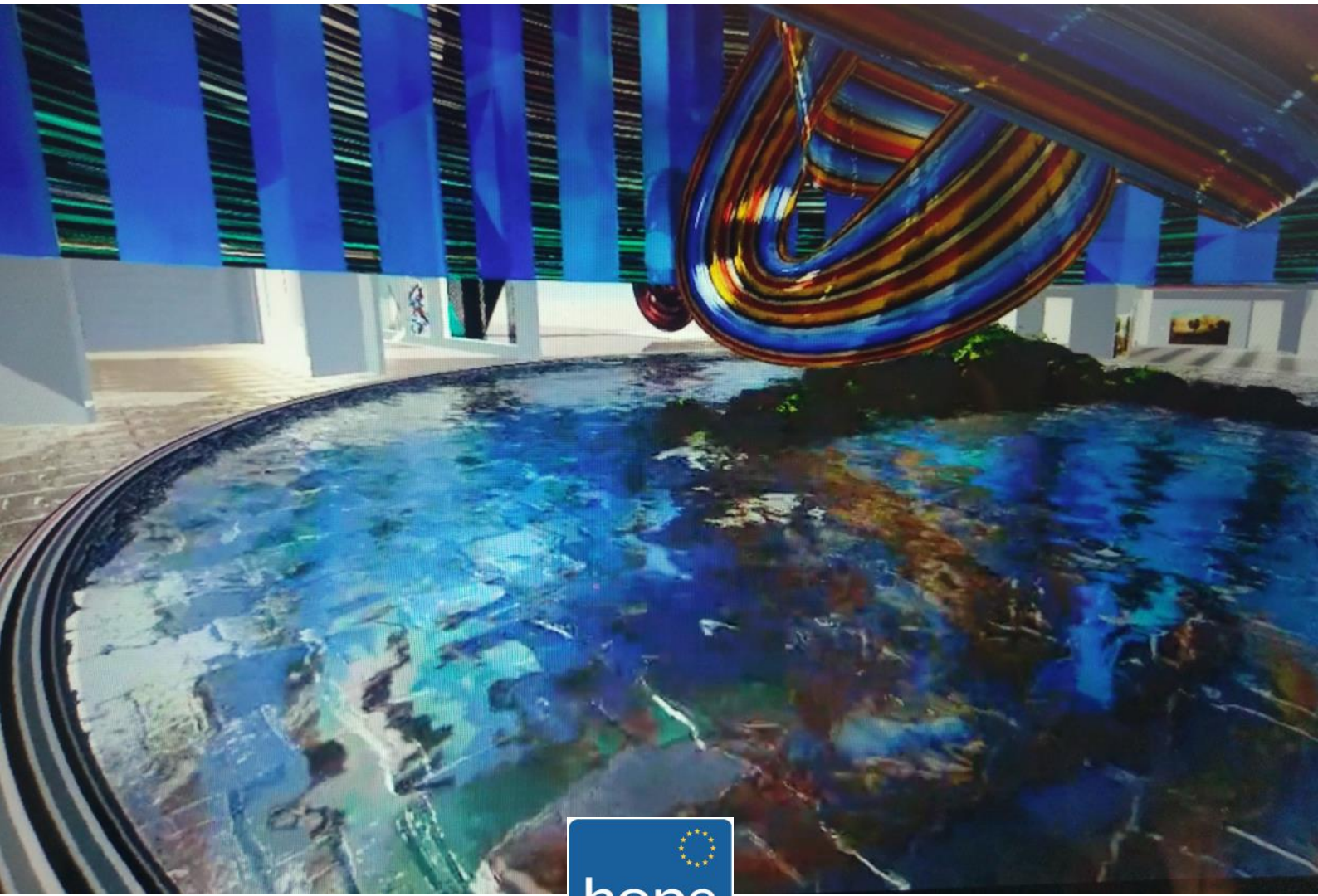
General Report

on the Activities of the

European Hospital and Healthcare Federation

2020



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Patients can choose and interact with the content projected.

Front page: Museum Illuminart le bassin
Illustration Chapter 1: Museum Illuminart salon de musique
Illustration Chapter 2: Museum Illuminart exposition peinture paysage
Illustration Chapter 3: Illumin'art projection
Illustration Chapter 4: Museum Illuminart exposition peinture paysage
Back page: Illuminart Couverture

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General Report on the Activities of the European Hospital and Healthcare Federation — 2020

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2020

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Chapter 4

Introduction

The year 2020 was a very unique year in Europe and globally. The COVID-19 pandemic strongly impacted European health systems and economies, as well as daily life. The European hospital and healthcare services were and still are at the forefront of the battle against the outbreak of COVID-19. A large part of the European Institutions' activity in 2020 was dedicated to fighting the pandemic and its adverse effects.

In 2020, European politics were also strongly marked by the Brexit transition period negotiations. The negotiations started in March and were intensified through the summer. Major implications for patients and health and social care workers both in the UK and the EU27 were at stake. An agreement was finally reached on 24 December 2020.

On the legislative side, negotiations between the European Parliament and the European Council on Health Technology Assessment (HTA) were still running while the ground has been prepared for a legislative proposal on Artificial Intelligence to be released in early 2021.

Some past topics came back on the agenda due to the evaluation of current regulations, such as the Blood Tissue and Cells Directive, the GDPR, the Orphan Drugs Regulation, as well as environment-related topics: Energy Efficiency Buildings, Fluorinated Greenhouse Gases, Emissions Trading Scheme, Water Pollution.

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 Cybersecurity Package, eHealth, European Health Data Space, Antimicrobial Resistance, Vaccination, and the European Pillar of Social Rights, to name but a few.

New topics also came up: Cancer, Pharmaceutical Strategy, Ageing, Farm-to-Fork Strategy or Climate and health.

In 2020, HOPE also contributed to the EU non-legislative agenda through several European projects. The projects EURIPHI on value-based procurement and MedEye on medication safety reached their final stages while TeNDER, about digital tools applied to integrated care and which started in 2019, further developed its activities in 2020 with HOPE as a partner. Two new projects kicked off in November 2020: PERISCOPE, focusing on pan-European response to COVID-19 and future pandemics and epidemics, and ALADDIN, which aims to develop a specific training programme on additive manufacturing in hospitals. Three other applications were successful in 2020 and will start in 2021.

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.

The HOPE Exchange Programme for healthcare professionals (and subsequently the HOPE Agora) was postponed for the first time since its creation 40 years ago, due to the COVID-19 outbreak.

Lastly, HOPE published a report: Hospital Healthcare Europe 2020, which was released in December 2020 and focuses on COVID-19 and cancer.

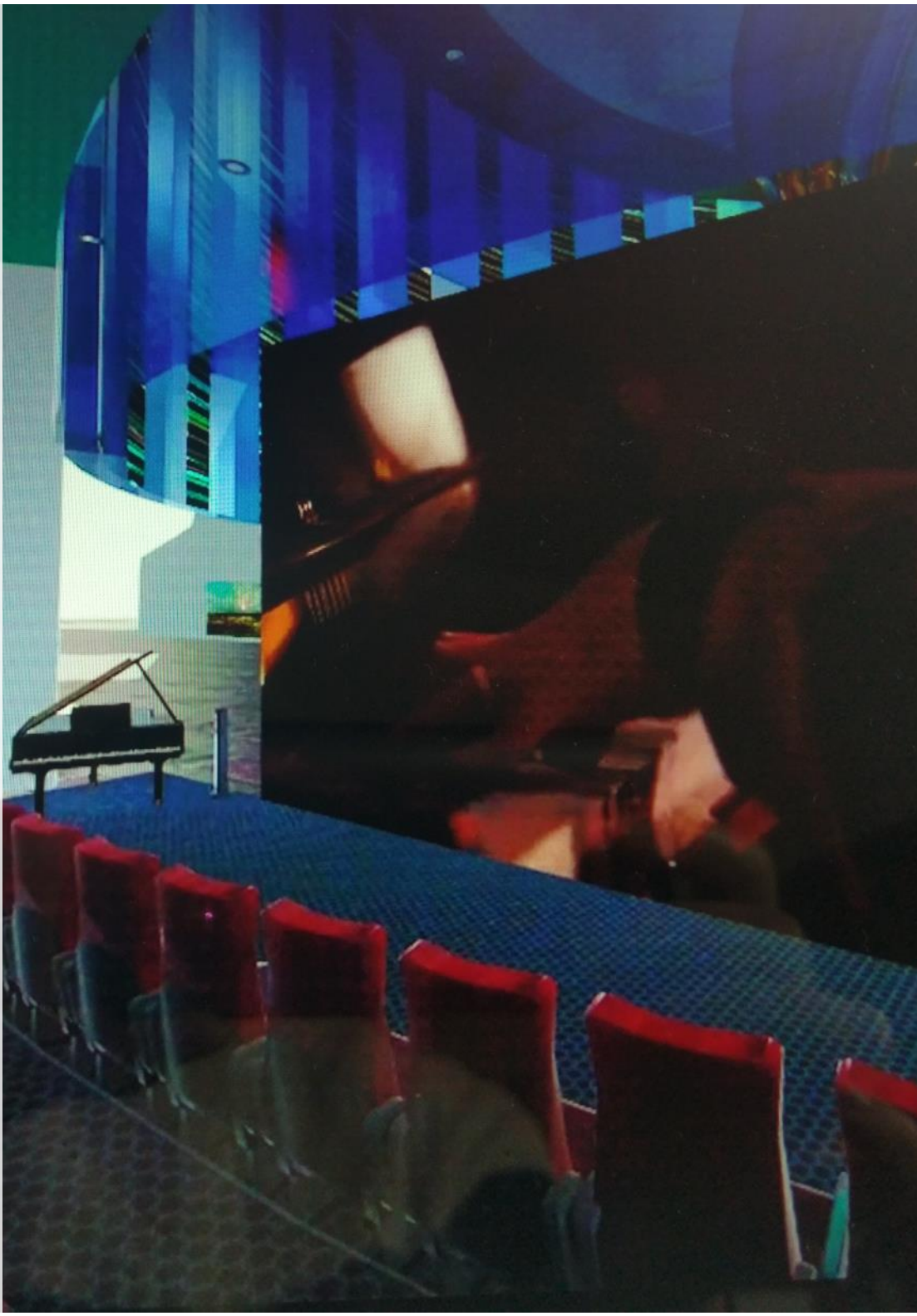
Chapter 1

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.

New HOPE President and Vice-President were elected during the online Board of Governors meeting on 5 June 2020.



Governance

HOPE gathers 36 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 online in 2020: on 5 June and on 26 October. On 5 June, a new President and a new Vice-President were elected for a three-year term. Dr Urmas Sule, President of the Estonian Hospital Federation, Governor for Estonia, became President, while Mr Eamonn Fitzgerald, Governor for Ireland, was elected Vice-President.

The President's Committee (PsC) now consists of the President Dr Urmas Sule, the Vice-President Mr. Eamonn Fitzgerald (Governor for Ireland) and three Governors: the two former Presidents Dr Sara C. Pupato Ferrari (Governor for Spain) and Mr. Georg Baum (Governor for Germany), and Mr. Simon Vrhunec (Governor for Slovenia). Two Governors are part of it as co-opted member: Dr Jaroslaw Fedorowski (Governor for Poland) and the former President Mrs. Eva M. Weinreich-Jensen (Governor for Denmark). 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 29 April and on 25 September 2020 to discuss the Board of Governors' agenda and the meetings of the Liaison Officers, and to decide on the organisation's priorities.

HOPE Liaison Officers meeting, Brussels, March 2020

The role of the network of Liaison Officers is to enhance activities and deliver objectives. In 2020, HOPE Liaison Officers meetings took place three times: once on 12 March in Brussels, and twice online on 19 November and on 14 December. 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.

The network of National Coordinators of the HOPE Exchange Programme met online to discuss the programme on 26 November 2020.

Located in Brussels, Belgium, the Central Office is managed by the Chief Executive, Mr. Pascal Garel. Ms. Laurie Andrieu is EU Policies and Communication Officer, Ms. Lucia Gonzalez is Comparative Activities Officer, and Ms. Ana Sofia Carbonell is part-time EU Project Officer. HOPE also welcomed three interns through the year: Ms. Marie Nabbe (FR), Mr. Noah Schermann (AT) and Ms. Natalie Öhl (DE).

GOVERNANCE IN 2020

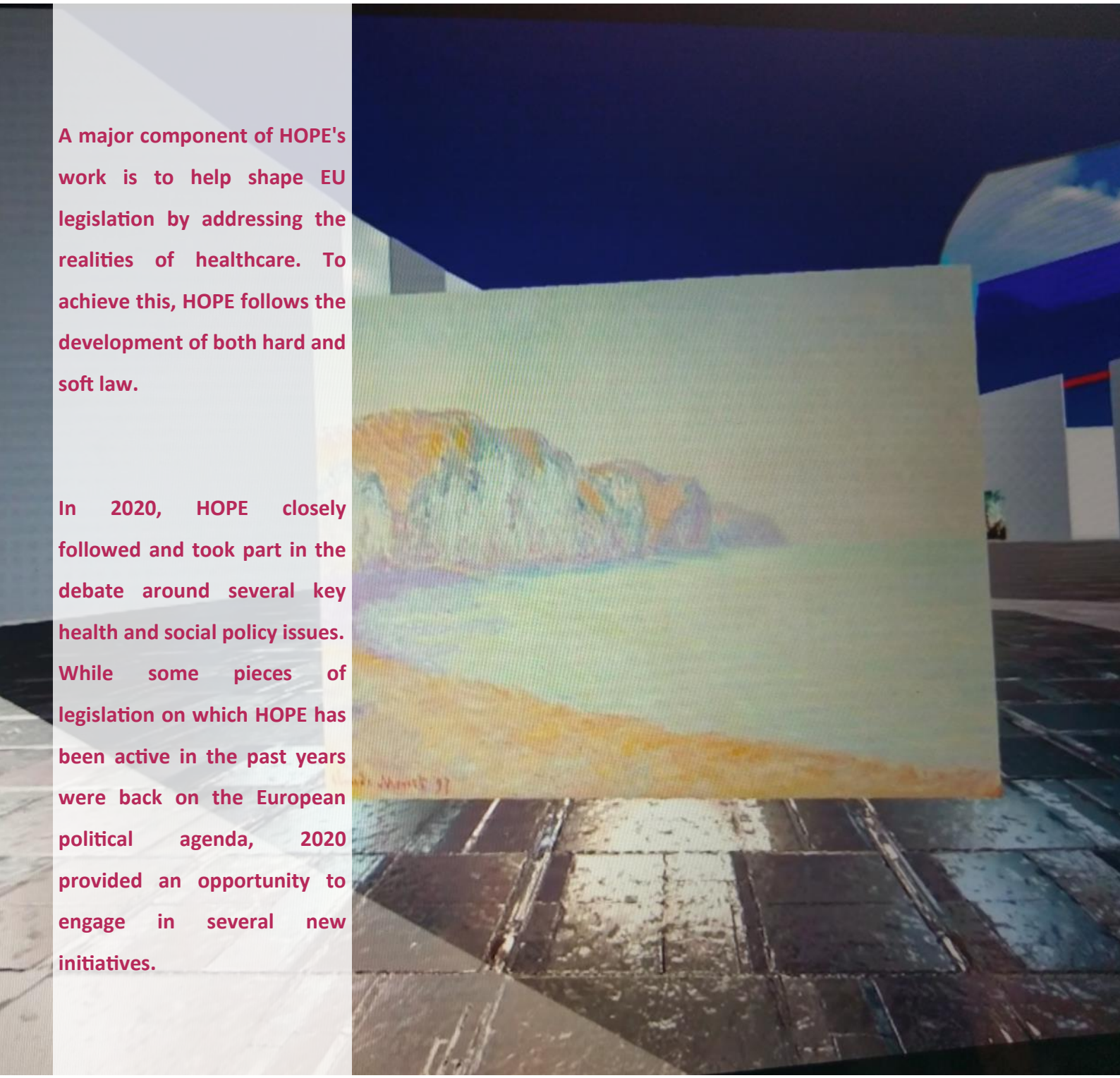
President	Urmas Sule, Estonia
Vice-President	Eamonn Fitzgerald
Chief Executive	Mr. Pascal Garel

GOVERNORS AND HEADS OF DELEGATION

Austria	Nikolaus Koller
Belgium	Francis De Drée
Bulgaria	Krasimir Grudev
Croatia	Željko Plazonic
Cyprus	Elisavet Constantinou
Czech Republic	Roman Zdarek
Denmark	Eva M. Weinreich-Jensen
Finland	Hannele Hakkinen
France	Zaynad Riet
Germany	Georg Baum
Greece	Yannis Skalkidis
Italy	Domenico Mantoan
Latvia	Jevgenijs Kalejs
Lithuania	Dalis Vaiginas
Luxembourg	Marc Hastert
Malta	Denis Vella Baldacchino
The Netherlands	Sander Gerritsen
Poland	Jaroslaw J. Fedorowski
Portugal	Carlos Pereira Alves
Serbia	Georgios Konstantinidis
Slovakia	Marián Bencat
Slovenia	Simon Vrhunec
Spain	Sara Pupato Ferrari
Sweden	Erik Svanfeldt
Switzerland	Anne Bütikofer
United Kingdom	Niall Dickson

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 2020, 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, 2020 provided an opportunity to engage in several new initiatives.

HOPE Infuence

HOPE'S RESPONSE TO COVID-19 OUTBREAK

On 11 March 2020, the WHO characterized COVID-19 as a pandemic. On 13 March 2020, Europe was recognised as the epicentre. Europe had more reported cases and deaths than the rest of the world combined, apart from China. More cases were being reported every day than in China at the height of its epidemic.

After it was warned about shortages medical devices produced in China in late February, HOPE was quick to share information and knowledge systematically then on. Contacts were made with the WHO Regional Office for Europe on the guidelines for the preparation of hospitals. Then together with other European stakeholders HOPE has also addressed the European Commission to welcome efforts and measures to overcome the crisis.

In light of the situation and on the basis of a risk assessment, HOPE's Board of Governors decided to postpone the HOPE Exchange Programme along with the associated HOPE Agora. It would be the first time since its creation 40 years ago that the event has been postponed. Initially rescheduled for 2021, the exchange is due back in 2022.

Exchange of information and press release

HOPE gathered information about the response to the COVID-19 outbreak from all its members.

A first questionnaire was sent on 11 March about medical equipment shortages. This was followed by a more comprehensive set of questions related to organisational aspects, during and after the Liaison officers face-to-face meeting on 12 March.

Since then, HOPE staff from different lockdown areas have been helping to circulate information. Weekly updates containing additional insights to what is publicly available are sent to Liaison Officer. This is completed with more detailed information in the HOPE monthly newspaper.

HOPE was in contact with the European Commission on many occasions. A meeting of HOPE President and CEO with the Cabinet of Vice-President Vestager on 11 March was the first opportunity. There were contacts as well with several other European associations and a joint letter was, for example, sent to the President of the Commission and the Commissioner for Health.

HOPE worked on an analytical framework to collect and structure information in order to learn from what was happening. Colleagues from OECD and Amsterdam University who were helping for the Agora kindly agreed to work on such an analytical framework as well. HOPE drafted a document collecting the specific COVID-19 information pages from the HOPE members' websites as well as from the European health professionals' organisations.

Lastly, a press release was published on 26 March 2020 to show our support to professionals and the message was reiterated on several occasions.

Joint letter to the European Commission on COVID-19

On 18 March 2020, HOPE, AIM (International Association of Health Care Mutuals and Health Care Funds), CPME (Standing Committee of European Doctors) and ESIP (European Social Insurance Platform) sent a joint letter to the European Commission concerning the COVID-19 pandemic.

The letter welcomed the Commission's efforts and measures to deal with the crisis and it praised the commitment of healthcare professionals. And it welcomed the European Commission's intentions to oversee stocks of essential protective clothing for those frontline healthcare workers. The organisations also underlined the need for structured discussion with the healthcare community, once the crisis has passed, about issues such as medicine shortages or investments in research and development, and about ensuring a better response for future crises.

HOPE CONTACTS WITH THE EUROPEAN COMMISSION

New commissioners were contacted. On 11 March 2020, HOPE President and CEO met with the cabinet of Margaret Vestager, Vice-President of the Commission.

Since several topics are covered by several Commissioners and Directorates General but coordinated by Vice-President Vestager, the meeting focused on Artificial intelligence, Research and Innovation, Digital skills, E-health, Sustainability and the Digital Age, A European Green Deal. Unfortunately, due to the pandemic this was the only face to face meeting.

Virginijus Sinkevičius, Commissioner for environment, was met online by HOPE President, Vice-President and CEO on 4 May 2020. They discussed circular economy, sustainable products, EU procurement and zero pollution.

Thierry Breton, Commissioner for the Internal Market, in charge of the Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs Services in the Single Market and Digitalisation replied to HOPE's letter saying that he values the activities and commitment of HOPE in shaping European policies related to hospitals and health care services. He looks forward to working with HOPE and to discuss, among others, our current efforts to improve the Single Market. This includes adding its cybersecurity dimension, embracing digitalization in the health care sector, tapping into the potential of artificial intelligence and other related topics.

Nicolas Schmit, Commissioner for jobs and social rights replied that the Commission had launched a broad discussion on a possible action plan to pursue the Pillar's implementation, and he warmly invited HOPE to participate in this consultation, which HOPE did. As children in particular are vulnerable and often marginalised, DG Employment, Social Affairs and Inclusion will lead the work on a European Child Guarantee to help ensure that every child in Europe at risk of poverty or social exclusion has access to the most basic of rights like healthcare. HOPE contributed to the consultation.

Vice President Dubravka Šuica, as Vice President in charge of Democracy and Demography in the European Commission also replied as part of the preparation of the Green paper on ageing.

Health Commissioner Stella Kyriakides had been due to participate in the HOPE Agora 2020, but it unfortunately had to be cancelled. However, HOPE head office had multiple contacts with DG SANTE throughout the year.

Hard Law

Hard law refers to legislation that take 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 2020, 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. Some legislation was adjusted, such a Medical Device Regulation's entry into force being postponed for one year.

Another major issue on the legislative agenda was Brexit and the attempt to reach an agreement during the transition period between the EU27 and the United Kingdom. An agreement was finally reached on 24 December 2020. Among the other key health policies closely followed by HOPE over the past years, are the Delegated act on the safety features appearing on the packaging of medicinal products for human use (the so-call “Falsified Medicines Directive”) which fully applies since February 2019 and the implementation of the Medical Devices Regulations.

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

In addition, several other initiatives remain on the EU political agenda: the Health Technology Assessment, the European Pillars of Social Rights and the ePrivacy Package. A legislative proposal on Artificial Intelligence is also expected for early 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

BREXIT

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 had called on the EU and UK to prioritise patients in the Brexit negotiations. The action continued in 2018, 2019 and 2020 with regular meetings organised at HOPE central office with European stakeholders.

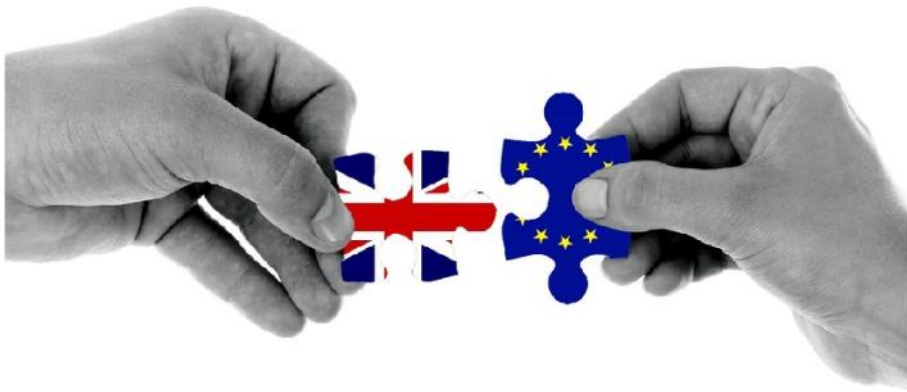
Negotiations started in March but were unfruitful. On 15 June 2020, EU and UK leaders met via video conference and agreed to intensify the negotiations on the future partnership, with a view to concluding and ratifying a deal by the end of 2020. On 19 June 2020, a group of 18 pan-European healthcare stakeholders, including HOPE, launched the statement "COVID-19 and Brexit – Protecting patients across Europe from pandemics" which highlights the importance of addressing health issues as part of the agreement on the future relationship between the EU and the UK.

In July 2020, more than 100 researchers and organisations, including HOPE, released a statement calling for science and research to be at the core of the future relationship between the EU and the UK, and for full association of the UK to Horizon Europe, calling for a quick agreement on the terms of association.

On 9 July 2020, the European Commission adopted a Communication to help national authorities, businesses and citizens prepare for the end of the transition period. Changes occur to cross-border exchanges between the EU and the UK as of 1 January 2021– irrespective of whether an agreement on a future partnership has been concluded or not.

After intense negotiations until the very end of the year, 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.

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.



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

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.

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 Hospital Pharmacists Association. 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 the creation of EMVO, meetings have taken place on a regular basis (usually monthly): Board of EMVO, stakeholders' meetings, project managers' meetings and EFPIA-Medicines for Europe project managers' meeting.

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 informs Liaison officers and experts identified by Liaison officers on a regular basis. The main new development in 2019 was the push for aggregation which was strongly supported by HOPE 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 will be further analysis in several countries.

In parallel, HOPE central office kept members informed of other developments. On 30 September 2020, HOPE attended online the event "Patient Safety and the Implementation of the Falsified Medicines Directive (FMD) in the Hospital Environment" organised by the pharmaceutical organisation European Alliance for Access to Safe Medicines (EAASM).

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. This will 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 concerning in vitro diagnostic medical devices will apply five years after publication (May 2022). The one on medical devices was supposed to apply from 26 May 2020 but it has been postponed for one year by an extraordinary measure, in view of the COVID-19 outbreak, adopted on 23 April 2020. It will then apply as of 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.

In February 2019, the European Commission launched an informal stakeholder consultation on Medical Devices and common specifications for products without a medical purpose. HOPE, together with the European Social Insurance Platform (ESIP), the International Association of Mutual Benefit Societies (AIM), Prescrire and the Standing Committee of European Doctors (CPME), released a joint

position paper calling for the timely application of the new rules on medical devices. This will allow the rules' adequacy to be evaluated and provide complete transparency concerning high-risk medical devices with public access to EUDAMED.

On 25 November 2019, the Council of the European Union published a set of corrections as part of a corrigendum for the EU Medical Devices Regulation (MDR), giving manufacturers of certain Class I devices an additional four years to comply.

On 26 February 2020, the European Commission sent HOPE a draft “Questions & Answers” document on “Custom-Made & Adaptable Devices” jointly developed by the CAMD Transitional Working Group and Medical Devices Coordination Group Market Surveillance Working Group.

On 24 March 2020, the European Commission adopted decisions on harmonised standards which will allow manufacturers to place on the market high-performing devices to protect patients, health care professionals and citizens in general. The standards will facilitate a faster and less expensive conformity assessment procedure. The revised harmonised standards play a pivotal role in the coronavirus pandemic because they relate to critical devices such as: medical face masks, surgical drapes, gowns and suits, washer-disinfectors and sterilisation. They were published in the Official Journal of the European Union on 25 March 2020. The use of these standards allows manufacturers of medical devices and other economic operators concerned, to comply with the today's EU health and safety requirements . These standards grant conformity of devices with the requirements of the three Directives on medical devices.

Moreover, upon the request of the Commission, the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC), in cooperation with their members made available a number of European standards for certain medical devices and personal protective equipment.

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 will assist and advise 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 will support the development process of the necessary specifications and technical functionalities related to EUDAMED.

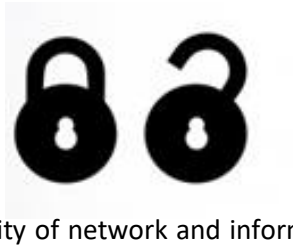
HOPE advocated that, when done in a safe way, multiple uses of medical devices are a way to reduce costs and contribute to the protection of the environment.

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 is scheduled to apply from May 2022. HOPE believes that patient safety and continuity of care could be endangered by this timeframe.

HOPE attended the first meeting of the EUDAMED subgroup on 19 October 2020. EUDAMED is the IT system developed by the European Commission to implement Regulation (EU) 2017/745 on Medical Devices and Regulation (EU) 2017/746 on In Vitro Diagnosis Medical Devices. The new Regulations contain great improvements including a much larger EUDAMED database than the one that currently exists under the Medical Devices Directives (Eudamed2). EUDAMED should improve transparency and coordination of information regarding medical devices available on the EU market. The system will be multipurpose. It will function as a registration system, a collaborative system, a notification system and a dissemination system (open to the public) and it will be interoperable. The meeting on 19 October 2020 was an opportunity for the Commission to present the roadmap and the state of play.

HOPE attended the meeting of the Medical Device Coordination Group (MDCG) with stakeholders organised by the European Commission on 20 October 2020. The main focus was on in vitro Diagnostics Regulation (IvDR) Implementation. The Commission reported on the activities of the MDCG IVD Working Group. Three meetings took place during the year on classification, guidance on performance evaluation and common technical specifications. The working group addressed COVID-19 issues, for example, serology tests.

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 pro-

posal, 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 information and communication technology cybersecurity certification (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 new European Commission 2019-2024.

In 2020, HOPE monitored information about cybersecurity incidents involving hospitals and relayed this to members. 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) in Q4 2020”. 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 19 May 2020, the European Commission announced that the EU invests, through the Connecting Europe Facility (CEF) programme, €7.6 million in projects which seek to strengthen the European Union's capacity and to deal more efficiently with cyber-threats and incidents.

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 is making 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, in a coherent and complimentary way.

A consultation on the NIS2 proposal was launched and is open until 11 February 2021. The new Commission proposal aims to optimise the previous NIS Directive for the future. To this end, the Commission proposal:

- 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. At the European level, the proposal strengthens supply chain cybersecurity for key information and communication technologies. Member States in cooperation with the Commission and ENISA, will carry out coordinated risk assessments of critical supply chains, building on the successful approach taken in the context of the Commission Recommendation on Cybersecurity of 5G Networks. The proposal introduces more stringent supervisory measures for national authorities, stricter enforcement requirements and aims at harmonising sanctions regimes across Member States.

- 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 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 set out priorities to address this crucial issue, and to boost the global competitiveness of the EU's IoT industry by ensuring the highest standards of resilience, safety and security. 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. This would include specifying the conditions for placement on the market.

The EU Agency for Cybersecurity ENISA is already working on cybersecurity certification schemes, and the conclusions invite the Commission to consider a request for candidate cybersecurity certification schemes for connected devices and related services.

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 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.

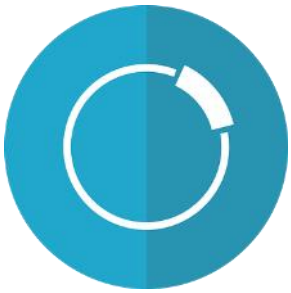
The Health Work Programme 2020 mentioned a joint action on the application of the GDPR. It aims to iron out differences in national GDPR implementation in the health sector — the development of a code of conduct for data processing (Article 40 GDPR).

The Commission organised during a webinar on 9 June 2020 the Joint Action addressing differences in national GDPR implementation in the health sector, including the European Health Data Space and the health data use.

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.

In its 2021 Work Programme the European Commission mentions a legislative data package: a Data Act and the Review of the Database Directive. They will both include an impact assessment at Q3 2021.



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 such 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.

The Health Work Programme 2020 mentioned a study to support follow-up actions to address shortcomings identified in the evaluation of the EU legislation on blood, tissues and cells (BTC). The expected result is an impact assessment of options for remedying these shortcomings.

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 25 March 2020, the European Commission has clarified that Substances of Human Origin (SoHO) are considered to be essential goods/services for which free circulation within the EU is crucial and the ECDC released a guidance document on COVID-19 and Substances of Human Origin (SoHO).

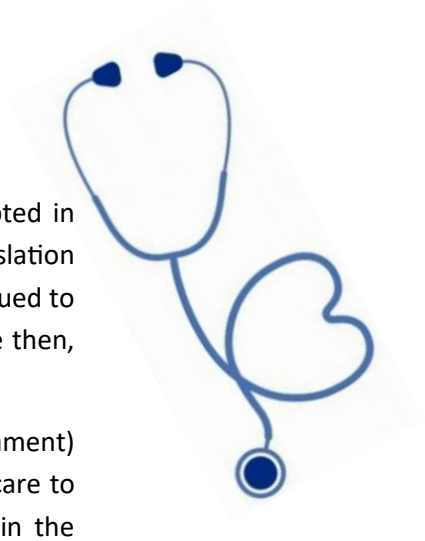
On 6 July 2020, the EU National Competent Authorities on Organ donation and transplantation released a Statement on Organ Donation and Transplantation and the COVID-19 pandemic.

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 adoption is planned for Q4/2021.

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. A comprehensive online public consultation on the policy options opened on 21 January 2021 until 15 April 2021.

HOPE has 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.

CROSS-BORDER HEALTHCARE



The Directive 2011/24/EU on Patients' Rights in Cross-Border Healthcare adopted in March 2011 is 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.

On 30 January 2019, the Rapporteur Ivo Belet (Member of the European Parliament) released its report on the application of patients' rights in cross-border healthcare to which HOPE had contributed. The report analyses the current shortcomings in the implementation of the Directive and makes recommendations for improving it. The report was widely welcomed by the Parliament and was adopted in a resolution on 12 February 2019. The report highlighted the issue of patients living in border regions, for whom it is often cheaper to get medical care in the closest hospital, which can actually be across a border. It was also reiterated that national information offices are important for citizens, and there is a need to improve their implementation in all Member States.

The Health work programme 2020 mentions a joint action for enhancing implementation of the cross-border healthcare Directive to ensure patients' rights in the EU. The objectives are:

- to help Member States share good practices in its implementation, e.g., reimbursement systems, prior authorisation and the use of prior notification;
- to ensure greater consistency and transparency in the application of the CBD, inter alia through legal expertise and analytical support;
- to improve the Commission's annual collection of Member State data on cross-border patient mobility in healthcare.

Expected results are Commission guidelines for Member States: measures to reduce administrative obstacles, improve information for patients and prevent waste in

healthcare; improvement in the Commission's annual collection of Member State data on cross-border patient mobility in healthcare (more user-friendly, complete and informative).

HOPE participated to the workshop organised by DG SANTE on 4 February 2020 on improving patient mobility data for the purposes of the Cross-Border Healthcare Directive. The workshop brought together academic, policy and data experts to explore:

- how to improve the data on patient mobility;
- other existing data sources and methods in the area of cross-border healthcare to complement the annual data collection;
- what new information could be collected, such as types of treatment;
- indicators other than patient mobility to measure the Directive's impact to start to build the evidence base for the Directive's evaluation in 2023.

The Commission also examined the transposition of the Directive into national law and launched 26 infringement procedures. The Directive allows Member States room for manoeuvre when it comes to transposition, but the Commissioner acknowledged that there is evidence of discrimination against EU citizens, as well as too much red tape. The Commission has launched two cases on reimbursement and is now discussing with EU countries to find ways to simplify procedures. In the meantime, the Commission agrees that Member States should provide sufficient funding for the national contact and information points.

On 3 April 2020, the European Commission issued practical guidance to Member States to support and encourage cross-border healthcare cooperation between national, regional and local authorities in the context of the COVID-19 outbreak.

The Commission Work Programme 2021 includes the Evaluation of the Directive 2011/24/EU on the application on patient rights in cross-border healthcare. The evaluation will look into the approaches implemented by Member States in practice, how effectively these are working and what areas still act as barriers to patients seeking healthcare across borders.

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, will begin 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 14 October 2020, the Commission, wishing to support frontline healthcare workers fighting the COVID-19 pandemic, announced it would fund a training programme for healthcare professionals in intensive care skills. Therefore, a contract was signed in August with the European Society of Intensive Care Medicine (ESICM) to develop a training programme in Intensive Care Fundamentals for Healthcare Professionals who do not usually in intensive care units. The training is free of charge and available for every doctor and nurse working in a hospital with an intensive care unit, in all 27 EU Member States and the United Kingdom.

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 29 July 2020, the British Medical Journal and the Nederlands Tijdschrift voor Geneeskunde published a highly critical article of the current orphan medicine rules and, more broadly, the pharmaceutical industry, claiming that the orphan medicine rules are overly generous for the sector and have turned these products into a "corporate cash machine".

On 25 November 2020, the European Commission launched a Roadmap to revise the rules on medicines for children and rare diseases. EU rules to foster the development of medicines for children and for people with rare diseases have been in place for nearly 20 years. This revision addresses shortcomings identified in a recent evaluation, and the objectives are to:

- foster research and development of medicines for rare diseases and for children, especially in areas of unmet need and in better alignment with patient needs;
- contribute to ensuring the availability and timely access of patients to orphan and paediatric medicines;
- ensure that the legislation is fit to embrace technological and scientific advances;
- provide effective and efficient procedures, for assessment and authorisation of orphan and paediatric medicinal products.

HOPE contributed to the consultation and is preparing a position statement to be released in 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.

On 17 September 2020, the European Parliament approved a resolution with 671 votes to 15 and 10 abstentions calling for new measures to tackle pharmaceutical pollution. While MEPs said in a press release that they welcomed the Commission’s communication from March 2019, they regretted the serious delay in presenting a strategic approach and concrete action.

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:

- The revised Surface Water Watch List, under the Water Framework Directive, was adopted in August 2020 and included additional pharmaceuticals. This watch list functions as an early warning system for pollutants in surface waters.
- Legal acts are currently being drafted under the Regulation on veterinary medicinal products, which aim to promote a more prudent use of antimicrobials in animals, and implement a wide range of concrete measures to fight antimicrobial resistance.
- New guidelines on hazardous household waste have been developed. Pharmaceuticals are also being considered in the impact assessment for the potential revision of the Urban Waste Water Treatment Directive.
- The last LUCAS soil survey sampled pharmaceutical concentration and antimicrobial genes in soil, with results expected in 2022.
- The EU has started work with Member States' health ministries, for instance to ensure health professionals consider environmental impacts of medication.

Additionally, the EU is funding several current and future research projects on pharmaceuticals in the environment.

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.

EMISSIONS TRADING SCHEME

Set up in 2005, the EU ETS is the world's first international emissions trading system. HOPE contributed at that time to the discussion, identifying the few hospitals concerned. The scheme was divided into a number of "trading periods". The first ETS trading period lasted three years, from January 2005 to December 2007. The second trading period ran from January 2008 until December 2012, coinciding with the first commitment period of the Kyoto Protocol. The third trading period began in January 2013, ending in December 2020. The legislative framework of the EU ETS for its next trading period (phase 4: 2021- 2030) was revised in early 2018 to enable it to achieve the EU's 2030 emission reduction targets and as part of the EU's contribution to the Paris Agreement.

In line with the European Green Deal and the EU's objective to become the first climate neutral economy by 2050, the Commission adopted on 21 September 2020 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 will enter 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 (it will include an impact assessment planned for Q2 2021).

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).

The Commission reiterated that the open consultation was accessible until 29 December 2020 and will be followed by a stakeholder consultation at the beginning of 2021. A workshop will also be organised in March 2021. The Commission plans to conclude the consultation during the summer and release a draft proposal at the end of 2021.

While all stakeholders welcomed the European Commission's Green Deal and all sectoral legislative revisions that it entails, one of the main points of discussion was pressurised metered-dose inhalers (pMDI), which are excluded from the current legislation. pMDI are mainly used in asthma and chronic obstructive pulmonary disease (COPD) relievers as a life-saving medication to avoid or stop asthma attacks and COPD exacerbations, or as an additional rescue medication in the even of an attack for any stage of asthma. They contain a hydrofluoroalkane (HFA) molecule (a type of F-Gas) that acts as a propellant to quickly release the liquid medication into the lungs effortlessly.

Isabel Proano, Director of Policy and Communications, EFA, raised concerns about how the change could impact the patients. Indeed, there needs first to be an alternative, and it has to be both affordable and efficient. Adequate training must be given to healthcare professionals so they can support the patients through the change and teach them how to use the new device. EFA called for a full integration of the human and patient health aspects in all the EU and national strategies, including impact and policy scenario assessments, and policies and actions to phase down F-Gases, especially those used as propellants in asthma and COPD treatments.

HOPE Chief Executive, Pascal Garel, expressed a similar position. He 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). This should be avoided as it can be a great suffering for patients to go through a hospitalisation, but it also has a great environmental cost. He also stressed the importance of the affordability and accessibility of an alternative treatment if a change should occur in the next years.

STATE AID

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

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

the rules on health and social Services of General Economic Interest (SGEIs) reached the objectives envisaged under the 2012 SGEI package, namely to support Member States in funding services of general economic interest that are of key importance to citizens and society as a whole while preserving the key aspects of State aid control. The Commission's adoption of a new proposal is planned for first quarter 2021.

On 15 December 2020, the European Commission published a Roadmap on a review of the state aid rules for research, development and innovation. The Roadmap was open for feedback until 12 January 2021. The fitness check evaluation concluded that the 2014 State aid rules for research, development and innovation (RDI) have been broadly effective and efficient. However, some targeted updates to reflect economic and technological developments are needed. This initiative will further simplify the rules applied by EU countries to implement RDI aimed at innovative solutions – for example, in digital, health and carbon-neutral technologies that support the transition to a green and digital economy.

In May 2020, HOPE released a Strategic Note on State-aid actions in the context of the COVID-19.

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". The European Commission has contracted Fondazione Giacomo Brodolini (Italy), COWI (Denmark) and the Institute of Occupational Medicine (United Kingdom) to carry out the study in the context of the evaluation of the Carcinogens and Mutagens Directive (CMD).

The purpose of this two-day conference was to present and discuss the first results and preliminary conclusions from the assessment of different policy options concerning the protection of workers from exposure to HMPs including cytotoxic medicinal products.

At this stage, the study has identified a short list of options organised into three types of options (in addition to Option 1 of no further EU action). The first type of options, Option 2, concern legal amendments to the CMD to further address HMPs. It comprises two sub-options, where sub-option 2.1 is assessed to increase legal clarity by explicitly listing substances for which occupational limit values are defined. This would increase awareness, including the need for exposure minimisation according to the CMD requirements for these substances. Sub-option 2.2 is also about clarity of the legislation and the definition of HMPs by adding to and thus explicitly listing the relevant pharmacotherapeutic groups of HMPs in Annex 1 of the CMD. Similar to 2.1, it may also contribute to increasing awareness.

However, according to the report it can be questioned whether an enlarged Annex 1 sufficiently closes the knowledge gap concerning the hazardousness of substances identified by this study as inclusion of pharmaceutical groups would not be very specific to HMPs with carcinogenic and mutagenic properties.

Option 3 then concerns legal amendments to relevant legislation outside the occupational safety and health (OSH) domain that includes provisions related to workers' protection from exposure to HMPs. The first sub-option 3.1 is about improving legal clarity by removing the MPs exemption from the CLP, i.e. by requiring classification under CLP of active substances and finished medicinal products. Similarly, sub-option 3.2 concerns the inclusion in the REACH requirements of developing safety data sheets (SDS) for finished products. Formally requiring SDSs (consultation with EFPIA has revealed that Safety Data Sheets are today prepared on a voluntary basis by the pharmaceutical industry) will contribute to ensuring information flows, that will also contribute to increasing awareness. The next two sub-options are then about amending the legal requirements of the authorisation process of MPs.

Option 4, finally, is about developing (or updating) non-legislative instruments at the EU level to improve the occupational safety and health of workers exposed to HMPs. Sub-option 4.1 is foremost about addressing the fact that guidelines for handling HMPs are in place in many Member States, but that they differ in quality. Sub-option 4.2 is about addressing the lack of a clear definition of HMPs without amending the legislation. It is designed to encourage easy access to a (non-legal) definition and associated identification of specific active agents and HMPs that will help employers identify when protective measures are required to comply with the CMD.

In parallel, it should be noted that EPSU (European Public Service Union) and HOSPEEM adopted on 24 September 2020 a document that calls the European Commission to include in its CMD4 report or accept Parliamentary amendments for the revision of the Carginogens and Mutagens Directive in 2020-2021 that include hazardous drugs, including cytotoxic drugs, as a category in Appendix I.

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. The campaign is focused on getting the European Commission, European Parliament and Council to include in the CMD carcinogenic cytotoxic drugs which cause cancer, such as leukaemia, in healthcare workers and patients in Appendix I, and reprotoxins, which harm all workers’ fertility, in the title of the CMD.

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 is 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.

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.

PROPOSED LEGISLATIONS

HEALTH TECHNOLOGY ASSESSMENT

Health Technology Assessment (HTA) is a key 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). HOPE released a position in June 2018. In parallel, HOPE was part of the stakeholder group provider in the Joint Action for Health Technology Assessment in Europe: EUNetHTA (see Projects for more information).

The proposal covers new medicines and certain new medical devices, providing the basis for cooperation at the EU level for joint clinical assessments in these areas. The proposal establishes a Member State Coordination Group on HTA (the 'Coordination Group') composed of representatives from national HTA authorities and bodies. The Coordination Group will be responsible for overseeing the joint clinical assessments and other joint work carried out by designated national experts organised into specific sub-groups dedicated to the specific types of joint work (e.g. subgroup on joint clinical assessments, subgroup on joint scientific consultations).

On 3 October 2018, the European Parliament (EP) adopted in Plenary session the Report drafted by MEP Cabezón Ruiz: 576 MEPs voted in favour, 56 against and 41 abstained (partial vote in view of opening interinstitutional negotiations). After a debate in plenary on 13 February 2019, Parliament adopted the report in a vote on 14 February. Parliament's first reading was thus closed.

In the ENVI committee meeting on 4 September 2019, MEP Tiemo Wölken (S&D, Germany) was named rapporteur for the subject, following on from last term's rapporteur, MEP Soledad Cabezón Ruiz (S&D, Spain).

At the Council level, the work continued during the Finnish Presidency (second semester 2019). The Finnish presidency of the Council proposed a compromise, which could lead to an agreement on how to take the subject forward. This compromise would delete Article 7 of the Commission's proposal, which refers to a list of health technologies that have been officially assessed at the EU level. Deleting the Commission's role in making a joint report official, under Article 7, would basically eliminate the requirement to use joint work, a requirement that has been opposed by Germany, France, Spain and Poland. Remaining would be a requirement "not to duplicate the

requests" for data from manufacturers. The Commission's role would be diminished for sure, yet some countries supportive of its initial proposal may accept the compromise just for forward movement.

The subject could not be carried over at the Council Employment, Social Policy, Health and Consumer Affairs Council (Health), which was planned for 19 March 2020.

In its June 2020 progress report, the Croatian Presidency concluded that the outbreak of the pandemic emphasised the importance of having a legally sound and functioning HTA system in place but the first reading was not closed for the Council. The German Presidency has accelerated its efforts on a unified HTA process through negotiations in the Council's Working Party on Public Health but no consensus was reached.

The Health work programme 2020 mentioned a joint action financing on the EU Health Technology Assessment (HTA) cooperation, with a focus on joint clinical assessments. The main overall objective of this action is to ensure that joint clinical assessments continue to be produced until planned legislation on HTA comes into effect. The EUR 2 million tender was launched on 27 October 2020.

HOPE was invited to join the 10th meeting of the network of national authorities responsible for Health Technology Assessment (the HTA Network), set up by the Directive on patients' rights in cross-border healthcare (2011/24/EU - Article 15).

Following the welcome and opening by Andrzej Ryś (DG SANTE), the different services of the Commission provided feedback on HTA-relevant activities: Pharmaceutical strategy, European Health Data Space, Horizon Europe, Europe's Beating Cancer Plan, Medical Device Regulation, EU4Health. The update from EUnetHTA – achievements, challenges and lessons learned was provided by Marcus Guardian, National Health Care Institute/Zorginstituut Nederland. Supporting scientific and technical aspects of EU cooperation on HTA after May 2021 was covered in a note with issues to be addressed in the near future (e.g. methodological challenges, involvement of stakeholders in joint work) and the Health programme 2020. Finally, COVID-19 related activities were presented. The EUnetHTA collaborative reviews for COVID-19 treatments and testing methods were covered by Claudia Wild, Austrian Institute for Health Technology Assessment and Luciana Ballini, Regione Emilia -Romagna, Italy. The EU CCP Database - COVID-19 convalescent plasma collection and transfusion in the EU was presented by Orsolya Nagy, DG SANTE B4.

EUROPEAN PILAR 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 trends in work patterns and societies and to gather views and obtain feedback on the role of the European Pillar of Social Rights.

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

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

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 the ground for the Pillar’s Action Plan (to be presented in early 2021), the Commission launched a broad discussion with all EU countries and regions and with all partners to which HOPE contributed. The Commission therefore 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.

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.

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.

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) in Q1 2021 according to the adjusted Commission Work Programme 2020 presented in May 2020. The European Commission ran a public consultation between February and June 2020.

HOPE contributed to the consultation on this White Paper in May 2020.

The AI High Level Expert Group of the European Commission organised three workshops on healthcare on 16, 21 and 23 April 2020. All three days had the same agenda but with different participants. HOPE attended the meeting on 23 April. Participants were

European organisations based in Brussels, researchers and academia, national organisations from the healthcare sector, businesses and national authorities.

Delegates started by discussing the importance of a definition of AI and where the medical devices regulation fits in with the planned AI framework. HOPE raised the issue that there are no guidelines, nor established methodology on how to assess or monitor AI-based medical devices after they enter the market under the current Medical Devices legislation. But a while ago it emerged, during Medical Devices Coordination Group and stakeholders meeting, that in the future the European Commission/MDCG will work on such guidelines as part of the Medical Devices Regulations. How will this articulate with the HLEG on AI remains a question. The Commission answered that there will be a two-level approach because of the jurisdiction levels in the EU. Parts will be covered by the Medical Devices Regulation (e.g. infectious diseases), but there will be national jurisdiction as well. Discussing AI and Big Data, it was also mentioned that the European Medicines Agency is working on guidelines.

Participants addressed the impact of AI on genomic data, which is given to a bio bank and the relation to the GDPR. When data is used for public interest, e.g. research on cancer or COVID19, no consent is necessary.

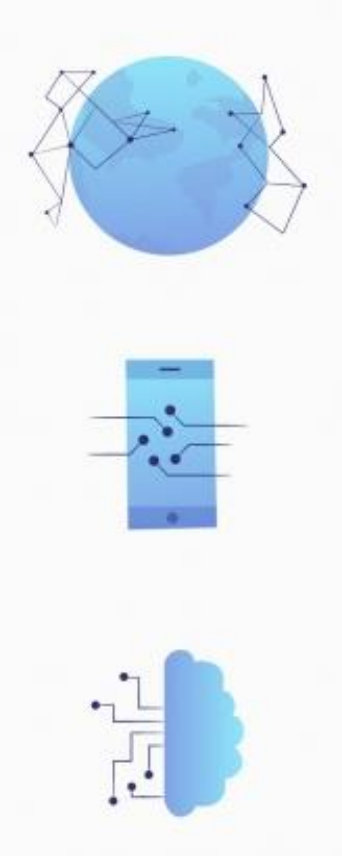
Regarding the training on AI for hospital staff, HOPE said that the issue is not only medical schools or other healthcare schools but all healthcare professionals who are practising today, meaning a clear need for continuous education. It was suggested to include an intermediary person as patients and doctors might be overloaded with the information.

There are several types of risk assessment in the hospital and healthcare services sector in Europe and, of course, AI raises new issues around transparency and accountability, in particular in the context of being able to get insured on litigation. When it comes to risk classification, it was said that low-risk AI tools might change to a high-risk tool and the question how to deal with that. Explanations on the algorithm should be case-based.

Stakeholders from the public and private sectors in their large majority support the design of a regulatory framework for AI (e.g. regulation, certification and labelling) and the revision of the existing Product Liability directive to cover particular risks engendered by certain AI applications.

In the European Parliament, the Legal Affairs (JURI) committee discussed in May 2020 three draft reports on artificial intelligence: 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).

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 9 October 2020, HOPE attended to the second European AI Alliance Assembly. The European AI Alliance is a forum that engages more than 4000 European citizens and stakeholders in a dialogue on the future of AI in Europe. It was set up in parallel to the High-Level Expert Group on AI as broad multi-stakeholder forum that would, among others provide input from the different parts of society to the work of the AI HLEG and EU policy-making more generally. This full-day event allowed for discussions on various topics from the use of Artificial Intelligence (AI) against coronavirus to biometric identification. The speakers included Commissioner Thierry Breton, representatives of the German Presidency of the European Council as well as other high-level participants. This year's edition had a particular focus on the European initiative to build an Ecosystem of Excellence and Trust in Artificial Intelligence (AI).

On 20 October 2020, MEPs adopted the three proposals on how the EU can best regulate Artificial Intelligence (AI) in order to boost innovation, ethical standards and trust in technology.

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 Artificial Intelligence (AI). Indeed, Deloitte and Timelex are currently under contract with the European Commission, Directorate-General for Justice and Consumers (DG JUST), to undertake a study to support the Commission's policy development on liability for artificial intelligence (outside of product liability). The study's aim was to assess whether the current national civil liability rules are 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.

A legislative proposal is expected in 2021.

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, eHealth, European semester, environment, antimicrobial resistance, vaccines, cancer, ageing, mental health and safety of public places.

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 recent 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.

And lastly there is the European Trade Union Confederation study about services standards.

For the Commission representatives there is not much of a change, certainly not on the health front. Following the recent consultation, the Commission plans to focus for next years on recovery from the current situation and on long-term vision on digitalisation and greening (standardisation of eco-design). It considers that only 20% of standards are developed on the basis of a Commission request. Although, the Commission representatives mentioned the internal focus group on Artificial Intelligence in CEN/CENELEC. For more than a year three meetings took place to which the Commission is invited. The Commission sees a major weakness in only having ISO – a US-led approach – to deal with this. For the Commission, this concerns a number of issues that are important to Europeans. It expects that in the next months, CEN/CENELEC will decide if it becomes a permanent committee.

On 27 October 2020, CEN and CENELEC hosted a half-day interactive online workshop on "Artificial Intelligence in healthcare: paving the way with standardisation". The event included case studies, tech-talks, deep dives, break-out sessions and different panels.

Consistent standards related to AI technology in the healthcare sector are needed, according to CEN, to provide tools that are transparent, safe, trustworthy, and ethical. The participants agreed that standardisation at the research stage plays a key role for developing tools that are not only fit for purpose, but also fit for practice. For comparing performance of different algorithms benchmarks and links between new developments are important instruments. Also, stakeholder engagement in co-creation helps to build trust and to develop user-friendly tools.

According to CEN, there is a strong need for certification of continuously learning AI and for defining quality standards such as quality reporting. There was broad consensus that standards should be made on an international or European level instead of separate national standards. Therefore, the European regulatory framework for healthcare including MDR and IVDR were discussed intensively.

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.

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 2020, three webinars were organised, one on 25 February 2020 on IHI Health Improvement Alliance Europe (HIAE) work, one on 23 June 2020 on the Medication Safety System MedEye and one on 6 October on the Development of Regional Strategy for Patient Safety improvement in Belgium.

PHARMACEUTICAL STRATEGY

A Pharmaceutical Strategy for Europe was mentioned in the Commission's work programme 2020 for a publication on Q4 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 to ensure patients have access to innovative and affordable medicines and to support the competitiveness, innovative capacity and sustainability of the EU's pharmaceutical industry. The strategy will allow Europe to cover its pharmaceutical needs, including in times of crisis, through robust supply chains. Europe's Pharmaceutical Strategy has four main objectives:

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

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

The Pharmaceutical Strategy for Europe 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.

HOPE office has been and will continue collecting positions and priorities of HOPE members.

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.

On 3 March 2020, HOPE took part in an event hosted by Medicines for Europe (the European generic medicines association), the Permanent Representation of Hungary and the Croatian Presidency of the Council of the European Union entitled “A European Union that Ensures Patient Access and Sustainability”. The event explored the ways to ensure a more equitable and sustainable access to medicines in the European Union (EU).

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 21 September 2020, HOPE attended the 3rd Meeting of the EURIPID Stakeholder Dialogue Platform on Pricing of Medicinal Products (a Grant Agreement of the European Commission). EURIPID General Secretary is managed by the Austrian National Public Health Institute GÖG. The meeting was an opportunity to present an overview on the European Commission activities in the field of pharmaceuticals and on EURIPID Activities since last meeting: results of a Price Transparency Survey among EURIPID members and EURIPID's input to the EU Pharma Strategy discussion.

Among other presentations the Patients’ Access Working Group presented the work for the collection of ideas for measuring patients' access to medicinal products in Europe.

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 28 April 2020, the European Parliament released a briefing entitled "Addressing Medicines Shortages". It gives an overview of the issue as well as the European Institutions and EU Members States actions. It states that in January 2020, the Parliament's Environment, Public Health and Food Safety (ENVI) committee coordinators decided to adopt an oral question with a motion for a resolution on the issue of medicines shortages.

On 30 April 2020, the Committee on the Environment, Public Health and Food Safety (ENVI) at the European Parliament released its "Draft Report on the shortage of medicines - how to deal with an emerging problem". In this resolution, the European Parliament insists on three aspects:

- Securing supplies in the interests of patients and restoring health sovereignty
- More vigorous action at European level to better coordinate and supplement Member States' health policies
- Closer cooperation between Member States

On 16 June 2020, the European Commission launched an online public consultation on the Pharmaceutical Strategy for Europe in which one of the four specific objectives mentioned was tackling medicine shortages.

On 14 July, 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 a 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 to ensure patients have access to innovative and affordable medicines and to support the competitiveness, innovative capacity and sustainability of the EU's pharmaceutical industry. 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.

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 2020 European Semester and regularly reported on it via its monthly newsletter.

As part of the European Semester process, the European Commission published the country reports for each European Union Member State on 26 February 2020.

These reports are part of the Winter Package and address the economic, social and health system challenges faced by each Member State. They include an economic situation and outlook, reform priorities and progress in country-specific recommendations. For the first time, the reports had a focus on sustainability and included a summary assessment of the Sustainable Development Goals and raised awareness about different policies that can help deliver them. The reports focused on progress in reforming health care and long-term care among Member States, identifying the development made in addressing the country-specific recommendations in these areas, as well as, a number of states that require particular attention in healthcare and/or long-term care systems.

On 16 April 2020, Ministers agreed on the simplification of information requirements for 2020 cycle of the European Semester. Given the high degree of uncertainty as a result of the socio-economic fallout of the COVID-19 pandemic, the Commission put forward a simplified process for 2020 European Semester exercise. This was intended to maintain the European Semester's main milestones, while taking into account the challenging times member states were facing. In particular, there would be a streamlined approach for the submission of national reform and stability or convergence programmes (NRPs and SCPs) by member states.

On 19 May, the Council adopted conclusions on the European Semester 2020 country reports and the implementation of the 2019 country-specific recommendations. On 20 July, the Council approved the draft recommendations and opinions on Member States' economic and fiscal policies for 2020.

On 20 July 2020, the Council adopted its 2020 recommendations and opinions on the member states' economic, employment and fiscal policies, as well as the recommendation for the euro-area.

This year's country-specific recommendations take into account the specific

context of the COVID-19 pandemic and the activation of the general escape clause under the Stability and Growth Pact on 20 March 2020. They are lighter, more focused and less prescriptive than in previous years.

They reflect the following economic priorities:

- invest in access, effectiveness and resilience of health care;
- preserve employment and address the social impact of the crisis;
- focus on research and development;
- ensure liquidity provisions and the stability of the financial sector;
- preserve the single market and the circulation of goods and services.

The adoption of proposals for country-specific recommendations is a key step in the European Semester. Although Member States are responsible for their own health policy and the organisation and delivery of care, the EU can issue a recommendation on certain aspects of its health system to an EU country. The rationale is that EU governments spend an average of 15% of their health budgets, making it one of the largest and fastest-growing areas of expenditure. However, health is also an investment. The health sector is a major source of employment, and timely access to high-quality healthcare contributes to social inclusion.

In September 2020, HOPE released a Strategic Note on the European Semester 2020.

On 18 November 2020, The European Commission presented its autumn economic policy package, including the opinions on euro area Draft Budgetary Plans (DBPs) for 2021 and policy recommendations for the euro area. This is the second step in the 2021 European Semester cycle, which started in September with the publication of the Annual Sustainable Growth Strategy (ASGS) with the concept of competitive sustainability at its heart. The ASGS also provided strategic guidance for Member States in drafting their Recovery and Resilience Plans and set out the relationship between the Recovery and Resilience Facility (RRF) and the Semester. The Autumn package draws upon the Autumn 2020 Economic Forecast – prepared against a backdrop of high uncertainty – which projected that the economic shock caused by the coronavirus pandemic would leave output in the euro area and the EU below its pre-pandemic level in 2022.

E-HEALTH

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”. The European data strategy and the policy options to ensure the human-centric development of Artificial Intelligence (AI) were presented.

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 July the Commission held the first meeting of the relaunched eHealth Stakeholder Group, as an on-line event. The first meeting was originally planned for March but was postponed due to COVID-19.

The group will support the Commission in the development of actions for the digital transformation of health and care in the EU. The meeting introduced the new member organisations of the group, and discussed topics for a work programme during the course of its three-year mandate. In addition, the Commission presented the EU digital health response to the COVID-19 pandemic, and the current situation with regard to the development of a European Health Data Space and the Digital Transformation of Health and Care.

The eHealth Stakeholder Group will provide advice and expertise to the Commission, particularly on topics set out in the Communication on enabling the digital transformation of health and care in the Digital Single Market, which was adopted in April 2018. In particular in relation to the following areas:

- Health Data, including taking forward the Commission Recommendation on a European Electronic Health record exchange format and the further elaboration of the baseline set of technical specifications and better interoperability
- Digital health services
- Health data protection and privacy issues
- Cybersecurity for health and care data
- Digital tools for citizen empowerment and person-centred care
- Artificial intelligence and health
- Other cross cutting aspects linked to the digital transformation of health and care, such as financing and investment proposals and enabling technologies

The eHSG held a second online meeting on 4 December 2020. As an introduction, COVID-19 challenges and tracing apps were presented.

Some eHealth solutions answer directly to COVID-19 challenges such as the UV disinfection Robots that are procured and distributed to EU hospitals thanks to the ESI Programme (Emergency Support Instrument), technological solution for fast diagnosis of COVID that help radiologist to analyse scans and highlight pneumonias thanks to AI.

The Commission also opened an emergency call for H2020 COVID projects: On 11 August 2020, it announced that 23 projects were shortlisted for funding with a total of €128.2 million and involving 344 research teams from 39 countries in Europe and beyond.

The Commission presented its priority and put emphasis on the development of a European data space, which will require strong commitment from Member States and stakeholders.

The health-related topics of Digital Europe were presented:

- Cybersecurity and trust: support to the health sector
- Data Spaces: Genomics and cancer imaging
- Artificial intelligence: Testing and Experiment Facilities for health
- Accelerating best use of technologies: digital transformation of health and care and an ecosystem for digital twins in healthcare

EUROPEAN HEALTH DATA SPACE

In 2018, the European eHealth Digital Service Infrastructure started operating, which shares 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, will invest 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. The programme focuses on areas where no single Member State acting alone can guarantee success, and where public spending is likely to make the highest impact. The Commission also proposed to fund new digital infrastructure in the EU in 2021-2017 with a renewed Connecting Europe Facility. A Political agreement on a €7.5 billion was reached on 14 December 2020.

On 29 January 2020, a workshop took place in Brussels to explore how Member States are implementing the GDPR for the protection of personal data in the field of health, in order to identify possible differences and examine how this may affect the cross-border exchange of health data in the EU. It was the first of a three-part series of workshops between January and April 2020, which aimed to contribute to a legal study commissioned by the Commission in view of the future establishment of a European Health Data Space.

HOPE participated in the virtual workshops on “Common governance principles for the re-use of health data”. The three workshops were organised as online focus group meetings under the umbrella of eHAction – Joint Action supporting the eHealth Network and took place on 23-24-25 June 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) aims at making the most of the potential of digital health to provide high-quality healthcare and reduce inequalities. It 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. This initiative is part of the Commission Work Programme for 2021. The COVID-19 pandemic has highlighted the importance of having timely access to health data for research and policy-making purposes, and the European Council has recognised the urgency to make progress towards the EHDS.

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.

The first topic addressed was the circular economy mentioned in the letter of President Von der Leyen sent to Commissioner Sinkevičius.

HOPE stressed that the hospital and health care sectors use a lot of single-use products for safety reasons but sometimes also because the industry has an advantage in defining products as single use.

HOPE has been advocating for the European legislation concerning the Medical Devices not to hinder the policies in place to reprocess “single use” medical devices for no reason. The Medical Devices Regulation implementation has been postponed to next year, but a delegated act is under discussion. The most recent version was going against the circular economy principles. We hope that the Commission will keep up the version where the single use label from the producer is not solely the determinant for what can be reprocessed.

The second issue addressed was consumer empowerment, which includes the fact that consumers will have access to reliable information on issues such as the reparability and durability of products to help them make environmentally sustainable choices. Consumers will benefit from a true ‘Right to Repair'. Hospital and healthcare sectors are major consumers and they support the Commission in keeping this topic high on the political agenda.

The third issue addressed was the focus on the sectors that use the most resources and where the potential for circularity is high. The hospital and healthcare sector is concerned by many sectors either as a purchaser or a producer (electronics and ICT, vehicles, textiles, construction and refurbishment of buildings, food).

Therefore, HOPE expressed its strong interest in being involved in the decisions taken on this matter and confirmed it would be available for highlighting how big an impact different measures would have.

The fourth issue discussed was waste. This is also a concern for hospital and healthcare services for many different aspects, including food waste for which HOPE has good practice examples. Hospitals and healthcare services have created in most countries separate collection of waste, taking into considering the risk (of infections for example).

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. Indeed, in the annex to the EU Action Plan for Circular Economy concrete initiatives and priority initiatives are listed such as Mandatory Green Public Procurement (GPP) criteria and targets in sectoral legislation and phasing-in mandatory reporting on GPP. The second topic addressed was zero pollution. HOPE argued that stricter standards together with strengthened implementation and enforcement of current policies could save many lives. According to a recent European Environment Agency report, enforcement of existing policies on the air quality standards remains a problem, and it is estimated that more than 50% of the 400,000 premature deaths from in Europe could be avoided if current

policies were fully implemented. Generally, particle air pollution is assumed to be the most harmful. The large reductions in NO2 concentrations in Europe will likely lead to fewer asthma-related emergency department and hospital admissions.

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.

CLIMATE

On 12 May 2020 the European Commission released a Roadmap (open until 30 June 2020) and on 14 May a Public Consultation (open until 20 August 2020) on a new strategy to help the EU adapt to the effects of climate changes.

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". Before the meeting, the Commission shared with participants the Draft Recommendations on this topic to guide the discussion.

The hosts first introduced themselves as an independent committee of experts which aim is to give independent advice to the European Commission. They are from various backgrounds: biology, sociology, etc. and they do not conduct research but compile already existing research. They are currently working on several topics: climate change and health, energy and biodegradability.

The rationale behind the Draft Recommendations was presented: Climate change has an impact on health and needs to be mitigated through adaptation. The core question is: What could strengthen the resilience of the health sector in Europe in view of the climate change?

They put emphasis on vulnerable groups, regions and the urban environment, considering specifically the impact from vector-borne infectious diseases, heat and heat waves.

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.

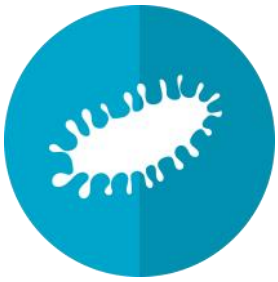
On 15 and 16 October 2020, HOPE joined the Farm to fork conference, hosted by the European Commission. The conference was the first annual meeting of European stakeholders across the food value chain willing to engage and shape the EU's path towards a sustainable food system. The conference focused on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

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 2020. 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.

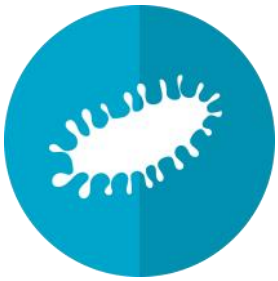
In January 2019, HOPE joined the Stakeholder Network on Antimicrobial Resistance and signed the Roadmap for Action against AMR. The AMR Stakeholder Network comprises over 80 leading organisations and individuals committed to tackling AMR at national, regional and European level, covering all dimensions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

On 13 January 2020, the EU Health Policy Platform hosted a webinar organised by the Antimicrobial Resistance (AMR) Stakeholder Network, led by EPHA - the European

Public Health Alliance – to present its Roadmap for Action on Antimicrobial Resistance (AMR).

On 19 February 2020, HOPE took part in the launch of the MEP Interest Group on Antimicrobial Resistance (AMR) at the European Parliament in Brussels, as a member of the AMR Stakeholder Network. The event was opened by the European Commissioner for Health and Food Safety, Stella Kyriakides, who stressed that antimicrobial resistance is one of the top ten global public health threats we currently face. She said that taking effective action to tackle it is one of the Commission's key priorities in the area of health and called for a strong collaboration with the European Parliament.

The group, composed of fifteen MEPs from across the political spectrum, is the only AMR-dedicated group in the European Parliament. Driven by a comprehensive strategic work programme guiding its activities for the parliamentary term 2019-2024, the MEPs AMR Group champions a cohesive and ambitious One Health approach addressing human, animal and environmental health.



On 12 February 2020, the European Commission published its 4th progress report on the implementation of the European One Health Action Plan against Antimicrobial Resistance. Substantial progress has been made since the last progress report published mid-2019. This includes meetings of the AMR One Health Network and of the Health Security Committee to enhance cooperation and coordination on AMR and One Health visits to Member States to support the implementation of national One Health action plans. Other milestones include the publication of two overview reports, respectively on measures to tackle AMR through the prudent use of antimicrobials in animals and on a series of audits carried out in 2017 and 2018 in order to evaluate the monitoring and reporting of AMR in zoonotic and commensal bacteria in certain food-producing animal populations and food.

On 28 February 2020, the Council released the outcomes of the Finnish Presidency questionnaire to the Member States on Anti-Microbial Resistance. 25 of 28 Member States (89%) provided responses to the questionnaire. The outcomes mainly present the National Action Plan (NAPs) and some good practices. Member States pronounce themselves mostly in favour of a strengthening of forums enabling the exchange of information and good practices. They also wish more sustained dialogue with the European Medicines Agency (EMA).

On 5 October 2020, the MEP Interest Group on AMR released a letter to European Commission Vice-President Schinas and Commissioner Kyriakides calling for the Pharmaceutical Strategy to integrate more provisions related to fighting AMR.

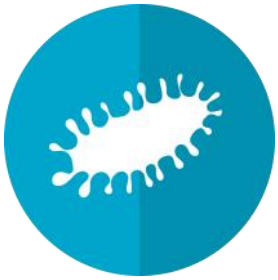
HOPE also collaborates with the European Centre for Disease Prevention and Control (ECDC) to review activities carried out and material disseminated as part of the European Antibiotic Awareness Day (EAAD) campaign. Since 2008, the ECDC has been coordinating activities as part of EAAD, which takes place 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.

EAAD 2020 was organised as an online campaign. HOPE supported the initiative by disseminating information and EAAD promotional material via its network.

On the same occasion, the AMR Stakeholder Network launched a call to collect examples of actual action, pragmatic interventions and practices implemented to support its message toward the EU Institutions.

Moreover, with the aim of raising awareness in society, EU-JAMRAI presented the first global symbol representing the fight against antibiotic resistance. It was selected among more than 600 applications from 44 countries. The jury was made up of members of several organisations involved in the fight against antimicrobial resistance, such as HOPE, the ECDC (European Centre for Disease Prevention and Control), JPI-AMR (Joint Programming Initiative on Antimicrobial Resistance), or the OECD (Organisation for Economic Co-operation and Development). The winning emblem consists of two iconic red and white capsules in the shape of a cross, easily recognisable as medicines, which are formed by assembling a red and a white heart.



On 19 November 2020, following the online campaign for the European Antibiotic Awareness Day led by the ECDC, HOPE released a Position Paper on Antimicrobial Resistance structured around three priorities: (1) Foster the One Health Approach and involve civil society stakeholders (2) Put prevention at the core of Antimicrobial Resistance policies (3) Promote the development of new antimicrobials.

On 14 December 2020, the European Commission published its 5th progress report on the implementation of the European One Health Action Plan against Antimicrobial Resistance. The progress report shows that a number of AMR initiatives have been continued or put in place in recent months. For example, the Commission has adopted in the EU Farm to Fork Strategy a target aiming to reduce by 50% the overall EU sales of antimicrobials for farmed animals and in aquaculture by 2030. This objective will be supported by the implementation of the recent Regulations on Veterinary Medicinal Products and on Medicated Feed for which implemented and delegated acts are currently being drafted. Another of the main updates of the Action Plan includes the new Commission Implementing Decision (EU) 2020/1729 on the monitoring and reporting of AMR in zoonotic and commensal bacteria. The recently adopted Pharmaceutical Strategy for Europe also flagged the fight against AMR as a key objective. The next progress report is planned to be published in mid-2021.

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.

A European Vaccination Information Portal (EVIP) was launched during the European Immunisation Week in April 2020. Via this portal, the general public can access objective, transparent and updated information on vaccination and vaccines, their benefits and safety, and the pharmacovigilance process.

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.

CANCER

On 10 December 2019, HOPE attended the event "Europe's Beating Cancer Plan – Better access to cancer care in Europe?" jointly organised by EU40, MEP Tomislav Sokol (EPP, Croatia) and MEP Nicolae Stefanuta (RE, Romania) at the European Parliament in Brussels. During the event, 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 occasion of the world cancer day.

On 20 January 2020 the European Parliament announced the creation of a Special Parliamentary Committee, whose goals include raising awareness of the importance of cancer prevention and timely medical examinations among EU citizens, as well as applying the same health standards in all member states.

On 4 February 2020, HOPE attended the event organised by the European Commission at the European Parliament Hemicycle and supported by the MEPs Against Cancer Interest Group for the launch of its Europe's Beating Cancer Plan.

During the event, the European Commission presented Europe's Beating Cancer Plan which will propose actions at every key stage of the disease:

- Prevention measures: Prevention is the easiest and most effective way of reducing cancer in the EU. Measures on prevention could include improved access to healthy diets and vaccination coverage; measures to reduce environmental risk factors such as pollution and exposure to chemicals; research and awareness raising.

- Early detection and diagnosis: Measures to improve the chance of a better health outcome through early diagnosis could include increasing the coverage of the target population for cancer screening; increased use of digital solutions and technical support to Member States.
- Treatment and care: Measures to improving outcomes of cancer care and treatment could include improving the access to high-quality treatment and uptake of new therapies; measures to ensure the availability and affordability of essential medicines; innovation and research.
- Quality of life: Measures to ensure the best possible quality of life for cancer patients, survivors and carers could include measures to improve professional reintegration; prevent discrimination; the provision of palliative care and transfers of best practice.

2 consultations were launched:

- A public consultation, open for 12 weeks and available in all EU official languages,
- A better regulation roadmap, open for 4 weeks but only available in English and more policy oriented and technical.

The results of the consultation helped identify the areas and the scope of future action.

On 1 July, HOPE attended the launch of the European Parliament Challenge Cancer Intergroup. The chair of this intergroup is the MEP Cristian Silviu Buşoi (EPP, RO).

HOPE attended on 10 September 2020 a webinar organised by the European Commission "Townhall meeting: Europe's Beating Cancer Plan".

As part of the consultation process, the European Commission invited stakeholders to participate in a virtual town hall meeting where key findings emerging from the consultation were presented. It was facilitated by Dr Josep Figueras, from the European Observatory on Health Systems and Policies, and chaired by Professors Jose M Martin-Moreno and Tit Albreht.

In the first session the Commission presented the process. The roadmap feedback consultation received 400 answers while the public consultation received 2000. Targeted stakeholders meetings took place: focus groups, expert interviews, member states survey through the Steering Group on Health Promotion and Disease Prevention and consultation with the European Parliament Special Committee on Cancer. Bilateral meetings took place as well as individual submissions by stakeholders.

Professors Jose M Martin-Moreno and Tit Albreht presented the findings and key messages. The Europe's Beating Cancer Plan should address the whole cancer control continuum. The convergence of synergies with other EU initiatives is also a real asset and

should be coordinated. Access and equity are uneven both within and between countries across Europe and the EU should address this. Existing screening could usefully be updated and optimised while new programmes are in development and introduced based on sound criteria. The EU has a very positive role to play in early detection, which should be strengthened as it is complementary to screening.

The consultation process started before COVID-19 and has not therefore been able to fully reflect the cancer community's concerns as the impact on cancer prevention, early detection, treatment and so on become clear. The Commission aims to integrate lessons learned on this.

The Commission postponed the publication of the plan for January 2021.

On 7 October 2020, HOPE attended the European Health Policy Platform Thematic Network presenting: 'The Financials of CRC Screening – Better Investments to Save More Lives'. Discussion points included:

- How the extraordinary Basque programme can be used as a model for other European countries and how it should be integrated into the European Commission's Beating Cancer Plan.
- How such population-based programs in the EU are successful mainly due to the high commitment of and close cooperation with the primary care sector.
- The fact that women participate more than men, while men have a higher chance to be affected.
- The need to face such challenges of inequalities - of gender, deprivation and access. Important factors that must be overcome for optimal prevention program participation rates, both at EU and national levels.
- How one potential solution to such inequalities is the use of free tests, and the active role of GPs breaking taboos and motivating people.

In all, the discussion concluded that screening for CRC cancer is complex and requires financial investment, but it is highly cost-effective with clear and proven benefits that save lives.

HOPE is involved in iPAAC Joint Action (JA) which aims to developing innovative approaches in cancer control. On 9 September 2020 HOPE attended the webinar "Facing the harsh reality of pancreatic cancer: policy measures and health system strategies", an online webinar held under the umbrella of the iPAAC Joint Action that continued in activities related to the improvement of pancreatic cancer care and the "Bratislava Statement".

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, the main objective of which is to increase the average healthy lifespan of EU citizens by 2 years by the year 2020. In particular, HOPE is involved in the Action Group on Functional Decline and Frailty.

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.

In the mission letter for Vice-President Dubravka Šuica, the President tasked her to present a Green Paper on ageing, launching a debate on long-term impacts, notably on care and pensions, and on how to foster active ageing.

On 17 June 2020 the Commission presented a Report on the Impact of Demographic Change, setting out the relevant evidence and analysis and being based on the most recent demographic projections by Eurostat (April 2020).

On 16 November 2020, the European Commission released a Green Paper on Ageing Initiative.

The Green Paper 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.

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).

The key message was that mental health is highly prevalent and increasing in Europe and that it is a cross-sectorial subject that should be involved in all policies. In previous years, the Commission paid explicit attention to mental health by means of activities such as the 2005 Mental Health Green Paper, the 2008 European Mental Health Pact and the 2013 Joint Action on Mental Health. An EU Framework for Action on Mental Health was adopted in 2016 but was never implemented. Since 2018, the Commission has opted to address mental health as part of its overall activities in the field of chronic illness.

The event was made to raise awareness on the topic of mental health and MEPs called the Commission for action, following the EPSCO conclusions. The outcome of the conference was that the challenge today is not to create new documentation on the subject but to act on practical implementation, at Member States level. Some strategies already exist and a new one should come in to build on them.

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 in 2017, 2018, 2019 and 2020.

The European Commission Directorate-General Migration and Home Affairs – DG HOME (Directorate D: Law Enforcement and Security, Unit D.2 Counter-Terrorism) invited HOPE to a virtual consultative workshop with national critical infrastructure operators, European critical infrastructure associations and other stakeholders regarding the protection and resilience of critical infrastructures in the EU on 31 March 2020.

The annex to the European Commission's Adjusted 2020 Work Programme released on 27 May 2020 envisages a "proposal for additional measures on critical infrastructure protection" to be adopted during the fourth quarter of this year. The development of this proposal will be informed by, among other things, the outcomes of an external study launched by the Commission's Directorate-General for Migration and Home Affairs (DG HOME). The objective of the study, which is being carried out by EY in conjunction with RAND Europe, is to provide to the Commission with a set of recommendations concerning different possible measures aimed at further enhancing the protection and resilience of critical infrastructures (CI) in the EU. The study, which takes into account a broad range of measures at European level, follows the recent evaluation of the European Critical Infrastructure (ECI) Directive.

HOPE participated to a virtual consultative workshop organised by DG HOME with European critical infrastructure associations and national critical infrastructure operators regarding the protection and resilience of critical infrastructures in the EU on 30 June 2020.

A Communication from the Commission on the EU Security Union Strategy was published on 24 July 2020 and it also mentions Critical infrastructure protection and resilience.

At the same time, Member States have exercised their margin of discretion by implementing existing legislation in different ways. The resulting fragmentation can undermine the internal market and make cross-border coordination more difficult – most

obviously in border regions. Operators providing essential services in different Member States have to comply with different reporting regimes. The Commission is 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.

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.

The Commission is committed to enhancing the EU Forum on the protection of public spaces, which has brought together a wide group of people with responsibility over the security 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.

Critical infrastructure, including transport hubs, power stations, health care infrastructures and water treatment facilities, can be terrorist targets. Critical infrastructure operators are responsible for providing services that are essential in meeting vital societal needs. At the same time, these operators continue to grow increasingly dependent on one another and face an ever more complex risk environment. Such risks include terror attacks, natural disasters, accidents, and malicious threats. In order to ensure the dependable provision of essential services across the EU and the reliable functioning of the internal market, it is vital to ensure that critical operators of essential services are resilient, i.e. sufficiently prepared to prevent, mitigate, and recover from disruptions. The Commission will adopt a set of measures aimed at enhancing the resilience of operators in the face of both physical and digital risks.

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 2020, many events were cancelled, 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

ALADDIN

ALADDIN, which kicked off in November 2020, 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).

Over two years, ALADDIN will develop 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.

PERISCOPE—PAN-EUROPEAN RESPONSE TO THE IMPACTS OF COVID-19 AND FUTURE PANDEMICS AND EPIDEMICS

PERISCOPE is a Horizon 2020 large-scale research project that brings HOPE together with 31 other European organisations.

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.

From 1 November 2020 to 31 October 2023, PERISCOPE will be:

- gathering 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;
- carrying out innovative statistical analysis on the collected data;
- identifying best practices that could be applied at pan-European level for a better containment of the pandemic and its related socio-economic impacts;
- developing 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.

PERISCOPE is coordinated by the University of Pavia (Italy).

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.

TENDER—AFFECTIVE BASED INTEGRATED CARE FOR BETTER QUALITY OF LIFE

In 2019, HOPE joined a new EU project funded under the Horizon 2020 Programme. The TeNDER project officially started in November 2019.

In Europe alone, the World Health Organisation estimates that more than 10 million people are living with dementia, and that by 2030 these numbers will likely double. The prevalence of Parkinson's Disease is also set to rise, according to the European Brain Council, with more than 1.2 million patients currently living in Europe. In addition, these patients are often simultaneously afflicted with cardiovascular diseases, diabetes and other chronic illnesses.

affecTive basEd iNtegrateD carE for betteR Quality of Life (TeNDER) is a multi-sectoral project. From the end of 2019 to the end of 2022, it will develop an integrated care model to manage multi -morbidity in patients with neurodegenerative diseases. The consortium partners are: the Polytechnic University of Madrid (Universidad Politécnica de Madrid), Madrid Health Service (Servicio Madrileño de Salud), Madrid Parkinson Association (Asociación Parkinson Madrid), University of Rome - 'Tor Vergata' Hospital, Schoen Clinic Bad Aibling (Germany), Alzheimer Slovenia (Združenje Spominčica), Centre for Research and Technology Hellas (Greece), Ubiwhere (Portugal), DataWizard (Italy), Free University of Brussels (Vrije Universiteit Brussel), Maggioli Group (Gruppo Maggioli, Italy), Elgoline (Slovenia) and HOPE.

By combining user-friendly technologies and substantial research experience, our project aims to help improve the quality of life of patients and those who surround them. Moreover, it will test ways to facilitate communication between different health and care providers who treat patients with multi-morbidities.

To this end, TeNDER will perform 5 large-scale pilots targeting patients who suffer Alzheimer's or Parkinson's with co-morbidities. In each pilot setting (i.e., in-hospital acute care, at home, and in day- and full-time nursing homes), patients will be monitored using sensors, cameras that capture movement, affective recognition technology, and wristbands that record basic vitals, etc. TeNDER's technical, legal and ethical experts will ensure that all personal data is protected according the General Data Protection Regulation (GDPR) and that our approach complies with rigorous ethical guidelines.

TeNDER partners had to adapt to increasing restrictions throughout 2020. Intra- and inter-project collaborations took place online: from consortium meetings in the spring and autumn, to online campaigns and joint web articles.

On 1 November 2020, TeNDER marked its first year. The recruitment process for the first-wave pilots (preliminary) was launched in December 2020. HOPE helped lay the groundwork for the next couple of years. HOPE produced recruitment materials for user partners and ensured that all communication channels are ready for the timely dissemination of results. In addition, we are currently working on project standardisation, so that by the end of the three-year cycle, TeNDER's integrated care model can be beyond pilot settings.

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.

In June 2020, iPAAC launched a survey on existing programs for the real-life monitoring of innovative therapies in Europe. Within iPAAC, the Work Package (WP) 9 is dedicated to innovative therapies in cancer. Thanks to this survey, the WP9 intends to map existing programs for the real-life monitoring of innovative therapies in Europe. The focus had been given on the real-life monitoring of patients treated with CAR-T cells, more especially for indications already approved in Europe as of June 2020: acute lymphoblastic leukaemia (ALL) and B-cell lymphomas.

An online webinar that continued in activities related to the improvement of pancreatic cancer care and the “Bratislava Statement” was held on 9 September 2020 under the umbrella of the iPAAC Joint Action. It involved representatives from medical societies, patient associations, cancer plan organisations, and other relevant European health care stakeholders. Pancreatic cancer is one of the most lethal tumours, and it is the fourth cause of cancer death in Europe. Despite its major public health impact, however, there are no effective treatments or high-visibility research efforts. This alarming situation is emblematic of a larger group of cancer diseases, the so-called “neglected cancers”. After conducting a systematic review of the literature, a central discussion took place during a meeting in Bratislava on 16–17 September 2019. This led to a definition of the key steps that health care systems can rapidly implement to address pancreatic cancer while maximising the value of health care resources.

This initiative resulted in twenty-two consensus recommendations for providing high-quality care for patients with pancreatic cancer.

iPAAC
INNOVATIVE PARTNERSHIP
FOR ACTION AGAINST CANCER

EU-JAMRAI

HOPE contributed to the Joint Action on Antimicrobial Resistance and Healthcare Associated Infections (JAMRAI) which was launched on 1 September 2017 and ended in 2020. 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 AMR and 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 Antimicrobial Resistance (AMR) and control Healthcare-associated Infections (HCAI) in line with the One Health approach and ongoing EU and international policies.

EU JAMRAI was originally supposed to end in 2020 but was extended to 28 February 2021. EU-JAMRAI released, in January 2021, policy briefs presenting concrete actions and recommendations developed by the joint action to fight antimicrobial resistance in humans and animals:

- Appropriate use of antibiotics in a One Health perspective
- The need to develop core elements at the European level on antimicrobial stewardship (AMS) and infection prevention and control (IPC)
- The need to develop indicators and targets for AMR action plans in the EU
- The need for a reinforced AMR One Health Network
- The urgent need to foster research on infection prevention and control to improve health security
- Incentivising antibiotic access and innovation

HOPE AS A PARTNER – COMPLETED PROJECTS

EURIPHI

EURIPHI is a Horizon 2020 Coordination and Supporting Action that kicked off in Brussels on 31 January 2019. The project's aim is to adopt cross-border value-based procurement for innovation and integrated solutions in health and care systems in Europe. The consortium, led by MedTech Europe, gathers 25 organisations, including public procurement organisations covering more than 500 service providers throughout Europe, as well as, research organisations, associations and networks, and private companies.

In the EURIPHI project, partners involved or interested in value-based procurement and PPI (Public Procurement of Innovation)/PCP (Pre-Commercial Procurement) teamed up around the novel approach of Most Economically Advantageous Tendering Value Based Procurement (MEAT) to achieve the following goals:

- establish a sustainable community of practice using innovative procurement methods and developing legal guidance for efficient cross-border, value-driven procurement with localised decision-making;
- adapt existing tools, performing market consultations, and deploying cross-border value-based procurement in the field of rapid diagnostics for infectious diseases, as well as in new models of patient-centred integrated care;
- develop a EURIPHI network that includes representatives of health authorities, policymakers, and payers who, in collaboration with other key stakeholders, will further prioritise investments and foster the deployment of value-based PPI/ PCP.

HOPE joined the consortium as a partner to help create a community of practice; to support actions that enable market readiness for the Europe-wide deployment of cross -border value-based PPIs; to identify suitable test environment for open-market consultations and learning cases; and to raise awareness about the project activities and its results.

On 16 July 2020, EURIPHI held a Final Dissemination Webinar online. The webinar presented the main outcomes

MEDEYE

The MedEye Project was officially launched on 28 February 2017 and ended in June 2020. HOPE was a partner of this project, funded from the Horizon 2020. HOPE was involved as leader of the project Work Package on Dissemination and Exploitation of project results.

Medication errors occur daily and are a major burden to society. They often lead to adverse drug reactions, lengthened hospital stays, increased healthcare costs, and in the most severe cases, increased mortality. Medication errors pose a significant risk to the European population. Research has shown, however, that 50% of medication errors can be stopped with an automated check at the patient's bedside.

MedEye is an innovative medication verification suite that scans, detects, and verifies medication at the bedside. MedEye stops medication errors from taking place by verifying medication before it is administered to patients.

It has already been tested and validated in several Dutch hospitals with excellent results. Thanks to the support of Horizon 2020 – Fast Track to Innovation Programme, activities will be performed to enhance MedEye and facilitate its deployment on a large scale.

Two studies were performed to establish transnational performance and cost effectiveness. One for the hospital sector at the Newcastle Upon Tyne Hospitals Foundation Trust in partnership with Durham University and one for long-term care through central pharmacy Pharmaforce.

It focuses on patient safety as a priority. As more care is provided in-home, the complexity of treatment for patients in long-term care facilities has increased. The latter must find ways to cover costs while providing quality care.

MedEye provides nurses and healthcare workers with a single place where they can verify all medications – oral solids, injections, compounded and repackaged medication. Administration details are then automatically stored on a patient's medication administration record. Benefits for hospitals and long-term care facilities include a reduction in medication errors, a common workflow for all nurses, and greater flexibility in logistics which can help increase efficiency.

On 23 June 2020, HOPE and PAQS ASBL (the Platform for Continuous Improvement of Quality of Care and Patient Safety) hosted the fourth webinar of the Quality & Safety network covering the Medication safety system MedEye.

It explained that the system has already been tested and validated in several Dutch hospitals with outstanding results. Recently, MedEye has been able to enhance its activities and improve its deployment on a large scale thanks to the funding from Horizon 2020-Fast track Innovation programme.

The webinar presented the overall results of the MedEye project, focusing on specific results in long-term care and hospital care. Remco Wijngaarden from MINT briefly introduced the MedEye system along with some of the results of MedEye implementation. This was followed by a presentation by Clare Tolley from the Faculty of Medical Sciences, Newcastle University, on the outcomes of a study performed in a hospital in Newcastle. Finally, Remco Wijngaarden presented the implementation of MedEye in a long-term facility in Belgium.

MedEye Technology

EUNETHA

EUnetHTA was established to create an effective and sustainable network for Health Technology Assessment (HTA) across Europe – working together to help develop reliable, timely, transparent and transferable information to contribute to HTAs in European countries.

EUnetHTA supports collaboration between European HTA organisations that brings added value at the European, national and regional level through:

- facilitating efficient use of resources available for HTA
- creating a sustainable system of HTA knowledge sharing
- promoting good practice in HTA methods and processes.

HOPE was a partner of the EUnetHTA Joint Action 3 (2016-2020) through its Stakeholder Forum. Joint Action 3 aimed to design and implement a sustainable model for scientific and technical cooperation on HTA in Europe. The voluntary cooperation within and between national and regional HTA bodies was essential in this joint action. The EUnetHTA collaboration has grown to 81 organisations from 29 countries, forming a network of strong partners across Europe working together for better access to health technologies for European citizens.

HOPE AS AN ADVISOR

SPHINX - A UNIVERSAL CYBER SECURITY TOOLKIT FOR HEALTH-CARE INDUSTRY

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.

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.

SUPPORT FOR THE HEALTH WORKFORCE PLANNING AND FORECASTING EXPERT NETWORK

HEALTH WORKFORCE PLANNING AND FORECASTING EXPERT (SEPEN) NETWORK

The "Support for the health workforce planning and forecasting expert network" (SEPEN) three-year term joint tender was launched in September 2017 as a new action in the field of European health workforce planning. The action is supported by the Health programme of the European Union and aims to establish an expert network on health workforce planning and forecasting.

The purpose of this joint tender is to sustain cross-country cooperation and provide support to Member States in increasing their knowledge, improving their tools and achieving higher effectiveness in health workforce planning processes and policy. It builds on the results and work undertaken by the Joint Action on European Health Workforce Planning and Forecasting (EU JAHWF). HOPE joined the network in July 2018.

On 10 September 2020, HOPE participated in the online workshop "Digital Health: What are the implications for supply, demand, monitoring and organisation of Health Workforce? – How eHealth/ mHealth can improve health workforce productivity, monitoring, planning and forecasting" organised by SEPEN.

On 28 October 2020,HOPE joined the SEPEN closing event discussing 'SEPEN and beyond: how can the EU support to Member States' health workforce planning policies contribute to healthier societies?'

The aim of the "Support for the health workforce planning and forecasting expert network" joint tender (SEPEN) was to activate a community and to establish an expert network on health workforce planning and forecasting. SEPEN is a joint action on workforce planning co-financed by the European Commission.

The event was welcomed by Dr Miklós Szócska, Semmelweis University, SEPEN Consortium leader and Dr Andrzej Rys, Director for Health systems, medical products and innovation at DG SANTE

The results of SEPEN were presented:

- The community of the SEPEN Expert network – Sarada Das, Standing Committee of European Doctors (CPME)
- Results of the SEPEN Mapping Study - health workforce planning and policy developments in the EU - Prof. Walter Sermeus and Michel Van Hoegaerden, Katholieke Universiteit Leuven
- Essential steps of more advanced health workforce planning – Paolo Michelutti, Italian National Agency for Regional Healthcare Service
- Emerging issues of health workforce planning– Dr Eszter Kovacs, Semmelweis University

Targeted commentaries followed delivered by Ortwin Schulte, Health Attaché, German Presidency of the Council of the EU; Gabrielle Jacob, WHO Europe; Kristine Klavina, Ministry of Health Latvia; Vootele Veldre, Ministry of Social Affairs Estonia.

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 2020 – 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 2021 and then to 2022.

NEWS FROM HOPE EXCHANGE PROGRAMME 2019

HOPE Exchange Programme 2019 participants joined a survey conducted in collaboration with researchers from the HealthPros project with the Amsterdam Medical University and the OECD.

Many also participated in the discussion on preliminary results that took place during our Agora Meeting in Ljubljana.

In April 2020 the results of 2019 survey and talks with HOPE Exchange Programme and AGORA participants were published in a scientific article in PLOS ONE “Why, what and how do European healthcare managers use performance data? Results of a survey and workshop among members of the European Hospital and Healthcare Federation”.

HealthPros
International Training Network for Healthcare Performance Intelligence Professionals

HOPE Agora 2019 Conference in Ljubljana

Conferences

CONFERENCES CO-ORGANISED BY HOPE

HOPE-PAQS WEBINAR: IHI HEALTH IMPROVEMENT ALLIANCE EUROPE (HIAE)

On 25 February 2020 HOPE and PAQS organised a Quality & Safety network webinar to present the work of HIAE. The panellists described specific examples of members' work and discussed some of the ongoing learning that is emerging through HIAE. The webinar is available on YouTube.

10TH EUROPEAN CONFERENCE ON RARE DISEASES & ORPHAN PRODUCTS (ECRD)

HOPE joined the organisation of the ECRD 2020 on the theme "The rare disease patient journey in 2030" on 14-15 May 2020. ECRD 2020 put a spotlight on emerging trends in best practices, promising technologies, and cutting-edge thinking for rare diseases.

HOPE-PAQS WEBINAR: MEDICATION SAFETY SYSTEM MEDEYE

On 23 June 2020 HOPE and PAQS hosted the fourth webinar of the Quality & Safety network covering the medication safety system MedEye. The webinar presented the overall results of the MedEye project, focusing on specific results in long-term care and hospital care. The webinar is available on YouTube.

ICIC20 VIRTUAL CONFERENCE: 20TH INTERNATIONAL CONFERENCE ON INTEGRATED CARE

Between 9 – 30 September 2020 the ICIC20 Virtual Conference took place to discuss the shared vision and values of integrated care, as well as the implementation science and improvement outcomes of integrated care across the whole life course.

HOPE-PAQS WEBINAR: DEVELOPMENT OF REGIONAL STRATEGY FOR PATIENT SAFETY IMPROVEMENT

On 6 October 2020 HOPE and PAQS organised a webinar to underline the importance of patient safety improvement strategies at regional levels. An ongoing initiative in Belgium was presented to show how a Regional Strategy for Patient Safety Improvement can be developed. The webinar is available on YouTube.

CANCER & IMMUNOTHERAPY: GREATEST CHALLENGES AND NOVEL THERAPIES INSPIRING EUROPEAN CITIZENS

On 17 November 2020 HOPE and the FEAM European Biomedical Policy Forum organised an online lecture to discuss progress and new emerging treatments for cancer in Europe. The event showed how policymakers can help to support research into novel therapies, and ensure the newest treatments reach patients across Europe.

8TH INTERNATIONAL HOSPITAL CONGRESS – HEALTH 6.0: PEOPLE AND TECHNOLOGY

The Portuguese Association for Hospital Development (APDH) with support of HOPE hosted the 8th International Hospital Congress on 26-27 November 2020. The participants discussed the enormous evolution in technological innovation in the health sector as well as its impact on organisations.

8º CONGRESSO
INTERNACIONAL DOS HOSPITAIS
SAÚDE 6.0: PESSOAS E TECNOLOGIA

TWO EXAMPLES OF CONFERENCES WITH HOPE AS A SPEAKER

EUROPEAN SPECIALISED NURSES ORGANISATION (ESNO) – CONGRESS

HOPE was invited to speak at the ESNO CONGRESS that took place in Brussels on 20 February 2020.

For this second edition, Walter Sermeus, Professor at the University Leuven Institute for Healthcare Policy, set the scene of Health Workforce Dynamics and the future of Nurse Specialists. He was followed by Donna Walsh, Executive Director of the European Federation of Neurological Associations (EFNA) with a keynote speech on “Neurological Nurse Specialists: A Vital Resource”.

Nico Decock, Chair of the ESNO Education Committee presented the ESNO survey European Specialist Nurses. Almost 300 nurses replied to this survey that identified 118 “specialties” in nursing!

Then, sixteen parallel workshops in four episodes were organised around a specialty: Wound Care Nurses, Peri Operative Nurses, Nurses in Rheumatology, Nurses in Transplant and Renal Care; Nurses in Dermatology, Endoscopy Nurses, Nurse Practitioners, Nurse Anaesthesia in France, Oncology nursing, Intensive Care Nurses, etc.

HOPE was invited to lead the session on the cross-border challenges of a harmonised training for nurses in advanced position. It became clear and was also highlighted in the conclusions of the conference that the specialised nurses should not spend too much to build a Common Training Framework at EU level. It might even be against their interest as it is made to facilitate mobility of professionals and not to improve the quality of care which seems to be the main goal of ESNO.

CENTRALISING CANCER CARE?

On 14 October 2020, HOPE CEO was invited to debate during a virtual event, “Centralising cancer care? Quality, costs and the future of hospitals in Europe”.

Centralising cancer care has been a hot topic for quite some time. Many argue that hospitals are often too small and treat too few patients. Only by pooling resources and specialists in comprehensive cancer centres could high-quality care and equal access to innovative therapies be guaranteed.

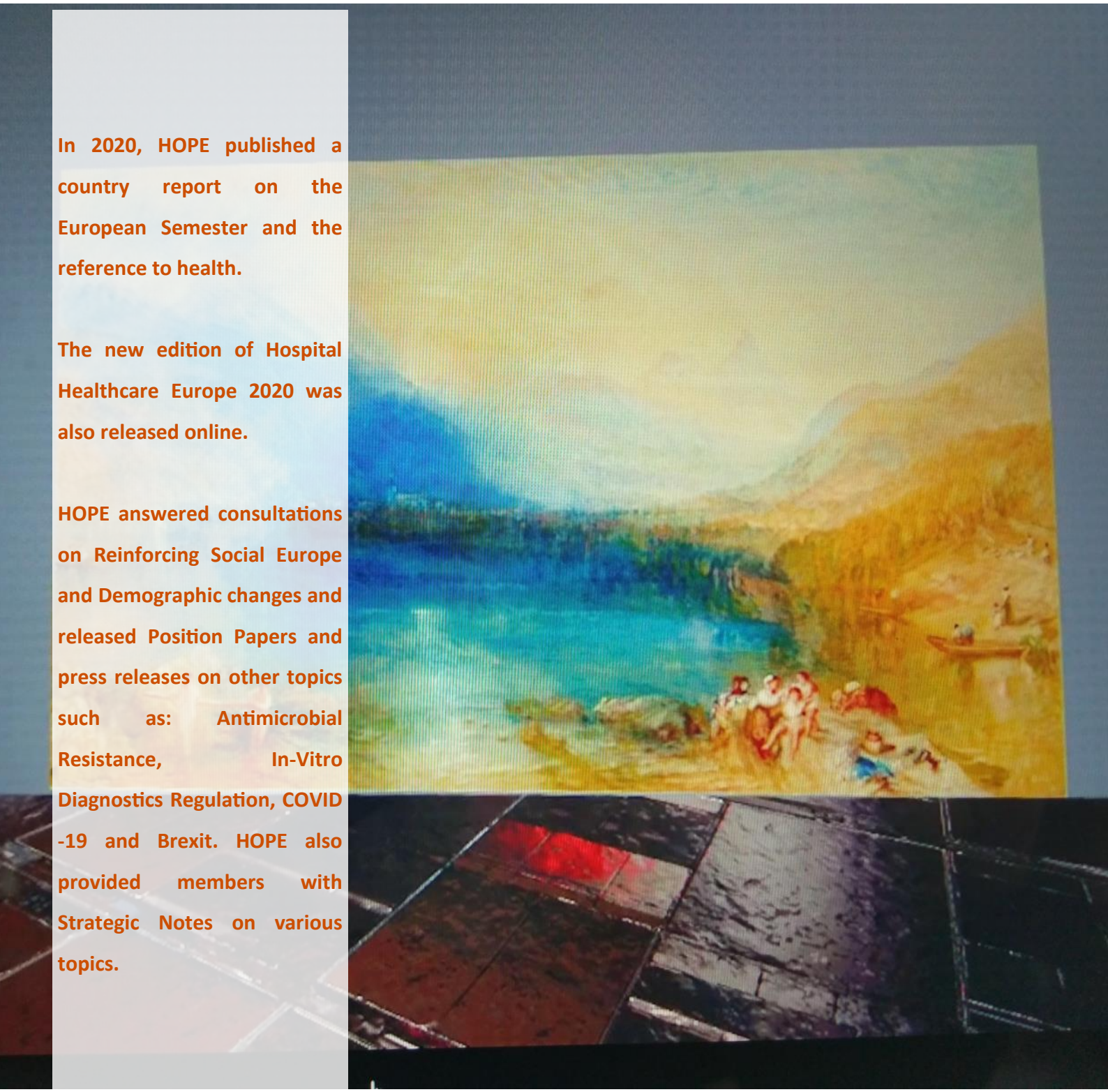
Yet, the Covid-19 pandemic has shown that reducing the number of hospital beds may also be problematic for the quality of care. Broad availability of hospitals can help intercept epidemic outbreaks and maintain medical expertise – also in oncology.

What should the future of inpatient cancer care look like in Europe? Is centralisation still the way forward, or do we need to maintain broad operational readiness and expertise?

Stefan Gijssels, Executive Director, Digestive Cancers Europe and EuropaColon, promoted more transparency, while Pascal Garel asked for more comparability. He showed how diverse systems are in terms of capacity but also in the way they are organised. There remains debate about the optimal model of organising cancer care. He also raised several barriers to optimal care: the main ones being an ageing health workforce and expensive biological drugs.

Chapter 4

PUBLICATIONS



In 2020, HOPE published a country report on the European Semester and the reference to health.

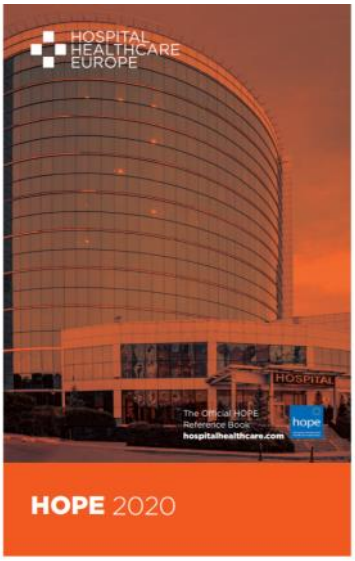
The new edition of Hospital Healthcare Europe 2020 was also released online.

HOPE answered consultations on Reinforcing Social Europe and Demographic changes and released Position Papers and press releases on other topics such as: Antimicrobial Resistance, In-Vitro Diagnostics Regulation, COVID -19 and Brexit. HOPE also provided members with Strategic Notes on various topics.

Publications

HOPE central office produced for internal use 11 HOPE Monthly Newsletters and 25 COVID-19 HOPE Weekly Review. For external use, 11 HOPE News and Updates were released. HOPE also regularly fed its social media channels with updates about EU Policies, campaigns or events. Through the year, HOPE posted 113 tweets and also retweeted many relevant posts, 28 posts on Facebook and 37 posts on LinkedIn.

HOSPITAL HEALTHCARE EUROPE 2020



In December 2020, 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 2020 issue focuses on COVID-19 and cancer.

EUROPEAN SEMESTER – COUNTRY REPORT – REFERENCE TO HEALTH

On 26 February 2020, HOPE released a comparative synthesis of the European Semester Country Reports and especially health aspects. For 25 EU countries, HOPE synthesis gives an overview of situations and improvements on topics such as Country Specific Recommendations, healthcare and hospital spending, public spending in long-term care, cost efficiency, access to care or even digitalisation.

The countries are: Austria, Belgium, Bulgaria, Croatia, Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden.

POSITION PAPERS

HOPE POSITION ON IN-VITRO DIAGNOSTICS REGULATION

In September 2020, HOPE adopted a position paper on the In-Vitro Diagnostics Regulation (IvDR). HOPE pointed out that expert panels and reference laboratories are not yet operational, and that a new real time frame for the introduction of the IvDR should be established, considering the consequences of the COVID-19 pandemic.

HOPE POSITION ON ANTIMICROBIAL RESISTANCE (AMR)

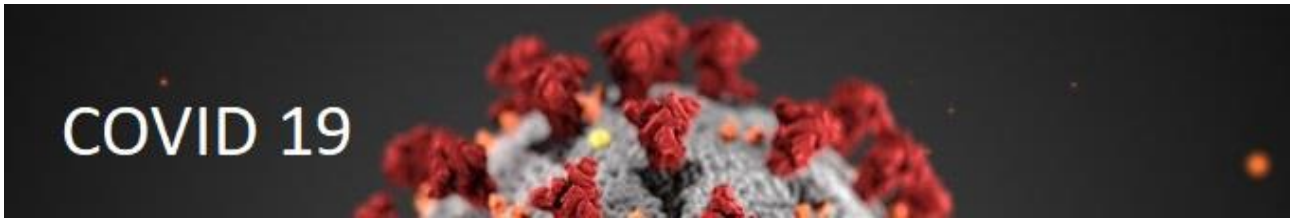
In November 2020, HOPE released a position paper on "Antimicrobial Resistance" (AMR) at the World Antibiotic Awareness Week, organised by the WHO and the European Antibiotic Awareness Day and promoted by the European Centre for Disease Prevention and Control (ECDC). HOPE called for further action at EU level and drew attention to three aspects: focusing on prevention policies, fostering the One Health Approach and promoting the development of new antimicrobials.

HOPE POSITION ON REINFORCING SOCIAL EUROPE

On 14 January 2020, the European Commission presented a roadmap for a Strong Social Europe for Just Transitions. Simultaneously, to support the implementation of the European Pillar of Social Rights and prepare the ground for the Social Economy Action Plan (to be presented in 2021), the Commission launched a broad discussion with all EU countries and regions and with all their partners. In November 2020 HOPE contributed to the Commission initiative on "Reinforcing Social Europe" and published its contribution. The paper underlines that the coherence of EU policies impacting health and social care must be increased and that fragmented approaches have to be avoided.

HOPE POSITION ON THE INITIATIVE 'DEMOGRAPHIC CHANGE IN EUROPE - GREEN PAPER ON AGEING'

In November 2020 HOPE contributed to the European Commission the initiative "Demographic change in Europe – green paper on ageing" and published a Position Paper. 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.



PRESS RELEASE ON COVID-19

On 26 March 2020 HOPE published a press release on the COVID -19 pandemic, acknowledging the tremendous work of health care professionals.

HOPE has developed a systematic exchange of information and knowledge and made important contacts during the pandemic.

JOINT LETTER TO THE EUROPEAN COMMISSION ON COVID-19

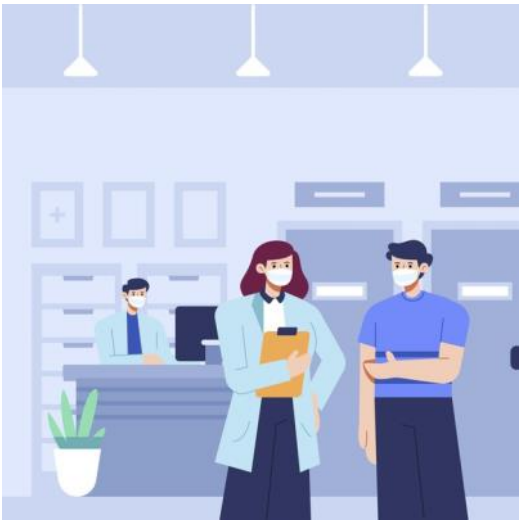
On 18 March 2020, the representatives of the health care community on European level AIM, CPME, ESIP and HOPE wrote a joint letter to the European Commission on the COVID-19 pandemic.

They invited the Commission to set up a discussion to share experiences and lessons-learned from COVID-19 once the emergency situation has passed.

COVID-19 AND BREXIT - PROTECTING PATIENTS ACROSS EUROPE FROM PANDEMICS

In June 2020, HOPE together with other healthcare associations published a paper on “COVID-19 and Brexit – Protecting patients across Europe from pandemics”.

The paper showed the various risks for the healthcare sector and the population if there is no deal or a bad deal for the Brexit.



ANALYSES - HOPE STRATEGIC NOTES

THE EU DIRECTIVE ON WORK-LIFE BALANCE FOR PARENTS AND CARERS

In January 2020, HOPE released a Strategic Note on the EU Directive on work-life balance for parents and carers. On 13 June 2019, the Council adopted the Work-life balance Directive, a piece of legislation that aims at helping working parents and carers to reconcile work and family responsibilities, setting new or higher minimum standards across EU countries. It was published in the Official Journal of the EU on 12 July 2019 and came into force on 1 August 2019.

The objective of this HOPE Strategic Note was to stress to HOPE members the changes brought about by the new directive and the aspects on which the Member States have a room for manoeuvre in the transposition phase.

HOPE 2019 ARTICLES AND REPORTS SELECTION

On February 2020, HOPE released a Strategic Note gathering articles and reports by thematic issue, such as well-being, emergency care, integrated care, financing, workforce, informal carers, access to care, quality and patient safety, digitalisation, diseases, medical devices and pharmaceuticals.

The following reports, articles and their links are selection of the different articles and reports that were included in the HOPE newsletters from January to December 2019.

INTENSIVE CARE CAPACITY IN EUROPE

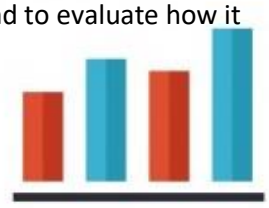
On 30 March 2020, HOPE released a Strategic Note on Intensive care capacity in Europe in relation with COVID-19 outbreak.

Intensive Care Units (ICUs) are key in the fight against COVID-19 and a lot of wrong information is circulating. This note tries to capture what figures were available before the crisis started. It shows how difficult it was to know the reality of ICUs capacity. A lot of countries were increasing the intensive care beds but it was not possible to track this information yet.

COVID-19: CROSS-BORDER THREAT IN THE EUROPEAN UNION

On 30 March 2020, HOPE released a Strategic Note on EU response to cross-border threats in relation with COVID-19 outbreak.

This HOPE Strategic Note captures the legal basis, the mechanisms in place and the activities until January 2020 related to the EU (European Commission and Member States in particular) responsibilities in dealing with such a pandemic. It is only descriptive and does not intend to evaluate how it worked or works now.



STATE-AID ACTIONS IN THE CONTEXT OF THE COVID-19

In May 2020, HOPE released a Strategic Note on State-aid actions in the context of the COVID-19. State aid is an advantage given by a government that may provide an organisation with an unfair competitive edge over its economic rivals. Such State aid can be delivered in a variety of ways, such as through the allocation of grant subsidies, the provision of interest and tax relief, or the purchasing of goods and services on preferential terms.

In the scheme of the pandemic of COVID-19, the European Commission adopted on 19 March a Temporary Framework to enable Member States to further support the economy. The Temporary 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.

EUROPEAN SOLIDARITY DURING THE COVID-19 OUTBREAK

In June 2020, HOPE release a Strategic Note on European solidarity during the COVID-19 outbreak. During the COVID-19 outbreak, across the European Union, countries, regions and cities are stretching out a helping hand to neighbours and assistance is given to those most in need: donations of protective equipment such as masks, cross-border treatments of ill patients and bringing stranded citizens home.

This Strategic Note gives an overview of solidarity between countries, according to three fields of action:

- in treating patients
- in protecting health workers and citizens
- in bringing people home.

EUROPEAN SEMESTER 2020: COUNTRY-SPECIFIC RECOMMENDATIONS IN HEALTHCARE

In September 2020, HOPE released a Strategic Note on the European Semester 2020 and the country-specific recommendations in healthcare.

On 20 July 2020, the Council adopted its 2020 recommendations and opinions. Those country-specific recommendations take into account the specific context of the COVID-19 pandemic and the activation of the general escape clause under the Stability and Growth Pact on 20 March 2020.

The document presents extracts of the recommendations in the area of healthcare for the European Union Member States, as well as for the United Kingdom.

General Report on the Activities of the European Hospital and Healthcare Federation 2020

hope
European Hospital and Healthcare Federation