour, 92 against and 70 abstentions. During the plenary debate, a large majority of MEPs called for an updated, solid regulatory framework that guarantees the safety and effectiveness of pharmaceutical products, fair and transparent price setting, and ensure industry meets its environmental commitments.

In parallel, the Commission 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 legislative proposal is expected by the end of 2022.

ACCESS TO MEDICINES

HOPE worked on expensive medicines by adopting a 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 in Brussels, the European Commission and the European Medicines Agency (EMA), with support from HOPE, organised another multi-stakeholder event on biosimilar medicinal products to promote the sharing of knowledge and best practices in biosimilars use and uptake.

The EU is taking measures to foster the competitiveness of EU producers of generic medicines and biosimilar products. 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 will be 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.

SPCs are intellectual property rights that extend patent protection (for up to five years) for medicinal products that must undergo lengthy testing and clinical trials before approval for the EU market. The aim of SPCs is to avoid patent protection being curtailed by the period that elapses between the date of filing of the patent application and the date of the authorisation to place the product on the market in the EU.

Until June 2022, the regulation will affect only SPCs that are applied for on or after the date of entry into force of the regulation (June 2019). From then on, the regulation will also affect SPCs applied for before June 2019, but which have become effective after June 2019. The final text was published in the official journal in June 2019 and is now in force.

In parallel, on 10 April 2019, HOPE took part in the kick-off meeting of the Stakeholder Dialogue Platform of the EURIPID collaboration on Pricing of Medicinal Products in Brussels. EURIPID is a voluntary and strictly non-profit cooperation between mostly European countries on building up and maintaining a database with information on national prices and pricing regulations of medicinal products in a standardised format. It is funded by the European Commission. The EURIPID database contains data on the official prices of publicly reimbursed, mainly outpatient medicinal products. The database is currently only available for national authorities dealing with pricing and reimbursement, and has over 24 European countries participating.

The Health work programme 2020 mentioned that it would finance the OECD for work on pharmaceutical innovation and access to medicines. With the financial support of the EU Health Programme, the OECD has since then undertaken several projects to further identify ways to increase pharmaceutical expenditure efficiency and better prepare to changes in the market.

Access to medicines is one of the key aspects of the Pharmaceutical Strategy for Europe published by the European Commission on 25 November 2020. In a Q&A released at the same time, the Commission said that some initiatives currently considered by the Commission, such as a modernisation of the (SPC) system, relate to both intellectual property and pharmaceutical policies. Any revisions of the rules on IP and pharmaceutical incentives will recognise the complementarity of their effects on the need to foster innovation and make medicines accessible and available to all patients at an affordable price. The Commission will support cooperation between national authorities on pricing, payment and procurement policies, to improve the affordability, cost effectiveness of medicines and health system's sustainability. The Commission will also help improve transparency on methods used for establishing the R&D costs of medicines.

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 runs for a total period of 18 months, from 25 March 2021. It was supported by the Human Pharmaceutical Committee. The pilot overall objective was to improve regulators' knowledge of the planned marketing of centrally authorised medicinal products (CAPs) and on 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 will provide 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.

The pilot began on 25 March 2021. It lasts for 18 months and is supported by the Human Pharmaceutical Committee. The overall aim is to help regulators better understand the planned marketing of centrally authorised medicinal products (CAPs) and the reasons for delayed market entry. This is achieved by engaging with prospective marketing authorisation holders with regard to specific CAP types in the pre-authorisation phase.

From 18 May to 10 September 2018 the Commission launched a stakeholder consultation on granting duplicate marketing authorisations for biological medicinal products (MPs) on the grounds that they would be a "first generic". More specifically, it aimed to seek stakeholders' views on the impact that such authorisations would have on the availability of biosimilars to healthcare professionals and patients.

One possible issue was that such authorisations could have anticompetitive effects and undermine other treatment options available to patients. Representatives from the generics and biosimilar industries, healthcare/patients organisations and most Member State Competent Authorities that participated in the consultation consider, in principle, that duplicate authorisations for generics of biological MPs may reduce availability, especially of biosimilar alternatives on the market. Accordingly, the introduction of an autobiological cannot be assumed to automatically increase availability and it would be for the applicant to demonstrate that this is the case. Representatives of originator companies consider that the current long-standing practice accepts that duplicate market authorisations for a first generic will generally increase availability and that there are no objective reasons to treat biological generics differently than their chemical counterparts. Consequently, the first introduction of an autobiological should be regarded as improving availability as it is currently assumed for generics of chemical products. Specifically, most Member State Competent authorities that responded to the consultation seem to recognise that autobiologicals may reduce availability in the long run. Most arguments, however, are made on a theoretical basis, as there is still not enough experience to draw practical conclusions on the issue.

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. The European medicines regulatory network aims to minimise the impact of medicine shortages on patients by:

- working with pharmaceutical companies to resolve manufacturing and distribution issues;
- sharing information with international partners about alternative sources of supply;
- seeking input from patients and healthcare professionals on the impact of medicine shortages, to support decision-making;
- taking measures to allow alternative medicines or suppliers to be used.

EMA and the Heads of Medicines Agencies (HMA) created an HMA/EMA Task Force on the Availability of Authorised Medicines for Human and Veterinary Use in December 2016 to provide strategic support and advice to tackle disruptions in supply of human and veterinary medicines and ensure their continued availability.

Since April 2019, the task force has been running a pilot programme on establishing a single point of contact (SPOC) network 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 a guidance for marketing authorisation holders on detecting and reporting medicine shortages. 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 on the Availability of Authorised Medicines for Human and Veterinary Use. In September 2019, the European Commission invited HOPE together with other European stakeholders for the first meeting on that issue.

The Health 2020 Work Programme of the Commission mentions the procurement of study “Future-proofing pharmaceutical legislation — study on medicine shortages”. It aims at providing data on the causes of medicine shortages by Member State and EU-wide.

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.

On 14 July 2020, Parliament's environment and public health committee adopted Own Initiative Report on Medicines Shortages calling for European health "independence" by securing supplies, restoring local drug manufacturing and ensuring better EU coordination of national health strategies. On 17 September 2020, the EP adopted the resolution by 663 votes to 23 and 10 abstentions. MEPs call for the EU to increase its response to this issue and to be more self-sufficient when it comes to medicines and medical equipment so that affordable treatments are available at any time.

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 capacity of EMA.

On 25 November 2020, the Commission adopted a Pharmaceutical Strategy for Europe. At this occasion, 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 26 April, the Committee on the Environment, Public Health and Food Safety (ENVI), the lead committee in Parliament for the Pharma Strategy question, published a draft own initiative report. The Committee on Industry, Research and Energy (ITRE) was the associated committee. In the draft report, some additional initiatives are put forward in relation with shortages: the rapporteur calls on the Commission and the Member States to promote more joint European public procurement, as has been done for Covid-19 vaccines, and innovative procurement procedures incorporating criteria such as 'Made in Europe'.

The work programme 2021 of the public health programme published in June 2021 includes a Joint Action 06 "Availability of medicines, shortages and security of supply". Several Member States have expressed interest (Austria, Belgium, Germany, France, Croatia, Italy, Luxemburg, Sweden, Slovenia and Spain), they will have until 15 February 2022 to build the joint action and agree with the Commission.

On 24 November 2021, the European Parliament adopted an own-initiative resolution on a pharmaceutical strategy for Europe (527 votes in favour, 92 against and 70 abstentions).

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

The Commission aims at presenting a legislative proposal by the end of 2022, including measures to address shortages.

DIGITALISATION

In April 2018, the European Commission published a Staff Working Document and a Communication on Digital Transformation of Health and Care in the Digital Single Market, empowering citizens and building a healthier society.

In June 2018, HOPE adopted a Position Paper on the Commission Communication on eHealth welcoming this Communication but asked to further clarify several aspects:

- Considering differences in epidemiology, wealth, culture and the huge diversity of the healthcare system at national and regional level, specificities should be recognised instead of being ignored with a one-size-fits-all approach.
- Moreover, the tool should not be mistaken for a goal. The aim of hospital and healthcare services is to provide high-quality care and cure, not to help set up a digital market and to build economies of scale in this industry.
- Digitisation can support the continuity of care across borders, but the vast majority of patients do not cross borders and optimally should be taken care close to their home. Health care systems should not be viewed only from this cross-border perspective.

HOPE has been regularly active in eHealth issues, first of all, as a member of the eHealth Stakeholder Group (eHSG).

On 7 February 2020 the Commission announced new member organisations of the eHealth Stakeholder Group 2020-2022. HOPE application was accepted, alongside with other umbrella organisations/associations with a European outreach, representing the following sectors/groups: the Health Tech industry, patients, healthcare professionals and the research community.

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. The text also highlights the impact of the digital transformation on fighting the pandemic, and its critical role in the post-COVID-19 recovery.

On 13 January 2021, HOPE was contacted by the European Commission Directorate-General for Health and Food Safety (DG SANTE), Health systems, Medical Products and Innovation to contribute to a study on health data, digital health and AI in healthcare. The European Commission is collecting information about potential regulatory gaps and

barriers to the cross-border provision of digital health services and products; development and deployment of AI in healthcare and access and exchange of health data for healthcare (primary use) as well as for research, policy making and regulatory purposes (secondary use).The European Commission has commissioned Open Evidence (Spain) in a consortium with EY (France) and LifeSTech (UPM, Spain) to carry out the research.

On 10 February 2021, following European Commission President von der Leyen's proposal for a common digital plan towards 2030, a Roadmap on a Communication 'Europe's digital decade – 2030 digital targets' was launched.

On 9 March, the European Commission released a Communication "Europe's Digital Decade: Commission sets the course towards a digitally empowered Europe by 2030". It responds to the European Council's call for a 'Digital Compass'; and builds on the Commission's digital strategy of February 2020. The Communication proposes to agree on a set of digital principles, to rapidly launch important multi-country projects, and to prepare a legislative proposal setting out a robust governance framework, to monitor progress – the Digital Compass.

On 12 May 2021, as a follow-up to the Digital Decade Communication of 9 March, the Commission launched a public consultation on the formulation of a set of EU digital principles. The consultation was open until 2 September. These principles will guide the EU and Member States in designing digital rules and regulations.

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. On the 16 September, the Commission opened a consultation on this proposal, open for feedback until 17 November 2021.

Regarding health more specifically, few elements of the proposal can be underlined:

- digitalisation of public services: a. 100% online accessible provision of key public services for Union citizens and businesses; b. 100% of Union citizens have access to their medical records (electronic health records (EHR)); c. at least 80% of Union 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

EUROPEAN HEALTH DATA SPACE

In 2018, the European eHealth Digital Service Infrastructure started operating, sharing patient summaries and e-prescriptions securely across borders. This communication infrastructure is provided jointly by the European Commission and the national healthcare systems.

In February 2019, the European Commission adopted a Recommendation on a European Electronic Health Record exchange format. The Recommendation supported the digital transformation of health and care in the EU by seeking to unlock the flow of health data across borders. Enabling citizens to securely access and share their health data across borders is one of the priorities of the Communication on enabling the digital transformation of health and care in the Digital Single Market.

Work on technical specifications for health data exchange was carried out under the e-Health Digital Service Infrastructure (eHDSI), which is implemented by the Commission and the Member States through the Connecting Europe Facility (CEF) Programme. The eHDSI connects eHealth national contact points allowing them to exchange two sets of health data: patient summaries and ePrescriptions. The first exchanges took place between Estonia and Finland in January 2019. By 2025, both services will be gradually implemented in 25 EU countries: Austria, Belgium, Croatia, Cyprus, Czech Republic, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Slovenia, Spain, Sweden, Slovakia, Latvia, and Bulgaria.

The eHealth Network, set up under the Directive 2011/24/EU on patients' rights in cross-border healthcare, gathers national authorities responsible for eHealth and gives direction to digital health developments in Europe. Some sub-groups have been set up to prepare the decisions of the eHealth network on some important issues.

On the budget side, in February 2019 the European Parliament and the Council of the European Union reached a provisional political agreement on the first-ever Digital Europe programme, part of the EU's long-term budget presented by the Commission. The programme, proposed in June 2018, invests in five key digital sectors: 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 aim is to strengthen European industrial technological leadership. A Political agreement on a €7.5 billion was reached on 14 December 2020.

In her State-of-the-Union address on 16 September 2020 before the European Parliament, European Commission President von der Leyen announced a new legislative proposal to create a European Health Data Space.

On 23 December 2020, the European Commission launched a new Roadmap, open for feedback until 3 February 2021, on 'Digital health data and services – the European data space'. According to the European Commission, the European Health Data Space (EHDS) should promote access to health data for research and innovation on new preventive strategies, as well as on diagnosis and treatment of diseases to improve health outcomes, while ensuring that citizens have control over their own personal data. A public consultation ran from 3 May to 26 July 2021.

The following activities started in 2021:

- A Joint Action with 22 Member States to propose options on governance, infrastructure, data quality and data solidarity and empowering citizens with regards to secondary health data use in the EU;
- Investments to support the European Health Data Space under the EU4Health programme, as well as common data spaces and digital health related innovation under Horizon Europe and the Digital Europe programmes;
- Engagement with relevant stakeholders to develop targeted Codes of Conduct for secondary health data use;
- A pilot project, to demonstrate the feasibility of cross border analysis for healthcare improvement, regulation and innovation;
- Other EU funding opportunities for digital transformation of health and care will be available for Member States as of 2021 under Recovery and Resilience Facility, European Regional Development Fund, European Social Fund+, InvestEU.

The EU Joint Action Towards a European Health Data Space (TEHDAS) is an implementation tool for the Common European Health Data Space as outlined in the European Strategy for Data and in the context of the EU4Health Programme. The TEHDAS joint action started on 1 February 2021 and will end on 1 August 2023. It officially launched on 1 March 2021 with the publication of an open call for stakeholders to join the project. The aim of the Joint Action is to develop and promote concepts necessary for the sharing of health data for citizens' and public health, treatment, research and innovation in Europe. Participation in the Joint Action provides the opportunity to shape General Data Protection Regulation (GDPR) implementation in the health sector with outputs including:

- a governance model for data-sharing at EU level
- guidelines on effective methods for enabling data use for public health and research
- options on the secondary use of health data, including the application of big data and artificial intelligence in health and long-term care

Following the third eHealth Stakeholder Group meeting in May 2021, the group is now organised in different working groups. HOPE is leading one, together with EFN (European Federation of Nurses Associations):

- Working group 1: Which concrete solutions do we identify and actions could we take, to promote cross-border access to health data and interoperability?

And also joined 3 others:

- Working group 2: Which concrete solutions do we identify and actions could we take, to promote the cross-border re-use of health data for research and policy-making?
- Working group 3: Which concrete solutions do we identify and actions could we take, to promote cross-border uptake of digital health services and products?
- Working group 4: Which concrete solutions do we identify and actions could we take, to promote cross-border uptake of AI for health care?

On 10 November 2021, HOPE took part in the eHealth Stakeholder Group webinar on the acceptance of the European Health Data Space. As leaders of WG1, HOPE and EFN presented at this occasion a Position Paper on Interoperability. Stakeholders' discussions on actions to take fed into the work on the EHDS legislative proposal.

⇒ **1+MG**

On 8 June 2021, HOPE took part in a webinar organised by the European Commission as part of the eHealth Stakeholders Group. 1+MG is a Member State driven initiative 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) will provide support and coordination to the implementation of the roadmap.

⇒ **Electronic Health Records**

On 14 October 2021, the European Commission released a study on the development of Interoperable Electronic Health Records (EHR) in EU Member States (as well as Norway and the UK). The survey results show a heterogeneous picture of EHR developments. While most countries have established health record systems, cross-sectoral interoperable EHRs are not yet a reality in most of the study countries. Nevertheless, legal frameworks and institutional settings are found to be advanced. Only a few countries lack key institutional drivers such as an eHealth authority or other bodies.

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 2021 European Semester and regularly reported on it via its monthly newsletter.

In a resolution voted on 11 March 2021, MEPs reiterate the importance of the social dimension in this year's Annual Sustainable Growth Strategy and in the national reform and resilience plans. MEPs call for fairness and social rights to have the same importance as macro-economic objectives in order to promote the well-being of people the EU. According to them, decent work with adequate wages, equal opportunities, fair mobility and robust social welfare systems are essential in the just transition to a sustainable and social EU. The resolution on the social dimension of the European Semester was adopted by 508 votes, to 121 and 64 abstentions.

The European Commission (EC) released on 2 June 2021 the European Semester Spring Package. The European Semester has been adapted this year given the links to Member States recovery and resilience plans, laying out the investments and reforms that the Recovery and Resilience Facility (RRF) will finance.

This year the Spring Package aims to provide financial advice to Member States as they gradually reopen their economies. Regarding the fiscal policy guidance and the application of the general escape clause, the EC has decided the clause will continue to be applied in 2022 and it is expected to be deactivated as of 2023, in light of the Spring 2021 Economic Forecast.

However, this does not suspend the procedures under the Stability and Growth Pact, a report under Article 126(3) of the Treaty on the Functioning of the EU (TFEU) for all EU Member States except Romania has been adopted. The analysis suggests that only three Member States fulfil the deficit criterion. Yet, the EC will reassess the Member States' budgetary situation based on the Autumn 2021 Economic Forecast. The EC also continues its surveillance under the Macroeconomic Imbalance Procedure. Three Member States continue to experience excessive imbalances and nine others are experiencing imbalances. A tenth enhanced surveillance report for Greece has been produced as well as reports for Ireland, Spain, Cyprus, and Portugal. Moreover, the Employment Guidelines, adopted in October 2020 will be carried over the current Employment Guidelines to 2021.

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 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. This year's Annual Sustainable Growth Survey (ASGS) sets out how the Sustainable Development Goals (SDGs) and how the Recovery and Resilience Facility (RRF), with a budget of €723.8 billion in grants and loans, will be more deeply integrated into the new European Semester cycle. As of today, the Commission has endorsed 22 national recovery and resilience plans and the Council has approved all of these. This has unlocked pre-financing disbursements of €52.3 billion for 17 Member States since August 2021. Overall, the plans approved by the Council so far represent €291 billion in grants and €154 billion in loans. The focus now turns to implementing the recovery plans on the ground.

The Commission's Opinions on the 2022 DBPs are based on the fiscal policy recommendations adopted by the Council in June 2021. The Alert Mechanism Report (AMR) is a screening measure to detect potential macroeconomic imbalances. This year's AMR concludes that in-depth reviews (IDRs) are warranted for 12 Member States: Croatia, Cyprus, France, Germany, Greece, Ireland, Italy, the Netherlands, Portugal, Romania, Spain, and Sweden. The Joint Employment Report (JER) confirms that the labour market is recovering, though employment is not yet back to pre-crisis levels. The COVID-19 crisis affected in particular young people, workers in non-standard forms of employment, the self-employed and third country nationals.

ENVIRONMENT

On 4 May 2020, HOPE President, Vice-President and CEO virtually met Commissioner for Environment, Oceans and Fisheries Virginijus Sinkevičius to discuss several topics that are on the Commission agenda: circular economy; consumer empowerment; sectors that use the most resources and where the potential for circularity is high; waste. HOPE also raised a question about procurement in order to understand what kind of mandatory steps and targets the Commission is considering regarding green public procurement. HOPE asked the Commissioner about the concrete proposals and measures he envisages under the new crosscutting zero-pollution strategy, and in relation with air pollution and water pollution.

On 12 May 2021, the European Commission adopted the EU Action Plan: "Towards Zero Pollution for Air, Water and Soil" – a deliverable of the European Green Deal. It sets out a reduction of pollution to levels that are no longer harmful to human health and natural ecosystems by 2050, as well as the steps to get there. Reviews of relevant EU legislation are foreseen to identify remaining gaps in EU legislation and where better implementation is necessary to meet these legal obligations. The Action Plan sets key 2030 targets to reduce pollution at source, in comparison to the current situation.

⇒ **Green hospitals and healthcare services**

In line with their mission to improve the health of the population, hospitals and healthcare services are deeply concerned by the impact on health and quality of life linked to the degradation of the environment and climate change.

Following a meeting on 4 May 2020 with Commissioner for Environment, Oceans and Fisheries Virginijus Sinkevičius, HOPE has launched a review of good practices in hospital and healthcare services. In 2021, HOPE continued this sharing of good practices of European hospitals.

CLIMATE AND HEALTH

On 13 May 2020, the European Commission Scientific Advice Mechanism invited HOPE to an online discussion on the topic "Adaptation to climate change-related health effects in Europe". The core question was: what could strengthen the resilience of the health sector in Europe in view of the climate change? The Draft Recommendations put emphasis on vulnerable groups, regions and the urban environment, considering specifically the impact from vector-borne infectious diseases, heat and heat waves.

On 4 March 2021, HOPE attended the webinar "Keeping healthy in climate change" organised by the European Policy Centre (EPC), in collaboration with the European Commission and the European Environment Agency (EEA). The moderator was Annika Hedberg, Head of the EPC Sustainable Prosperity for Europe Programme.

HOPE CEO was speaking at the online conference "Health and Climate Change: Common Challenges, Common Solutions?" organised by the Council of Europe bank on 6 May 2021.

On 10 May 2021, HOPE CEO Pascal Garel was a member of the panel of EASAC-FEAM webinar on "Decarbonisation of the Health Sector". In this 90-minute webinar the European Academy networks

EASAC and FEAM presented their latest commentary on the Decarbonisation of the Health Sector.

On 13 July 2021, Health Care Without Harm and Global Green and Healthy Hospitals (GGHH) launched the Climate Impact Checkup, a tool developed for any healthcare facility in the world to calculate and track its greenhouse gas (GHG) emissions, pinpoint priority areas to target, and design effective mitigation plans. The calculator estimates GHG emissions from health care institutions using data primarily from energy consumption, transport, waste management, and gases relevant to the sector. It also enables health systems and facilities to benchmark their footprint against similar facilities in their country, region, and globally.

HOPE attended a webinar on Climate and Health in Europe on 23 November 2021. This webinar was hosted by ASPHER (Associations of Schools of Public Health in the European Region) and part of the Thematic Network "Climate and health education in Europe", which aims at producing a joint statement.

FARM TO FORK STRATEGY

In May 2020, the European Commission adopted the Communication 'A Farm to Fork Strategy – For a fair, healthy and environmentally friendly food system' with the goal of providing European citizens with nutritious, affordable and safe food. It is the first time that the European Commission has presented a comprehensive approach covering every step in the food supply chain from production to consumption and supporting farmers' adaptation.

On 19 October 2020, the Council adopted a set of conclusions on the Farm to Fork Strategy, endorsing the goal of developing a European sustainable food system, from production to consumption. The conclusions entail a two-fold political message from the member states: ensure sufficient and affordable food while contributing to EU climate neutrality by 2050 and ensuring a fair income and strong support for primary producers.

On 15 and 16 October 2020, HOPE joined the Farm to fork conference, hosted by the European Commission. The conference was the first annual meeting of European stakeholders across the food value chain willing to engage and shape the EU's path towards a sustainable food system. The conference focused on the Farm to Fork Strategy.

On 5 July 2021, the Commission, alongside industry stakeholders, officially launched the EU Code of Conduct on Responsible Food Business and Marketing Practices, as part of the its Farm to Fork Strategy. Sixty five entities (26 food manufacturers, 14 food retailers, 1 from the food service sector, 24 associations) signed the Code. This Code was developed with EU associations and companies, with other stakeholders being involved, including international organizations, NGOs, trade unions and trade associations, and other the European Commission services.

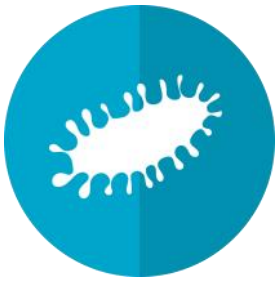
On 10 September 2021, MEPs on the Environment, Public Health & Food Safety and Agriculture Committees adopted the report on a Farm to Fork Strategy by 94 votes to 20 and 10 abstentions.

On 14 and 15 October 2021, the second edition of the Farm to Fork conference took place, preceding the World Food Day 2021. The 2021 conference focused on the rollout of the Farm to Fork strategy for a fair, healthy and environmentally friendly food system. It also looked at the challenges and opportunities linked to the global transition to sustainable food systems, as well as further thematic areas of intervention and ongoing research and innovation efforts.

ANTIMICROBIAL RESISTANCE

The phenomenon of antimicrobial resistance (AMR) is an ever-greater threat to patient safety. It refers to the ability of microorganisms to resist antimicrobial treatments, especially antibiotics. AMR is a huge threat to human health globally as it causes failure in the treatment of infectious diseases. For healthcare systems and hospitals, these treatment failures lead to prolonged hospital stays and a significant number of deaths.

In June 2017 the Commission adopted the new EU One Health Action Plan against Antimicrobial Resistance. It builds on the first Action Plan (2011-2016) and its evaluation (in which HOPE participated) and on other consultations. HOPE took part in the Commission debate with Member States and stakeholder representatives on the preparation of EU guidelines on prudent use of antimicrobials in human medicine.



HOPE joined the Joint Action on Antimicrobial Resistance and Healthcare Associated Infections (JAMRAI) launched in September 2017 and which ran until February 2021. JAMRAI was a collaborative project involving 44 partners and 38 collaborating stakeholders and building on existing works and initiatives by Member States as well as international organisations (OECD, ECDC, WHO Europe, OIE and FAO). Its overarching objective was to support EU Member States in developing and implementing effective one health policies to combat AMR and reduce healthcare-associated infections.

HOPE signed the joint statement on Antimicrobial Resistance (AMR) presented by the European Public Health Alliance (EPHA) on 27 November 2017 at the EU Health Policy Platform meeting. This statement – One Voice for One Health – calls for great improvements and resources for its implementation at the national level.

The own initiative report on "A European One Health Action Plan Against Antimicrobial Resistance" was adopted by the Environment, Public Health and Food Safety (ENVI) Committee of the European Parliament on 20 June 2018. The report stresses that the correct and prudent use of antimicrobials is essential to limiting the emergence of AMR and that developing national strategies to address AMR is essential.

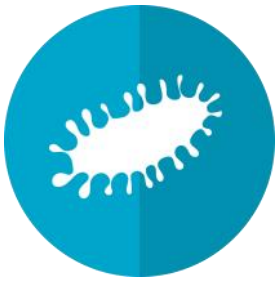
In June 2019, the Employment, Social Policy, Health and Consumer Affairs Council released its conclusions on the next steps towards making the EU a best practice region in combatting antimicrobial resistance.

In January 2019, HOPE joined the Stakeholder Network on Antimicrobial Resistance and signed the Roadmap for Action against AMR. The AMR Stakeholder Network comprises over 80 leading organisations and individuals committed to tackling AMR at national, regional and European level, covering all dimensions of the 'One Health' approach.

The Joint Action on Antimicrobial Resistance and Healthcare-Associated Infections (JAMRAI), which supported collaborative activities and policy development in Member States was finalised in February 2021.

On 26 July 2021, the Commission published the 6th progress report on the European One Health Action Plan against Antimicrobial Resistance. The report shows that a number of EU-level initiatives have progressed over the last six months. At regulatory level, the Commission has established tertiary legislation to implement the EU Regulations on Veterinary Medicinal Products and on Medicated Feed.

On 16 September 2021, the European Parliament Plenary voted on a resolution tabled by Martin Häusling (Greens/EFA, Germany) objecting to a Commission's delegated act on drug resistance. The act established criteria for the designation of antimicrobials to be reserved for the treatment of certain infections in humans and ban their use in animals to try to preserve their efficacy. The Draft Act had been released by the European Commission on 26 March 2021. Martin Häusling considered that the criteria were not stringent enough, and filed a motion calling for the Commission's proposal to be revised.



Together with CPME (Standing Committee of European Doctors) and other health stakeholders, HOPE reached out to MEPs on 14 September and argued that the European Commission's proposal was too far-reaching – and would mean reserve antibiotics could possibly be used metaphylactically in the group treatment of fattening animals, especially chickens, turkeys and pigs. HOPE urged MEPs to support the MEP Martin Häusling resolution against the Commission's proposal. However, Stella Kyriakides had addressed the Parliament's agriculture committee on 9 September to ask for their support for the Commission's Delegated Act. The Häusling resolution was rejected – 204 votes for, 450 against and 32 abstentions – and he attributed the result to the "large-scale lobbying campaign" by farming stakeholders.

HOPE also collaborates with the European Centre for Disease Prevention and Control (ECDC) to review activities carried out and material disseminated as part of the European Antibiotic Awareness Day (EAAD) campaign. Since 2008, the ECDC has been coordinating activities as part of EAAD, which takes place every year on 18 November. The campaign is aimed at raising awareness about the threat to public health of antimicrobial resistance (AMR) and about prudent antibiotic use, key to stopping resistant bacteria developing.

On 18 November 2021, a specific session of the European Scientific Conference on Applied Infectious Disease Epidemiology (ESCAIDE) taking place on 16-19 November was dedicated to the European Antibiotics Awareness Day (EAAD). HOPE participated in the event and supported the initiative by disseminating information and EAAD promotional material via its network. On the same occasion, the AMR Stakeholder Network launched a position paper endorsed by 18 organisations,

including HOPE. This paper puts forward 6 recommendations for measures to combat AMR in the EU Pharmaceutical Strategy:

- Empower and bring together all health professionals.
- Explore new business models, better fit for the antimicrobial market and antimicrobial management.
- Reduce dependence on antibiotics through consumption targets, prevention activities, research into non-antibiotic options and practices.
- Strengthen institutions and clarify the role of Health Emergency Preparedness and Response Authority (HERA).
- Walk the talk on environmentally sustainable antibiotics.
- Explore the role of health promotion and prevention, and patient resilience as a strategy of prevention.

VACCINES

The European Commission Directorate-General Health and Food Safety (DG SANTE) has been working 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, a public consultation also ran until 15 March 2018 and a stakeholder consultation was also conducted.

On 26 April 2018, the Commission issued a set of recommendations on how the EU can strengthen cooperation in the fight against diseases that can be prevented by vaccines. The Commission's proposal focuses on three pillars: tackling vaccine hesitancy and improving vaccination coverage; sustainable vaccination policies in the EU; and EU coordination and contribution to global health.

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 launched on 4 September 2018 in Paris. Building on existing initiatives, the EU-JAV will develop common and durable systemic cooperation to build concrete tools useful for EU and non-EU Member States' health authorities.

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 is a timeline for action through 2022.

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

The European Commission Health Work Programme 2020 is planning financing for stakeholder activities to support strengthened cooperation against vaccine-preventable diseases. The objectives are to implement the commitments made by the Coalition for Vaccination, in areas covered by the Council Recommendation.

On 17 June 2020, the European Commission presented a European strategy to accelerate the development, manufacturing and deployment of vaccines against COVID-19.

On 15 October 2020, the Commission adopted its Vaccination Strategy presenting the key elements Member States should take into consideration for their COVID-19 vaccination plans, as well as priority groups to consider for vaccination first.

In December 2020, the coalition for vaccination, including HOPE, supported the European Commission effort to inform on COVID-19 vaccines and promoted the new European Commission communication website on COVID-19 vaccines.

On 9 February 2021, the Coalition for Vaccination published a manifesto to encourage healthcare professionals to get vaccinated against COVID-19. The manifesto highlights key reasons why all healthcare professionals should get vaccinated against COVID-19 when they have the opportunity to do so and why they should help promote the vaccination against COVID-19 among the general public.

On 9 February 2021, HOPE also participated to the Consultation on European Immunization Agenda 2030 with a consortium of non-state actors in the WHO European Region during an online meeting.

On 11 March 2021, HOPE took part in the Coalition for Vaccination meeting as an associated member organisation. The meeting started with a discussion on the 2020 Coalition campaign on vaccination. Dr Jacques de Haller, CPME, reminded delegates that the launch of online advocacy campaign for vaccination had taken place in April 2020 and had then been completed in October 2020 in time for the flu season. The campaign was coordinated with WHO immunization week and the flu awareness week and targeted the vaccination of healthcare professional. Ms Kathryn Owen, DG SANTE, then presented the European Commission's COVID-19 vaccination communication efforts. Ms Alison Maassen, EuroHealthNet, presented the IMMUNION project ("Improving IMMunisation cooperation in the European UNION"), which kicked off on 1 April 2021 and runs for 2 years. It aims to improve the vaccine uptake by strengthening joint efforts amongst the Coalition for Vaccination members. Mr Alain Delgutte, PGEU, presented the Coalition COVID-19 Manifesto released on 9 February 2021. Dr Stefano del Torso, European Academy of Paediatrics (EAP), presented the EAP4vaccinations campaign. At the end a question was

raised about the vaccination of vulnerable populations. The Commission answered that several projects will be addressing that the issue: the H2020 project RIVER_EU, ImmuHubs, AcToVax4NAM (for recent migrants), RISE-Vac (for incarcerated populations), all starting in 2021. The IMMUNION project Work Package 6 will also focus on specifically increasing vaccine uptake in underserved communities.

At the 12 October 2021 Coalition for Vaccination meeting, the EU co-funded IMMUNION project presented the results of a pan-European survey conducted in the summer of 2021 among healthcare professionals (3,300 participants across Europe).

On 18 October, the Coalition for Vaccination, including HOPE, launched a statement and a campaign on influenza vaccination. It recommended all healthcare professionals and people belonging to at-risk groups to protect themselves, by getting an influenza vaccine. Moreover, it calls on the EU, national and regional health authorities to ensure timely supply of influenza vaccines and adequate support to healthcare professionals who give them.

CANCER

On 10 December 2019, HOPE attended the event “Europe’s Beating Cancer Plan – Better access to cancer care in Europe?” where the Commissioner for health and food safety Stella Kyriakides announced that the Commission will kick off the discussion on the ‘Europe’s beating cancer plan’ on 4 February 2020 on the world cancer day.

HOPE attended the European Parliament Public hearing “Beating cancer – empowering patients and their caregivers" that took place on 11 January 2021.

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. The plan is funded with €4 billion from EU4Health programme, Horizon Europe and the Digital Europe programme. On 23 February 2021, the Commission presented Europe's Beating Cancer plan to the Council working party on pharmaceuticals and medical devices.

On 24 February 2021, HOPE attended the webinar “EU Joint Action on Rare Cancers (JARC) recommendations towards implementing the Rare Cancer Agenda 2030” organised by the Challenge Cancer EU Parliamentary Intergroup.

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.

On 15 April 2021, the European Parliament Special Committee on Beating Cancer organised a Public Hearing on the topic "Cooperation is strength: sharing knowledge and data, improving cross-border care to beat cancer".

On 3 May 2021, the Porto Declaration on Cancer Research was launched during the European Cancer Research Summit 2021, at the Portuguese Institute of Oncology (IPO) in Porto under the Portuguese Presidency of the Council of the European Union. The declaration, presented by Portuguese Minister Manuel Heitor, is the result of the work done by several researchers, scientific and clinical leaders and political decision-makers, who have broaden Europe's Beating Cancer in order to significantly reduce cancer mortality by 2030, with a goal of 75% of cancer patients in Europe surviving for at least ten years.

The Commission Implementation Group, with a mandate to create an Implementation Roadmap for both the Cancer Plan and the Mission on Cancer, met first in April. The Stakeholder Contact Group, which discusses, advises and collaborates on implementation, had its first meeting on 28 May.

The EC Knowledge Centre on Cancer was launched on 30 June 2021. The Knowledge Centre is an online platform, which gathers evidence and coordinates action against the number one cause of death among under-65s in Europe.

The draft report by BECA Rapporteur Véronique Trillet-Lenoir "Strengthening Europe in the fight against cancer – towards a comprehensive and coordinated strategy" was released on 28 June 2021. Amendments to the draft report have been tabled in the Committee. The indicative plenary sitting date is 17 March 2022.

In July, HOPE released a strategic note on cancer in EU4Health Work Programme 2021. It focuses on 4 themes: network of comprehensive care centres, digitalisation, training, radiation technologies.

On 8 September, the European Cancer Organisation and Organisation of European Cancer Institutes (OECI) published a consensus policy paper: "Comprehensive Cancer Care Across the EU: Advancing the Vision". The paper provides essential areas for improvement on implementing the commitment of the European Commission to develop a new EU Network of Comprehensive Cancer Centres and meet an objective of 90% of eligible cancer patients achieving access to such Centres by 2030. The paper was developed with the participation of 21 healthcare professional organisations, 9 patient organisations and other organisations involved in the European Cancer Organisation's Quality Cancer Care Network. Key points of recommendation in the paper include:

- Ensuring precise objectives are set for the EU Network of Comprehensive Cancer Centres (reducing inequalities in diagnosis, treatment and care, and access to clinical trials; strengthening the quality of translational, clinical and outcomes research; integrating clinical care and research and evaluating the quality of cancer care throughout)
- Accompanying implementation of the EU Network of Comprehensive Cancer Centres with clear mapping and needs analysis
- Providing early attention to key mechanics of the new Network, including the development of new Comprehensive Cancer Centres in countries where these are not present, and the integration of general hospitals and primary care providers within com-

prehensive cancer care networks (CCCNs)

- Urging a strong focus on the scientific mission of the new EU Network of Comprehensive Cancer Centres, including the conduct of impactful research at both translational, clinical and outcomes research level.

On 15 September 2021, the Cervical Cancer Elimination Initiative knowledge repository was launched. The repository has been created as a publicly accessible web-based platform intended to provide one-stop access to documents and tools relevant to support the implementation of the Global strategy to accelerate the elimination of cervical cancer as a public health problem.

HOPE was invited to speak during the webinar 'Fostering system readiness in cancer care' that took place on 21 September 2021, coinciding with the 2021 European Society of Medical Oncology (ESMO) Congress.

HOPE attended on 27 September 2021 the webinar "Turning the tide on cancer: the view of national parliaments on Europe's Beating Cancer Plan" organised by the European Parliament Special Committee on Beating Cancer (BECA) in collaboration with the Directorate for Relations with National Parliaments.

On 17 November, the European Commission published an implementation roadmap and progress indicators for Europe's Beating Cancer Plan to monitor developments on the ten flagship initiatives as well as its other actions.

On 24 and 25 November 2021, HOPE attended two webinars organised by DG SANTE as part of the Cancer Stakeholder group in the EU Health Policy Platform. The first webinar was on the EU Mission on Cancer and the Europe's Beating Cancer Plan while the second dealt with the Cancer Inequalities Registry.

On 9 December 2021, the Parliament's Special Committee on Beating Cancer (BECA) adopted a report with its final proposals on how to strengthen the EU's role in the fight against cancer. Key recommendations include facilitating access to cross-border health care and clinical trials for cancer patients, extending the use of joint procurement procedures, managing shortages of cancer medicines, guaranteeing the "right to be forgotten" as well as ensuring equal access to innovative cancer drugs and treatments. The main lessons learnt from the public consultation held by BECA on the impact of the COVID-19 pandemic on cancer care in the EU are also incorporated in the report.

HOPE participated in the iPAAC (Innovative Partnership for Action Against Cancer) Joint Action, following especially the Work Package 10 on "Governance of integrated and comprehensive cancer care". This work package worked on the Comprehensive Cancer Care Networks (CCCNs), defined by the Joint Action as "multiple units belonging to different institutions dedicated to research, prevention, diagnosis, treatment, follow-up, supportive and palliative care and rehabilitation for the benefit of cancer patients and cancer survivors ". The Joint Action started in 2018 and ended in December 2021. More information about iPAAC can be found in the project section.

AGEING

The demographic growth, resulting from increasing life expectancy and decreasing fertility rate in most all European countries, produces a higher health consumption. Health systems face more and more challenges and pressure due to this. Therefore, it is important to put in place strategies and explore innovative solutions to ensure the older population can benefit from the best possible care.

Since 2012, HOPE is a partner of the European Innovation Partnership on Active and Healthy Ageing. In January 2017, HOPE released the paper "HOPE vision on Integrated Care" stressing the social aspect of integrated care, especially in the context of ageing population, as elderly patients are often chronically ill and subject to co-morbidities.

On 29 January 2020 the European Commission's new work programme was published. Under the sixth priority – 'A New Push for European Democracy' – the Commission announced its intention to launch a non-legislative initiative on the subject.

On 16 November 2020, the European Commission released a Green Paper on Ageing Initiative. It aims to set out the key issues and discuss ways to anticipate and respond to the socio-economic impacts of demographic change and to harness the opportunities. It will also reflect on the implications for the cohesion in our societies, looking beyond the purely economic side of demographic change.

HOPE contributed to the consultation on the basis of its position paper adopted in 2019 for the European elections. In its contribution, HOPE urges EU decision makers to avoid handling hospital, healthcare and social care issues separately, but instead promote cooperation activities on EU level.

In parallel, on 12 October 2020, the Council of the EU adopted conclusions on improving the well-being of older persons in the era of digitalisation.

On 27 January 2021, the European Commission launched a public consultation that ran until 21 April 2021. Among the main topics, there were questions about:

- healthy and active ageing policies through the life cycle,
- older worker participation in the labour market,
- social protection systems across generations, informal carers' pensions,
- healthcare and long-term care coverage (financially sustainable and affordable)
- digitalisation of health services

On 18 June 2021 the Council of the EU approved conclusions on the fiscal sustainability challenges arising from an ageing population. The conclusions draw on the main findings of the 2021 ageing report released by the European Commission on 7 May 2021 and call on Member States to address the economic and budgetary consequences of ageing.

On 10 August 2021, the World Health Organization (WHO) launched a call seeking experts to serve as members of the Technical Advisory Group for Measurement, Monitoring and Evaluation of the UN Decade of Healthy Ageing (2021-2030).

CHILD GUARANTEE IN THE EU

The Commission launched a broad discussion on a possible action plan to pursue the Pillar's implementation. As in particular children are vulnerable and often marginalised, DG Employment, Social Affairs and Inclusion will lead the work on a European Child Guarantee.

On 25 August 2020 the European Commission launched a new consultation on the Roadmap for a new initiative on ensuring basic services for all children in need in Europe. The consultation ran until 7 October 2020. The Child Guarantee is meant to ensure that all children in Europe who are at risk of poverty, social exclusion, or are otherwise disadvantaged, have access to essential services of good quality. It will recommend that EU countries invest resources and develop strategies and action plans to ensure that children in need have access to free or affordable services such as:

- education, including early childhood education and care,
- healthcare, nutrition and housing,
- culture and leisure activities.

This consultation checked where EU action could have added value and identify the main challenges as regards the well-being of disadvantaged children. HOPE identified several examples of good practices so that it can participate later in the discussion.

As planned in its work programme for 2021, the Commission adopted a proposal for a recommendation on establishing a European Child Guarantee on the 24 March 2021 and called on Member States to swiftly adopt it. Within six months of its adoption, governments are encouraged to submit, to the Commission, national action plans on how to implement it. The Commission will monitor progress through the European Semester and issue, where necessary, country-specific recommendations.

On 14 June 2021 the Council adopted a recommendation establishing a European Child Guarantee. The aim of the recommendation is to prevent and combat social exclusion of children in need by guaranteeing access to a set of key services, thereby also helping to uphold the rights of the child by combating child poverty and fostering equal opportunities. The strategy will be evaluated in 2024 with inputs from children.

On 4 May 2021, HOPE attended a workshop during a Flagship Conference organised by the Social Platform, in collaboration with the Portuguese Ministry of Labour, Solidarity and Social Security, under the Portuguese Presidency of the Council of the European Union. The workshop was entitled "Reducing inequalities from the first years of life – The role of early childhood development". It was co-organised by the European Public Health Alliance (EPHA) and Eurochild.

HEALTH WORKFORCE

On 20 September 2021, the new Health Workforce Projects Cluster on EU HPP was officially launched during a webinar. The aim of this network is to provide supporting tools and practical guidelines, and to improve sharing of best practices that can help Member States to design and implement their policies related to health workforce retention, task-shifting and tackling regional medical deserts. Contribution from key stakeholders to the policy dialogue is essential to advance on these challenging issues.

The Health Workforce Projects Cluster covers five EU co-funded projects under the umbrella of the 3rd Health Programme. The projects focus on three key topics – medical deserts, task shifting and retention policies – that will be investigated thoroughly in the coming years.

- Projects of the Health Workforce Projects Cluster:
- Action for Health and Equity - Addressing Medical Deserts: AHEAD
- MEnTal hEalth: fOcus on Retention of healthcare workers: METEOR
- prOmoting evidence-bASed rEformS: OASES
- Empowering EU health policies on Task SHIfting: TaSHI
- A Roadmap OUT of mEdical deserts into supportive Health WorkForce initiatives and policies: ROUTE-HWF

MENTAL HEALTH

Mental health has always been on HOPE agenda and in 1999 HOPE started to organise annual seminars bringing together professionals, patients and institutions. The 2005 seminar in Dublin dealt with “Quality and Choice in Mental Health”.

In 2005 the European Commission published a Green Paper on Mental Health**.** In June 2006 HOPE reacted by releasing a Position Paper on the Green Paper on Mental Health welcoming the Commission initiative on this topic.

HOPE was a partner in the Joint Action on Mental health and Well-being, which ran from 2013 to 2016. The objective of the Joint Action was to contribute to the promotion of mental health and well-being, the prevention of mental disorders and the improvement of care and social inclusion of people with mental disorders in Europe.

HOPE is closely following this issue by regularly attending events organised at the European Parliament by the MEP Alliance for Mental Health (established in 2009 as the European Parliament Interest Group on Mental Health, Wellbeing and Brain Disorders).

On 24 October 2019, the Employment, Social Policy, Health and Consumer Affairs Council (EPSCO) adopted the Council conclusions on the Economy of Well-being, stating the importance of making "greater efforts to promote good mental health and to advance […] prevention".

On 18 February 2020, HOPE joined the event "Shaping the future EU Mental Health Strategy: priorities and activities" organised by the Coalition for Mental Health and Wellbeing in the European Parliament (coordinated by Mental Health Europe) and the MEP Alliance on Mental Health (coordinated by GAMIAN-EUROPE).

On 27 January 2021, HOPE attended Mental Health Europe (MHE), the Coalition for Mental Health and Wellbeing in the European Parliament and the Institute for European Environmental Policy (IEEP) online event to discuss the links between the natural environment and people's mental health in European policies. The event saw the launch of the mental health and environment policy paper and a policy brief by the IEEP and Barcelona Institute for Global Health.

On 5 February 2021, the European Commission requested an Opinion of the Expert Panel on Effective Ways of Investing in Health (EXPH) on how to support the mental health of health workforce and other essential workers.

The questions asked to the expert panel are:

- What are the specific factors influencing mental health of the health workforce and essential workers?
- What interventions could be effective in addressing mental health support needs of health workers and essential workers, including those with pre-existing mental health conditions? What are the conditions for the delivery of these interventions in a cost- effective, affordable, and inclusive manner? Using existing data, assess the cost of mental health problems in the health workforce and the cost-effectiveness of mental health interventions.
- How can the EU address these concerns?

On 31 May 2021, the 74th World Health Assembly took place. Delegates endorsed the Comprehensive Mental Health Action Plan 2013-2030, including the plan's updated implementation options and indicators. For the first time, the plan includes an indicator on preparedness for providing mental health and psychosocial support during emergencies.

On 14 October 2021, HOPE took part in a Politico event presented by Janssen Pharmaceutical Companies of Johnson & Johnson entitled: "Tackling mental health".

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 2021, many events could not take place, such as the 39th edition of the HOPE exchange programme, and others were held online, allowing HOPE to participate as a speaker or contribute to several international events.

HOPE AS A PARTNER – ONGOING PROJECTS

RE-SAMPLE

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

On 31 May and 2 June 2021, the RE-SAMPLE consortium held a series of online workshops and presentations. The partners recapped and celebrated the first achievements, as everyone has been working to submit the protocols for ethical approvals to launch the cohort study at the hospital sites.

HOPE attended another consortium meeting on 15 and 16 September 2021. Partners discussed the functioning of the RE-SAMPLE system and the definition of its components.

HOPE is communication and dissemination leader (WP8). The first deliverable was handed back, and several dissemination activities were performed in the year with the partners. The first newsletter of the project was released in October 2021. An explainer video was also produced in November 2021 and shared by HOPE on the RE-SAMPLE social media channels.

HOSMARTAI

Early 2021 marked the beginning of HosmartAI project within the European Union's Horizon 2020 programme (Grant Agreement No 101016834). HosmartAI – "Hospital Smart development based on AI" – aims to be the most relevant player for the digital transformation of the European Healthcare sector, to make the European healthcare system stronger, more efficient, sustainable and resilient. It kicked off online on 9-10 February 2021 with HOPE as one of the project partners.

The European healthcare system is facing challenges that are set to increase in the future. There is an increasing need for more efficient and improved diagnosis and treatment, for improved efficiency in hospital logistics, and for support in clinical procedures and in the process of caregiving or keeping the elderly at home for longer.

HosmatAI has been designed to address these challenges. It aims to build an "Ecosystem of Trust and Excellence" as part of a new European AI landscape. As such, the project will introduce digital and robot technologies into new healthcare settings and analyse the results. A platform will be set up for digital healthcare tool providers to design, develop and test AI solutions.

In this manner, HosmartAI endorses the idea and principles of Responsible Research and Innovation (RRI) during its lifetime. A user-centred and cross-disciplinary approach will be applied, involving stakeholders and citizens in this methodology in order to develop a Healthcare system accepted by end-users.

For the purpose of tackling the 5 healthcare domains mentioned, HosmartAI will incorporate 8 large-scale pilots that will involve 3,000 patients, 300 healthcare professionals, 600 stakeholders including healthcare managers in 5 different European countries (Belgium, Italy, Greece, Slovenia and Spain). Targeting differentiated medical aspects and manifestations such as cancer, gastrointestinal disorders, cardiovascular diseases, thoracic disorders, neurological diseases, elderly care and neuropsychological rehabilitation, fetal growth restriction and prematurity. Furthermore, to encourage the integration of innovative tech solutions into the HosmartAI framework and its overall application into new healthcare facilities, two open calls will be issued to academia and the research community. These calls will seek technology startups/ SMEs to solve particular HosmartAI challenges, to provide new technologies for the HosmartAI platform and to develop new pilots. The latter would adopt HosmartAI technologies and explore new uses and customers.

Coordinated by INTRASOFT International, the HosmartAI consortium consists of 24 leader entities in fields of research, healthcare, innovation and business, from 12 European countries. The consortium is represented by Universities and Research Centres (Vrije Universiteit Brussel, Aristotle University of Thessaloniki, ETH Zürich, Univerza v Mariboru, ITCL Centro Tecnológico), SMEs (Green Communications, Telematic Medical Applications, ECLEXYS, F6S, PharmEcons, Tera Globus, Ninety-One, EIT Health Germany), Associations (European Hospital and Healthcare Federation, European Federation of Medical Informatics), Hospitals and Healthcare Centres (UKC Maribor, San Camillo IRCCS SRL, Hospital Universitario La Paz, CHU de Liège, Panepistimiako Geniko Nosokomeio Thessalonikis AXEPA, Fundación INTRAS) and Large Enterprises (INTRASOFT International, PHILIPS, VIMAR energia positiva). They will provide the background for ensuring a great impact.

On 13 October, HosmartAI project released its first newsletter. It contains information about the HosmartAI project, its pillars, work carried out until now and the next steps to take. Additionally, to offer a broader range of knowledge and opportunities to subscribers, the newsletter provides the major news of the health and care cluster integrated projects.

ALADDIN

ALADDIN is 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 health care sector. However, due to the lack of knowledge, skills and its very complex value chain, requiring the cooperation of actors from different backgrounds, the technology has remained widely unexplored in the sector.

The project brings 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, 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 will develop until September 2022 a specific training programme in hospitals for health professionals working in hospitals and engineering students with a future in the health sector. It will also include a teaching guide and an e-Learning platform. In addition, three multiplier events will take place in three different countries (Belgium, Ireland, Spain) during the course of the project to present the training courses and ensure the project reaches the target groups.

HOPE will lead 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.

In the beginning of 2021, ALADDIN's consortium produced a survey to help design a training course for both health professionals working in hospitals (doctors, surgeons, anaesthetists, biotechnologists, lab technicians, etc.), and engineering students with future in the health sector. The technical partners consolidated the data gathered from this survey into four different modules addressing the key priorities of the target audience into an eLearning platform supported by Moodle.

The project's third consortium meeting took place on 29 November 2021. Delegates discussed progress in training design in the run-up to 2022.

ALADDIN newsletters were released in May 2021 and in September 2021.

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. It will:

- 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 will participate in the dissemination activities, contribute to the analysis of the COVID-19 pandemic effects on health systems, support the creation of a public engagement platform for decision making and it will help to develop training and education for health workers, patients and health authorities.

The PERISCOPE project produced various outputs during 2021. The project released several podcasts, at least one every month. HOPE hosted one of these podcasts in the summer which focused on the effects of the pandemic on mental health.

In March 2021, the project finalised a conceptual framework for the classification and impact assessment of policy measures adopted in Europe since the start of the COVID-19 pandemic.

On 9 March 2021 PERISCOPE joined a COVID-19 crisis management project cluster, along with other EU-funded H2020 projects focusing on behavioural and social impacts of the pandemic and its management actions. This collaboration started with a workshop on 19 April 2020 with the projects: RESPOND, COVINFORM, RESISTIRE and SHARE-COVID. The workshop targeted the four key issues investigated across all of the projects involved: governance, socioeconomic consequences of the pandemic, vulnerability and communication and dissemination. The goal was to learn about the data used to better complement each other and enhance collaboration, as well as how to boost communication with the public and target audiences.

In June 2021, HOPE attended two PERISCOPE workshops. The first took place on 16 June 2021, entitled "Impacts of COVID-19 on mental health and well-being: From understanding risks to building resilience". The second took place on 24 June 2021 and explored "Holistic Guidance for Policymakers on Pandemic Response".

On 29 September 2021, HOPE attended a PERISCOPE workshop on the "impact of COVID-19 on health inequalities in Europe".

In November 2021, the project launched its COVID-19 Atlas, a tool that provides advanced visual analytics about several aspects of the pandemic, with a focus on its impact on health, economics and society.

In June 2021, the first PERISCOPE newsletter was released. The second newsletter was issued on 29 of December 2021.

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 suffering from Alzheimer's, Parkinson's, or cardiovascular diseases.

By combining user-friendly software and devices, our 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.

The first of three piloting waves has already taken place in 5 institutions in Spain, Slovenia, Italy, and Germany. 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 our approach complies with rigorous ethical guidelines.

HOPE helped lay the groundwork for communication and dissemination. HOPE produced recruitment materials for user partners and ensure that all communication channels remain updated and provide timely updates. In addition, we provide content and facilitate inter-project and inter-organization collaborations. Such efforts have led to speaking engagements in webinars organised by the World Health Organization, PlatformUptake.eu (a fellow EU project), among others.

Besides our weekly contributions to communication and dissemination, we also contribute to project standardisation, so that by the end of the three-year cycle, TeNDER's integrated care model can be used beyond the pilot settings.

HOPE also releases a TeNDER newsletter twice a year packed with news, partner information, and the latest blog posts.

HOPE AS AN ADVISOR

SPHINX

In April 2019, HOPE joined the Advisory Board of SPHINX – A Universal Cyber Security Toolkit for Health-Care Industry.

Hospitals and care centres are prime targets for cyber criminals, especially concerning data theft, denial-of-service and ransomware. This reflects the need of Healthcare Institutions for a Holistic Cyber Security vulnerability assessment toolkit, which will be able to proactively assess and mitigate cyber-security threats known or unknown, imposed by devices and services within a corporate ecosystem. SPHINX aims to introduce a Universal Cyber Security Toolkit, thus enhancing the cyber protection of Health IT Ecosystem and ensuring the patient data privacy and integrity. It will provide an automated zero-touch device and service verification toolkit that will be easily adapted or embedded on existing, medical, clinical or health available infrastructures, whereas a user/admin will be able to choose from a number of available security services through SPHINX cyber security toolkit. It will enable service providers to specify complete services and sell or advertise these through a secure and easy to use interface. Furthermore the SPHINX Toolkit will be validated through pan-European demonstrations in three different scenarios. The operational properties of the proposed cyber-security ecosystem and overall solution will be validated and evaluated against performance, effectiveness and usability indicators at three different countries (Romania, Portugal and Greece). Hospitals, care centres and device manufacturers participating in the project's pilots will deploy and evaluate the solution in business-as -usual and emergency situations across various use case scenarios.

In order to maximise user influence on project developments at all levels, an advisory board will be set up. Participation in the SPHINX Advisory Board will be mainly for prospective end users and for members of projects (ongoing or finished) in the domain of surveillance, Wide zones protection and impact assessment of security systems.

In 2021, SPHINX was recognised by the Innovation Radar of the European Commission for Excellent Innovations. The Innovation Radar is an initiative to identify high potential innovations and innovators in EU-funded research and innovation projects. The SPHINX Toolkit and 19 individual notable results among project's outcomes have been "picked up" on the radar as key innovations.

On Thursday, April 15, 2021, the sister-project CUREX, hosted the online workshop "Human-Centric Cyber Hygiene in Healthcare". The event was a synergy action as PANACEA, ProTego, ASCLEPIOS, and SPHINX projects are the co-organisers.

Healthcare organisations in Greece, Romania and Portugal provided segregated access to part of their infrastructure for the deployment and evaluation of specific SPHINX Toolkit functions according to pre-defined use-cases. Technical partners and pilot end-users set the key performance indicators to assess the Toolkit's tests in these pilot cases while training sessions were scheduled to fully prepare pilot participants on how to operate the prototype. User manuals, demo videos and presentations were produced by the developers of the SPHINX platform, so that tailored training activities could take place before the actual pilots.

EUNETHTA 21 - HEALTH TECHNOLOGY ASSESSMENT – JOINT ACTION 4

HOPE was invited to the first virtual EUnetHTA 21 Stakeholder Meeting on 3 December 2021. EUnetHTA Joint Action 3 came to an end and the EU is now entering a new phase of European HTA cooperation.

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. It is led by ZIN (The Netherlands) and includes the following HTA agencies: AEMPS (Spain), AIFA (Italy), AIHTA (Austria), GBA (Germany), HAS (France), INFARMED (Portugal), IQWIG (Germany), KCE (Belgium), NCPE (Ireland), NIPN (Hungary), NOMA (Norway) and TLV (Sweden). The contract will run for 24 months until 16 September 2023. EUnetHTA 21 will build on the achievements and lessons learned from the EUnetHTA Joint Actions and focus on supporting a future EU HTA system under the HTA Regulation.

Following an update on the HTA Regulation and next steps by Flora Giorgio (DG SANTE), the meeting introduced the EUnetHTA 21 as a consortium, its general governance principles and how it envisions future stakeholder interaction.

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 France by the INSERM (French National Institute for Health and Medical Research) in 1997. 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.

PHIRI: POPULATION HEALTH INFORMATION RESEARCH INFRASTRUCTURE

On 14 January 2021, HOPE joined the first edition of the Stakeholder Meeting 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 scientific activities of the project, presenting PHIRI activities relevant to researchers across Europe.

On 30 November 2021, HOPE attended the "PHIRI 1 YEAR" event. The event gathered speakers from key national and international organisations including the World Health Organisation (WHO), the Organisation for Economic Co-operation and Development (OECD), the European Commission, the Joint Research Centre (JRC), the European Centre for Disease Prevention & Control (ECDC), the European Observatory on Health Systems and Policies... The key outcomes of the project were showcased and put into perspective to stimulate discussion about three core PHIRI themes : 1. Crisis preparedness & rapid policy and research response; 2. Research questions on the impact of COVID-19 on population health and future scenarios; 3. A common vision on the future of facilitating the secondary use of health data. A video displaying the main achievements of the first year was shown at the event.

TEHDAS: TOWARD A EUROPEAN HEALTH DATA SPACE

HOPE has been selected 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 will focus on the following themes:

- a governance model for cross-border co-operation 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 will be to build a European governance model for the use of health data. The model could include creating a completely new organisation or incorporating the duties into existing EU institutions and organisations.

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

The TEHDAS joint project is based on the EU Health Programme 2020, which specifies the objectives and budget of the project.

HOPE has been selected to participate as a stakeholder in TEHDAS Joint Action in the Stakeholder forum and in the WP4 Policy forum. 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.

On 27 October 2021, TEHDAS organised its first stakeholder forum, which HOPE attended. The event gathered over 450 participants online and the discussions highlighted the need for common European guidelines for health data access and use, and closer collaboration with individuals.

Panellists stressed that EU Member States currently interpret the General Data Protection Regulation (GDPR) in the context of scientific research and decision-making in different ways, leading to fragmentary and uncoordinated approaches. The European Commission's upcoming legislative proposal on European Health Data Space is expected to harmonise the situation and bring about greater sustainability in the secondary use of health data. The EU's digital COVID certificate was discussed as an example of a policy decision with direct practical effects to people's lives. The debate also emphasised the importance of engaging individuals in sharing their health data for secondary purposes, such as research for new medicines. In the most personal exchange of the day, Birgit Bauer, Digital Health and Social Media Expert who has Multiple Sclerosis, spoke about the importance of sharing data from the patients' perspective and stressed that patients can be supported by directing them to verified sources of information about their disease. She said that the need for sharing health data is not that evident when a person is healthy, which is why communication about the tangible benefits of data use is essential. Rosie Richards, Assistant Director, NHS Confederation, European Office added that public trust is essential in this process and that citizen engagement needs to be front and centre.

On 14 December 2021, TEHDAS launched a consultation for European citizens in order to find out what they think about how their health data could be used in the future. The results will support recommendations made by the TEHDAS project to the European Commission and to the Member States. The consultation is being organised by three TEHDAS partners: public health research institute Sciensano (Belgium), Health Data Hub (France) and the NHS Confederation (United Kingdom).

COMPLETED PROJECTS

IPAAC—INNOVATIVE PARTNERSHIP FOR ACTION AGAINST CANCER

Funded under the Third Health Programme of the European Commission., the general objective of the iPAAC Joint Action (JA) is to develop innovative approaches in cancer control. The innovation that will be covered within the JA consists of: further development of cancer prevention, comprehensive approaches to the use of genomics in cancer control, cancer information and registries, improvements and challenges in cancer care, mapping of innovative cancer treatments and governance of integrated cancer control, including a new analysis of National Cancer Control Plans.

A key added value of the iPAAC is to support Member States in implementing recommendations from the iPAAC and CANCON. Additionally, iPAAC will provide better efficacy for dealing with neglected cancers through development of new key indicators to assess clinical patient pathways and healthcare-related costs of cancer and its interventions, particularly in the case of pancreatic cancer.

As part of work package 5, HOPE attended a webinar on Cancer Screening held on 14 January 2021 under the umbrella of the Innovative Partnership for Action Against Cancer (iPAAC) joint action. According to the results of work package 5, the current screening programmes are suboptimally implemented when looking at the European level. The work package identified several recommendations: Look for solutions to disparities between Member States and regions, between various population groups within the Member States and focus more on specific vulnerable groups; Priority area in this respect is HPV vaccination and improving governance of existing screening programmes; In risk-adjusted modifications of screening programmes, these modifications should be well-controlled and gradual, including testing effectiveness with indicators, such as the rate of advanced cancers, survival and quality of life after treatment.

On 21 April 2021 HOPE participated in the stakeholder forum of the joint action iPAAC. The stakeholder forum brings together iPAAC's collaborating partners (HOPE being one of them) and representative of related projects and initiatives. These annual meetings brief these partners on the project's development and progress, provide input to support the project and share views on iPAAC deliverables. The Roadmap on Implementation and Sustainability of Cancer Control Actions was presented before the participants joined breakout sessions.

On 30 September, HOPE attended the event “Governance of Integrated and Comprehensive Cancer Care – the case for Comprehensive Cancer Care Networks” organised by the European Cancer Patient Coalition on the behalf of the Joint Action Innovative Partnership for Action Against Cancer (iPAAC). The event aimed at discussing the ‘Recommendations from the iPAAC Joint Action how to tackle challenges in Cancer Care and improve its governance in the EU’.

On 13 and 14 December 2021, HOPE attended iPAAC's Final Conference 'Cancer Control in Europe: Finding Sustainable Solutions' which took place in Ljubljana and virtually as a parallel event of the Slovenian Presidency of the Council of the EU. The aims of the conference were to discuss and showcase the results of the iPAAC Joint Action, to assess progress on improving cancer control in Europe and to consider policy opportunities and priorities for advancing cancer prevention and health promotion in Europe. Four sessions took place on the first day: Cancer prevention and early detection; Innovation towards the future; The role and development of cancer registries; Cancer survivorship and the right-to-be-forgotten. Five sessions followed on the second day: Challenges in cancer care; Governance of comprehensive cancer care; Launch of the iPAAC Roadmap on Implementation and Sustainability of Cancer Control Actions; Action, cooperation and implementation at European Union and Member States level of the recommendations of the three cancer control Joint Actions; Future challenges in Cancer Policy and Cancer Control at Member States level.

EU-JAMRAI

HOPE contributed to the Joint Action on Antimicrobial Resistance and Healthcare Associated Infections (JAMRAI) which was launched on 1 September 2017 and was supposed to end in 2020 but was extended to 28 February 2021. EU-JAMRAI is a collaborative project built on existing works and initiatives by Member States and international organisations (OECD, ECDC, WHO Europe, OIE and FAO).

The Joint Action looked at the best programmes in each country and propose concrete steps to implement best practices to tackle antimicrobial resistance (AMR) and Healthcare-associated Infections (HCAI), so that good intentions lead to practical action shared by the Member States. EU-JAMRAI aimed at joining forces to draw up common European policies to fight AMR and HCAI in line with the One Health approach and ongoing EU and international policies.

On 11 and 12 February 2021, HOPE attended the EU-JAMRAI final conference. On the first day, the main achievements were summarised by stakeholders involved in the Joint Action. They first showed how networks have been strengthened and Member States have shared best practices with EU-JAMRAI. In brief, EU JAMRAI has highlighted the need for Member States to collaborate in a process of self-assessment, country-to-country visits and the elaboration of common indicators and targets. In addition, the two cases of Italy and Poland were presented. The second session addressed how EU-JAMRAI has aimed to increase awareness about AMR and the concrete actions which have been supported by stakeholders. Among others, campaigns on social media were launched, a tangible symbol was created and a micro combat app was set up. On the second day, a first session discussed differences and obstacles regarding the implementation of national programmes and proposed solutions to improve Antibiotic Stewardship across Europe. The second session focused on Infection Prevention and Control (IPC) and addressed the contribution of EU-JAMRAI in implementing guidelines framework to make IPC more effective. Speakers first debated the positive and negative impact of the COVID-19 pandemic on IPC. Then they discussed the main achievements, challenges and future prospects regarding the implementation of guidelines on IPC.

On 14 April 2021, the European Joint Action on Antimicrobial Resistance and Healthcare Associated Infections (EU-JAMRAI) released an EU-JAMRAI Layman Report with a full overview of the main outcomes and results of the EU-JAMRAI.

INTERNATIONAL INSTITUTIONS

WHO EUROPE

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 WHO/Europe website.

The WHO encourages HOPE to strengthen its collaboration with WHO/Europe technical units and country offices.

For HOPE the work with WHO Europe mainly started after 1989 with conferences "East meets West" and a programme of twinning's of hospitals 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.

The first collaboration HOPE envisages with the Regional Office for Europe in 2020–2022 would be on health workforce. This would involve working on the extension of the Framework for Action Towards a Sustainable Health Workforce in the WHO European Region and in addition working on the mobility of healthcare professionals, on the basis of the WHO Global Code of Practice on the International Recruitment of Health Personnel. The second area for collaboration would be on integrated care and more generally the coordination between the different health and social care actors around patients and their families. The entry point of this collaboration would be the content of the resolution on 10 evidence-based policy accelerators for strengthening primary health care in the region. Additionally, HOPE will continue its ongoing engagement and contribution to i) the consultation of the European Framework for Action on Integrated Health Services Delivery and ii) the Primary Health Care Advisory Group.

Exchange Programme

HOPE EXCHANGE PROGRAMME 2021– POSTPONED

European hospital and healthcare services are at the forefront of the battle against COVID-19. Drawing on a risk assessment, HOPE's Board of Governors decided to postpone the HOPE Exchange Programme along with the associated HOPE Agora (for the first time since its creation 40 years ago) to 2022.

NEWS FROM HOPE EXCHANGE PROGRAMME 2019

HealthPros
International Training Network for Healthcare Performance Intelligence Professionals

HOPE organised on 26 February 2021 a webinar "Beyond hospital data: COVID19-related data integration between hospitals and other health care organisations".

It was an opportunity for Damir Ivankovic to share the results of the short survey sent to HOPE Exchange participants and hosts 2019 and 2020.

A panel to discuss those results was moderated by Niek Klazinga, professor of Social Medicine at the Amsterdam UMC University Medical Centre of the University of Amsterdam and head of the Health Care Quality Indicator (HCQI) work of the OECD. HOPE has been collaborating with Prof. Klazinga and his team of PhD Fellows from the HealthPros programme for over two years. Four HOPE national coordinators agreed to share their views in the panel: Siobhan Regan (IE), Ton Roelofs (NL), Sofia Oliveira (PT) and Ieva Lejniece (LV).

Following introductions, the panel was structured in two parts. The first was a general discussion, focused on the survey results and reflecting on the (increasing) level of collaboration between hospitals and other stakeholders in the health care sector, as well as the nature and sustainability of this collaboration. ("What do you think of these results?", "Do you feel these results reflect the situation in your hospital / country?", "Why has the data exchange with public health institutions increased more than that with primary care providers?").

The second part of the panel was focused on data infrastructure and governance needed for more / better collaboration ("What is the interaction of hospital data infrastructure with that of other stakeholders?", "Are there mutual / shared databases?", "Are you able to 'pull' data from these?", "How would you characterise the integrativeness of your data infrastructure?").

Conferences

CONFERENCES CO-ORGANISED BY HOPE

THE NATIONAL SAFETY PROGRAMME IN THE NETHERLANDS

On 26 January 2021, HOPE co-hosted the webinar "The Dutch Hospital Patient Safety Programme". The other co-host was PAQS (Plateforme pour l'Amélioration continue de la Qualité des soins et de la Sécurité des patients).

This was the sixth webinar of the Quality & Safety Network series whose purpose is to promote and share best practices and experiences across Europe in the area of quality of care and patient safety. The webinar presented the Dutch Hospital Patient Safety Programme, introducing its implementation, outcomes and impact.

EURORDIS BLACK PEARL AWARDS

HOPE joined the organisation of the EURORDIS Black Pearl Awards, an annual awards ceremony that 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 2021, the event celebrated its 10th anniversary and took place online on 24 February.

FIFTEEN YEARS OF THE SPANISH PATIENT SAFETY STRATEGY: PITFALLS AND LESSONS LEARNED

On 20 April 2021, HOPE co-hosted the seventh webinar of the Quality & Safety Network series with PAQS (Plateforme pour l'Amélioration continue de la Qualité des soins et de la Sécurité des patients). Dr. Yolanda Agra Varela, PhD, MHs General Direction of Public Health Spanish Ministry of Health, provided an overview of the evaluation of the Spanish Patient Safety Strategy implemented since 2005.

WEBINAR: EU-UK TRANSFERS OF DATA: IMPLICATIONS FOR THE EUROPEAN HEALTHCARE SECTOR

This event was organised by the European Health Stakeholder Group on 6 May and tackled the challenge of international transfers of personal health data between the EU and the UK. The session focused on the importance EU-UK data transfers for the European health care sector, considered the likelihood of the UK being awarded adequacy, and raised awareness of additional steps health organisations will need to consider if adequacy is denied.

HEALTH AND CLIMATE CHANGE: COMMON CHALLENGES, COMMON SOLUTIONS?

On 6 May 2021, HOPE helped organise an online event entitled “Health and Climate Change: Common Challenges, Common Solutions?”. The event was organised by Decide Health Decision Hub and the Council of Europe Development Bank.

GDPR AND CYBERSECURITY IN HEALTHCARE

HOPE supported the organisation of the conference “GDPR and cybersecurity in healthcare“, which took place on 25 May 2021.

The online conference was organised by the Polish Hospital Federation, as part of the “GDPR in Health” cycle. The conference had the following aims: set up a platform to share knowledge and experience about applying the GDPR in the medical sector and about good practices in the field of data security; coordinate activities and initiatives related to the protection of personal data and cybersecurity standards in the medical sector; increase the awareness of patients and healthcare personnel about personal data protection.

PORTUGUESE PATIENT SAFETY CULTURE ASSESSMENT: LESSONS LEARNED

On 15 June 2021, HOPE co-hosted the eighth webinar of the Quality & Safety Network series with PAQS (Plateforme pour l'Amélioration continue de la Qualité des soins et de la Sécurité des patients). Margarida Eiras, Executive Board Member of the Portuguese Association for Hospital Development (APDH) presented the lessons learned from the Portuguese Patient Safety Culture Assessment.

28TH INTERNATIONAL CONFERENCE ON HEALTH PROMOTING HOSPITALS AND HEALTH SERVICES

HOPE supported the organisation of the 28th International Conference on Health Promoting Hospitals and Health Services (HPH) that took place online on 12 October 2021 was broadcasted from Paris. It is a forum of learning and exchange on health promotion in and by health services for HPH members, health professionals, consultants, researchers, academics and policy makers with 500 delegates on average per year.

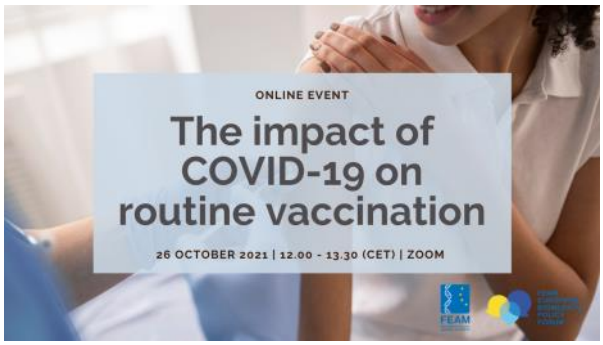
The main theme of the 2021 conference was "Development of health-oriented health care management systems".

QUALITY MANAGEMENT SYSTEM AS A BASIS FOR PATIENT SAFETY IN ESTONIA

On 12 October 2021 PAQS and HOPE organised the ninth Quality and Safety Network webinar "Quality management system as a basis for patient safety in Estonia".

Teele Orgse, Chief Quality Officer, MD, Pärnu Hospital gave an overview of patient safety activities in Estonian hospitals based on a study conducted in 2021 about quality management systems in Estonia.

FEAM FORUM EVENT: THE IMPACT OF COVID-19 ON ROUTINE VACCINATION



On 26 October, HOPE helped organise a FEAM European Biomedical Policy Forum event on "The impact of COVID-19 on routine vaccination". Experts from European authorities and stakeholders provided an overview on the impact that COVID-19 had on routine vaccination and on lessons learned from this pandemic, in order to improve planning and communication about vaccines across Europe.

APDH – CONFERENCE: "NEW TIMES. NEW CHALLENGES"

HOPE supported the organisation of the Conference "New Times. New Challenges" organised by APDH (the Portuguese Association for Hospital Development), which took place online on 22-23 November 2021. The event had over 1,450 live accesses and feedback was excellent and of great value. HOPE CEO Pascal Garel was a speaker in the Opening Ceremony of the Conference.

FEAM FORUM ANNUAL LECTURE: FASTENING EU DRUG DEVELOPMENT

On 25 November, FEAM European Biomedical Policy Forum organised a discussion on how we can accelerate the process of drug production in the European Union. Experts looked at how the EU drug development could function more efficiently, identifying challenges and lessons learned to date, especially in light of the COVID-19 pandemic.

CAPTURING THE PATIENTS' VOICES ON PATIENT SAFETY

On 14 December 2021, HOPE and PAQS organised the 10th Quality and Safety Network webinar. Quentin Schoonvaere described how the Patient Reported Incident Measure (PRIM) can help capture patients' voices to improve patient safety and gave an overview of preliminary results of this survey conducted among the Belgian-French speaking population.

EXAMPLES OF CONFERENCES WITH HOPE AS A SPEAKER

EASAC-FEAM WEBINAR ON "DECARBONISATION OF THE HEALTH SECTOR"

On 10 May 2021, HOPE CEO Pascal Garel was a member of the panel of the EASAC-FEAM webinar on "Decarbonisation of the Health Sector".

In this 90-minute webinar the European Academy networks EASAC and FEAM presented their latest commentary on the Decarbonisation of the Health Sector. It was followed by a presentation on principles and value of decarbonising the health sector by Professor Andrew Haines, London School of Hygiene and Tropical Medicine. This was followed by a presentation of “Commentary: How can EU policy-makers help the health sector achieve ambitious targets for decarbonisation (and improving health)?” by Dr Robin Fears, EASAC Biosciences Programme Director.

The commentary was discussed by a panel of subject-matter experts and relevant stakeholders moderated by Dr Rosa Castro, FEAM, with:

- Maria Nilsson, Professor at Department of Epidemiology and Global Health, Umeå University;
- Scott Brady, Climate Programme Manager, Health Care Without Harm Europe;
- Pascal Garel, HOPE CEO;
- Kirsty Reid, Director Science Policy at European Federation of Pharmaceutical Industries and Associations.

EQUINET WEBINAR - HEALTHCARE SERVICES AND SYSTEMIC EQUALITY: UNPACKING CHALLENGES’

On 28 June 2021, HOPE CEO Pascal Garel spoke at the third webinar ‘Healthcare services and systemic equality: Unpacking challenges’ hosted by Equinet as part of a webinar series ‘Equality, Diversity, and Non-Discrimination: Tackling systemic inequalities for a more egalitarian access to healthcare’. The event was moderated by Moana Genevey, Policy Officer at Equinet. The speakers discussed barriers and solutions to the unequal and discriminatory access to healthcare services, notably by considering the potential roles of Equality Bodies.

OUR HOSPITAL – CONFERENCE – BUCHAREST (ROMANIA)

HOPE CEO was invited to speak at the 6th edition of ROHO International Hospital Convention, which took place in Bucharest (Romania) and virtually on 23 September 2021. The main topic of the 2021 edition was "Our Hospital", being dedicated to the vital role of hospitals within the communities and to the recent major healthcare challenges.

The presentation in "European Major Healthcare Challenges" session was delivered by leaders of international, European and national organisations in the field of quality management in health in Belgium, France, Denmark, Bulgaria and Romania.

HOPE CEO addressed the major health issues caused by the COVID-19 pandemic in the European context, answering several key questions: What are the current health challenges? What problems has the pandemic caused? What solutions have been identified and what opportunities for the development of European medical systems have emerged in the new context?

HOSPITAL PHARMACISTS – OATH TO SOCIETY

HOPE CEO spoke at the event organised on 12 October 2021 in Brussels to celebrate the "Oath to Society" developed by the European Association of Hospital Pharmacists (EAHP) and the European Society of Clinical Pharmacy (ESCP).

Both organisations have collaboratively developed the document that acts as a contract for excellence in providing compassionate patient care, working as part of the healthcare team and advancing the pharmacy profession, and showcasing how clinical and hospital pharmacists work every day.

The Oath to Society is the promise that the members of EAHP and ESCP make to patients and the public they serve, the healthcare professionals they interact with and the health systems they work in. The Oath functions as a compass for pharmacists to adhere to the highest standards of ethics, integrity and professionalism, as they provide service to the community over the course of their careers. Touching on trust and respect, different aspects of the patient care pathway, the multidisciplinary care team, disease prevention and health promotion, education and the future development of pharmacy practice, the Oath to Society is all-encompassing.

Chapter 4

PUBLICATIONS

In 2021, the new edition of Hospital Healthcare Europe 2021 was released online.

HOPE answered consultations on European Health Data Space, Urban Wastewater Treatment Directive and the Pharmaceutical legislation and released Position Papers and press releases on other topics such as: Artificial Intelligence, cross-border healthcare Directive, cross-border health threats, e-evidence, pharmaceutical strategy and Horizon Europe.

HOPE also provided members with two Strategic Notes on cancer and EU funding programmes.

Publications

In 2021, HOPE central office produced for internal use 11 HOPE Monthly Newsletters and 29 COVID-19 Updates (weekly and then bi-monthly). For external use, 11 HOPE News and Updates were released. HOPE also regularly fed its social media channels with updates about EU Policies, campaigns and events. Through the year, HOPE posted 209 tweets and also retweeted many relevant posts, 21 posts on Facebook and 65 posts on LinkedIn.

HOSPITAL HEALTHCARE EUROPE 2021

In December 2021, the latest issue of Hospital Healthcare Europe was released online.

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.

The 2021 issue focuses on COVID-19 and cancer.

POSITION PAPERS

HOPE CONTRIBUTION TO THE ROADMAP ON A EUROPEAN HEALTH DATA SPACE

In February 2021, HOPE published its contribution to the Roadmap on a European Health Data Space. Released by the European Commission in December 2020, the Initiative aimed to : promote safe exchange of patients' data (including when they travel abroad) and citizens' control over their health data; support research on treatments, medicines, medical devices and outcomes; encourage the access to and use of health data for research, policy-making and regulation, support digital health services and clarify the safety and liability of artificial intelligence in health.

HOPE welcomed this Roadmap as an opportunity to further clarify certain aspects, in particular as the Commission mentions its priority to reduce inequalities, which are especially important in terms of digital access and digital literacy.

HOPE POSITION PAPER ON ARTIFICIAL INTELLIGENCE

In April 2021, the European Commission unveiled a proposal for a new Artificial Intelligence Act (AI Act) aiming to enshrine in EU law a technology-neutral definition of AI systems. The Commission proposed to adopt different set of rules tailored on a risk-based approach with four levels of risk.

In May 2021, HOPE released a Position Paper stating that AI uses in the healthcare field would require a specific regulatory approach, in addition to strong horizontal cross-sector regulation of AI. HOPE's key recommendations to ensure that the application of AI in healthcare benefit patients and consumers are as follows: a definition of Artificial intelligence for health care agreed at EU level; action on AI built on clear citizens' rights (and not only when they are patients); professionals prepared for and trained in AI ; good quality AI and adapted legislation.

COALITION FOR VACCINATION MANIFESTO

On 9 February 2021, the Coalition for Vaccination published a manifesto to encourage healthcare professionals to get vaccinated against COVID-19. The manifesto highlights three key reasons why all healthcare professionals should get vaccinated against COVID-19 when they have the opportunity to do so and why they should help promote the vaccination against COVID-19 among the general public: 1) To protect themselves from illness and possible severe or life-threatening complications; 2) COVID-19 vaccines are safe and effective; 3) To help safeguard healthcare capacity.

The Coalition for Vaccination brings together European associations of healthcare professionals and relevant students' associations in the field, as well as associated professional organisations working in the field of public health and immunisation, including HOPE.

HOPE POSITION PAPER ON THE EVALUATION OF THE DIRECTIVE ON CROSS-BORDER HEALTHCARE

In May 2021, HOPE published a position paper on cross-border healthcare. Indeed, the evaluation of the Directive 2011/24/EU and its interaction with other legislation, in particular, Regulation (EC) No 883/2004 on the coordination of social security systems, provides an opportunity to propose elements for adapting existing mechanisms.

In its position, HOPE suggests that hospitals should be able to bill crisis-related, cross-border treatments as emergencies via the European Health Insurance Card procedure, if the cross-border treatments are officially released by the competent authority.

HOPE POSITION PAPER ON THE PROPOSAL FOR A REGULATION ON SERIOUS CROSS-BORDER THREATS TO HEALTH AND ON THE MANDATE OF THE ECDC

On 11 November 2020 the European Commission proposed three regulations: the proposal for a Regulation on serious cross-border health threats, the proposal for a Regulation to extend the mandate of the European Centre for Disease Prevention and Control, and the proposal for a Regulation to extend the mandate of the European Medicines Agency. A Communication "Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats" was also published the same day.

In May 2021, HOPE published a Position Paper stating that Member States are and should remain responsible for organising their social protection and healthcare systems. The EU health policy should continue to supplement and support Member States in a meaningful way. In addition, it is essential that administrative and financial repercussions on hospitals and healthcare services resulting from new EU legislation are thoroughly scrutinised, evaluated and made transparent by the European legislator in terms of their added value.

HOPE CONTRIBUTION TO THE EUROPEAN COMMISSION CONSULTATION ON A EUROPEAN HEALTH DATA SPACE

In July 2021, HOPE released its contribution to the European Commission Consultation on a European Health Data Space. The consultation was launched by the European Commission on 3 May 2021 and was open until 26 July 2021.

HOPE CONTRIBUTION TO THE EUROPEAN COMMISSION CONSULTATION ON THE REVISION OF THE URBAN WASTE WATER TREATMENT DIRECTIVE

From 28 April 2021 to 21 July 2021, the European Commission launched a Public Consultation on the Urban Wastewater Treatment Directive. This initiative aimed to revise the Directive after a recent evaluation of it identified certain shortcomings and new societal needs that must be addressed. In July 2021, HOPE contributed to the consultation and released a document with its contribution.

DEMONSTRATING GAPS IN THE E-EVIDENCE REGULATION

On 20 October 2021, ahead of the next meeting of the Council Working Party on Judicial Cooperation in Criminal Matters (COPEN) held on 27 – 29 October 2021, HOPE, with 13 other organisations, released a new publication which highlights the shortcomings of the Commission's eEvidence proposal with regard to the respect of fundamental rights. This new document gathers four practical examples of how the Commission's proposal could seriously undermine the work of journalists, the protection of sensitive health data, the freedom to protest in Member States with systemic rule of law issues and the right to a fair trial. The paper also suggests a series of recommendations to address the shortcomings identified.

JOINT POSITION PAPER ON THE PHARMACEUTICAL STRATEGY FOR EUROPE

In November 2021, the AMR Stakeholder Network drafted a position paper on the European Pharmaceutical Strategy endorsed by 18 organisations, including HOPE. All signatories are members of the AMR Stakeholder Network and committed to the One Health approach in tackling AMR.

This paper puts forward recommendations that should ensure that the vision laid out in the Pharmaceutical Strategy is turned into reality and concrete action, with sound monitoring of the ways in which they contribute towards combating this global health threat.

HORIZON EUROPE RESEARCH STATEMENT

On 8 December 2021, the European Health Stakeholders Group, a consortium of pan-European health membership organisations, including HOPE, collaborating on shared EU-UK health interests, released a position paper on Horizon Europe.

Horizon Europe aims to tackle the major European and global challenges of our time but achieving this aim will be impossible without international collaboration. The COVID-19 pandemic has clearly highlighted the critical value of global partnerships to advance scientific discovery and innovation. With this in mind, the European Health Stakeholders Group is calling for the UK's association to Horizon Europe to be formalised as soon as possible.

HOPE CONTRIBUTION TO THE CONSULTATION – PHARMACEUTICAL LEGISLATION

As part of the EU pharmaceuticals strategy, and drawing lessons from the COVID-19 pandemic, the Commission plans to evaluate and revise the EU's general legislation on medicines for human use to ensure a future-proof and crisis-resistant medicines regulatory system. The revision will aim to ensure access to affordable medicines; foster innovation, including in areas of unmet medical need; improve security of supply ; adapt to new scientific and technological development ; reduce red tape.

From 28 September 2021 to 21 December 2021, the European Commission launched a Public Consultation. In December 2021, HOPE contributed to the consultation.

ANALYSES - HOPE STRATEGIC NOTES

HOPE STRATEGIC NOTE - CANCER IN EU4HEALTH WORK PROGRAMME 2021

The Europe's Beating Cancer Plan put forward by the European Commission in February 2021 is developing measures to target healthcare and not only prevention. In September 2021, HOPE released a Strategic Note after extracting several cancer activities related to healthcare provision from the EU4health work programme 2021.. The point “2.4. Cancer: Ensuring access to high standard cancer care diagnosis and treatment” includes in particular six important initiatives related to healthcare.

HOPE STRATEGIC NOTE - EU FUNDING PROGRAMMES

As there are numerous EU funding programmes, which makes them hard to track, HOPE released in September 2021 a Strategic Note presenting a selection of the most important one classified by financial importance.

Framework enables Member States to ensure that enough liquidity remains available to businesses of all types and to preserve the continuity of economic activity during and after the COVID-19 outbreak.

General Report on the Activities of the European Hospital and Healthcare Federation 2021

hope

European Hospital and Healthcare Federation