General Report

on the Activities of the

European Hospital and Healthcare Federation

2019

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Illustration Chapter 4: Exposition ADLC—18 ans de création artistique Illuminart
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General Report on the Activities of the European Hospital and Healthcare Federation — 2019

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European Hospital and Healthcare Federation

2019

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Introduction

2019 was a year of change in European politics and policies. The European Parliament Elections took place between 23 and 26 May in the 28 Members States and a new Commission took office on 1 December 2019, led by a new President, Ursula von der Leyen, with a new Commissioner for Health and Food Safety, Stella Kyriakides.

In 2019, European politics were strongly marked by the Brexit negotiations. Major implications for the NHS and for health and social care workers both in the UK and the EU27 were at stake. The Withdrawal Agreement was finally approved on 30 January 2020 and the transition period started on 1 February 2020 for one year.

On the legislative side, several new legislations were adopted: the Work Life Balance Directive and the Transparent and Predictable Working Conditions Directive. Negotiations between the European Parliament and the European Council on Health Technology Assessment (HTA) were still running.

Several other initiatives gained momentum on the European political agenda. HOPE closely monitored developments and joined discussions about several topics, such as eHealth, Artificial Intelligence, the implementation of the Falsified Medicines Directive and of the Medical Devices Regulation, the Cybersecurity Package, Antimicrobial Resistance, Vaccination, and the European Pillar of Social Rights, to name but a few.

In 2019, HOPE was also active in contributing to the EU non-legislative agenda, mainly through several European projects. The projects EURIPHI on value-based procurement and TeNDER on digital tools applied to integrated care both kicked-off respectively in February and December 2019 and the medication safety project MedEYE, which started in 2017, further developed its activities in 2019 with HOPE as a partner.

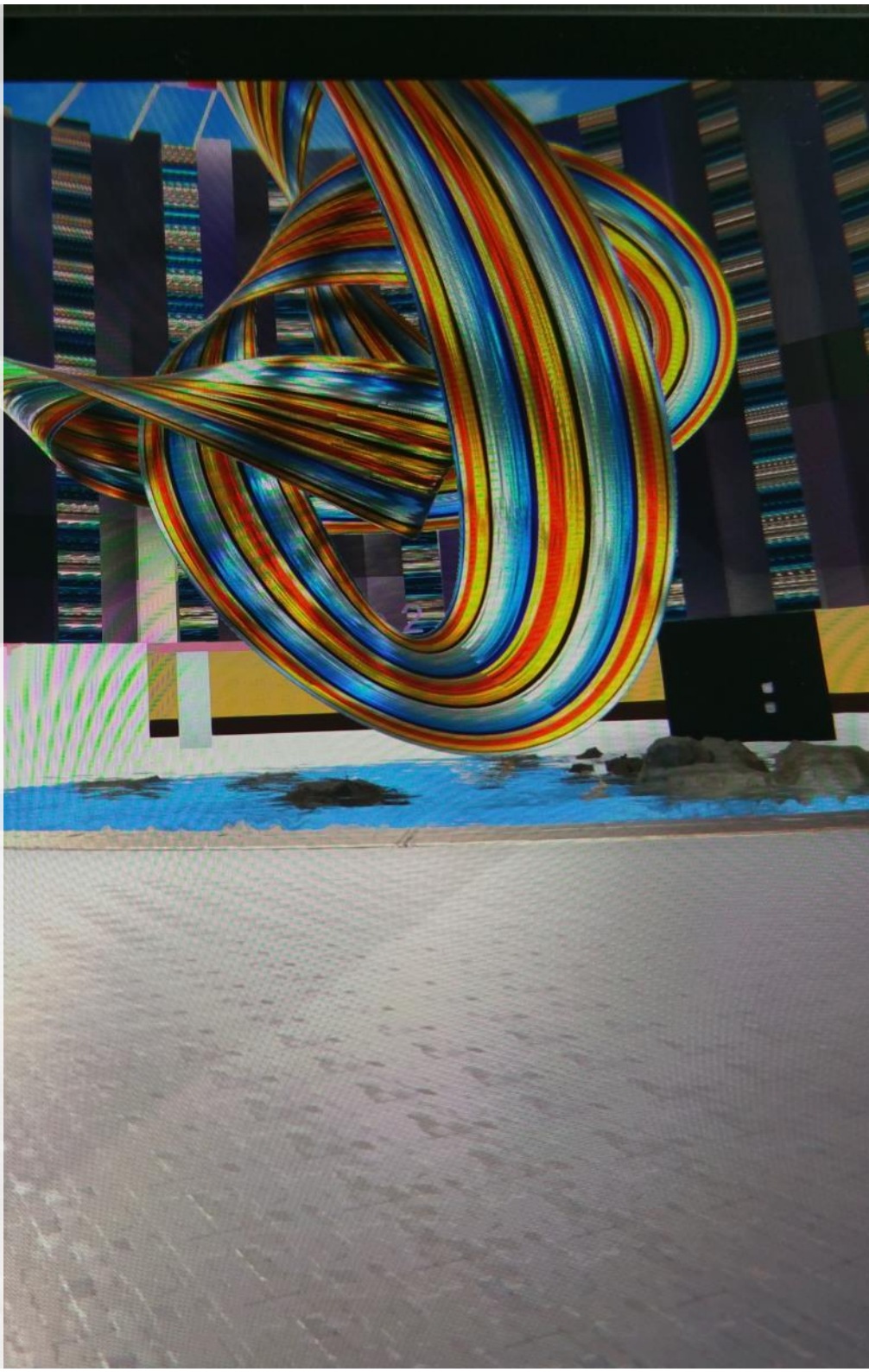
Consistent with HOPE's mission to facilitate cross-border exchange of good practices among its members and outside, HOPE staff and representatives participated as speakers or helped organise several European events.

The 2019 HOPE Agora focused on the theme “Evidence-Informed Decision-Making in Healthcare Management” and concluded the 38th edition of the HOPE Exchange Programme for healthcare professionals.

Finally, HOPE published two reports: the HOPE Agora Report 2019 gathering the main outcomes of the HOPE Exchange Programme “Evidence-Informed Decision-Making in Healthcare Management” and Hospital Healthcare Europe 2019.

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.

The HOPE Agora 2019 provided an opportunity to discuss "Evidence-informed Decision-making in Healthcare Management" in Europe. It also allowed the opportunity for the Board of Governors to meet on 4 June 2019 in Ljubljana (Slovenia).

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 in 2019: on 4 June in Ljubljana (Slovenia) as part of the HOPE Agora 2019, and on 28 October in London (United Kingdom). In Ljubljana, a new Governor was nominated for Cyprus: Dr. Elisavet Constantinou and one new head of delegation for Switzerland: Mrs. Anne Bütikofer.

The President's Committee (PsC) consists of the President Eva Weinreich-Jensen, the Vice-President Urmas Sule (Governor for Estonia) and three Governors: the two former Presidents Mrs. Dr Sara C. Pupato Ferrari (Governor for Spain) and Mr. Georg Baum (Governor for Germany), and Mr. Simon Vrhunec (Governor for Slovenia). The Governor from Poland Dr Jaroslaw Fedorowski is part of it as co-opted member and the Governor form Ireland Mr. Eamonn Fitzgerald joined the President's Committee as a new co-opted member. 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 on 17 April 2019 and on 26 September 2019 in Brussels (Belgium) to discuss the Board of Governors' agenda and the meetings of the Liaison Officers, and to decide on the organisation's priorities.

President's Committee meeting in Brussels

Liaison Officers meeting, Madrid

Board of Governors meeting, London

Governance

The network of Liaison Officers has a role of enhancing activities and of delivering objectives. In 2019, HOPE Liaison Officers meetings took place three times: on 27 March in Brussels (Belgium), on 2 June in Ljubljana (Slovenia) and on 21 November in Madrid (Spain). At these meetings, Liaison Officers discussed the latest project developments, major EU health topics of the year and the transposition of EU legislation.

Liaison Officers meeting, Ljubljana

As it does on a regular basis, the network of National Coordinators of the HOPE Exchange Programme met twice to work on the Programme: in Ljubljana during the Agora and in Madrid on 22 November 2019.

Located in Brussels, Belgium, the Central Office is organised and run by the Chief Executive, Mr. Pascal Garel. Ms. Laurie Andrieu is EU Policies and Communication Officer and changes of staff occurred during the year: Ms. Lucia Gonzalez is replacing Ms. Isabella Notarangelo as Comparative Activities Officer since December 2019, and a new part-time position of EU Project Officer was created and is now occupied by Ms. Ana Sofia Carbonell, who started in this new position in October 2019. HOPE also welcomed two interns through the year: Ms. Maria Queralt Tornafoch Chirveches for the comparative activities and M. Brunello De Vita for the EU policies. HOPE also received and met several delegations.

National Coordinators meeting, Madrid

Board of Governors, London

GOVERNANCE AT THE END OF 2019

President	Eva Weinreich-Jensen, Denmark
Vice-President	Urmas Sule, Estonia
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
Finland	Hannele Hakkinen
France	Zaynad Riet
Germany	Georg Baum
Greece	Yannis Skalkidis
Ireland	Eamonn Fitzgerald
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 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 2019, 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 adopted, 2019 provided an opportunity to engage in several new initiatives that gained momentum on the European political agenda.

Hard Law

Hard law refers to legislation that take precedence over national laws and are 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 2019, a major issue on the legislative agenda was Brexit and the attempt to draft a deal between EU27 and the United Kingdom. The Withdrawal Agreement was finally approved on 30 January 2020 and the transition period started on 1 February 2020 for one year. Another key health policy, which had been closely followed by HOPE over the past years, reached the end of its implementation process: 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. Two other Directives were adopted: the Work Life Balance Directive and the Transparent and Predictable Working Conditions Directive.

Other pieces of legislation that had been adopted in previous years were still on the agenda of HOPE, in the implementation process or reviewed by the European Commission: the Medical Devices Regulations, the General Data Protection Regulation, the Cybersecurity Package, the Cross -border Healthcare Directive and the Blood, Tissues and Cells Directives, the Re-use of Public Data Directive, the Water Directive and the State Aid Package.

In addition, several other initiatives remain on the EU political agenda: the Directive on Health Technology Assessment, the European Pillars of Social Rights and the ePrivacy Package. HOPE closely monitored developments and provided input, also participating in key meetings where these issues were debated and making 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 called on the EU and UK to prioritise patients in the Brexit negotiations.

The action continued in 2018 and 2019 with regular meetings organised in HOPE office with European Stakeholders.

On 12 September 2019, HOPE co-organised with several European health-related organisations a joint event at the European Parliament in Brussels: "Brexit: the European Parliament's role in prioritising patients, public health and health security across Europe".

The key message delivered was an immediate call for action in the event of a no-deal scenario:

- Co-ordinated contingency plans for prioritising imports of medicines and medical goods, including clinical trials materials, active pharmaceutical ingredients and raw materials for manufacturing medicines. This could for example include exempting certain goods from customs and border checks, fast-tracking them at ports and airports and/or enabling paperwork and regulatory checks to be completed away from the physical border;
- An extended deadline for transferring UK-based testing of medical products to EU countries, so that UK-tested products can continue to be placed on the EU market after Brexit for the benefit of EU patients;
- Mutual recognition by the UK and EU of all CE marked medical technologies granted by notified bodies;
- Continued participation by both EU and UK patients in clinical trials of innovative new medicines and treatments;
- Continued UK participation in key data sharing platforms that protect the public from health threats such as pandemics, unsafe medicines and products, and unsafe practitioners;
- Continued collaboration and knowledge exchange in medical and scientific research and innovation, and networks such as European Reference Networks;
- Reciprocal healthcare arrangements for EU and UK citizens visiting, working or living across the UK/EU border;
- Mutual recognition of healthcare professionals' qualifications so they can practice across the UK/EU border.

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 controlled. 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 urged the Commission to allow flexibility, so as to duly consider different contexts existing in Member States. The Regulation has taken HOPE position into consideration as it allows for verification and decommissioning at any time after arrival of the medicinal products into the hospital setting.

With a view to facilitating 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. 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 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 took 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 Saturday 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.

On 8 February 2019, EMVO held a press conference in Brussels to mark the start of the Operational Phase of the European Medicines Verification System (EMVS) HOPE emphasised on that occasion that hospitals are making huge efforts to put all the requirements in place and listed the difficulties identified in several countries.

HOPE informs on a regular basis Liaison officers and experts identified by Liaison officers. 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 at the end of 2019.

MEDICAL DEVICES REGULATIONS

In September 2012, the European Commission published two proposals for Regulations on medical devices and in vitro diagnostic medical devices. The aim of both proposals was to address inconsistencies in interpretation by the Member States of the current rules, increase patient safety and transparency, remove obstacles to the internal market and strengthen the rules on traceability.

The Regulations were meant to improve the safety of medical devices for the benefit of patients while preserving a timely access to innovative healthcare solutions. Following Council adoption of the texts in March 2017, the European Parliament adopted the same text without amendments during plenary on 5 April 2017.

The new rules will apply in May 2020 medical devices and May 2022 as regards in vitro diagnostic medical devices.

The agreed texts aim at increasing safeguards against counterfeit devices and guaranteeing traceability both in the pre- and post-market stages thanks to the introduction of systems such as Unique Device Identification (UDI). However, the core system of pre-market scrutiny of medical devices will still be based on decisions made by Notified Bodies, thus private companies, rather than public authorities as is the case for pharmaceuticals.

One of the main political issues at stake for HOPE concerned the reprocessing of single-use medical devices. This is an aspect for which HOPE has been constantly vigilant over the last ten years. 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. Re-use of medical devices reduces procurement costs, inventory, waste and overall consumption of raw materials and primary energy. It also results in the better use of cleaning and sterilisation equipment.

Following the agreement on the draft Regulations, HOPE published a summary of the main provisions of the coming legislation for its members, with emphasis on the changes that will extensively influence hospital activities.

The new Medical Device Regulations introduced the Unique Device Identification system based on a unique device identifier. The new UDI system will facilitate easier traceability of medical devices, significantly enhance the effectiveness of the post-market safety-related activities for devices and allow for better monitoring by competent authorities. It will also help to reduce medical errors and to fight against falsified devices. The use of the UDI system should eventually improve purchasing and waste disposal policies and stock-management by health institutions and other economic operators.

The new system will be applied to all medical devices placed on the EU market except custom-made devices and is based on internationally recognised principles including definitions that are compatible with those used by major trade partners. Article 27 of Medical Devices Regulation 2017/745 (and Article 24 of Regulation 2017/746) lays down what the UDI system shall consist of.

HOPE is part of the Stakeholders Medical Devices Coordination Group (MDCG). A meeting between of the Stakeholders MDCG for the Medical Devices Regulation/In Vitro Devices Regulation was organised on 14 February 2019 in Brussels. The main item was the implementation of the MDR/IVDR.

On 20 February 2019, the European Commission DG for Internal Market, Industry, Entrepreneurship and SMEs launched **an information stakeholder's consultation on Medical Devices and common specifications for products without a medical purpose.**

Following this, on the 25 February 2019, the European Hospital and Healthcare Federation (HOPE), 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 two things to improve the Regulations:**

- the timely application of the new rules on medical devices that will allow the evaluation of their adequacy;
- a complete transparency concerning high-risk medical devices with public access to Eudamed to ensure traceability, vigilance and surveillance.

HOPE was invited on 21 May 2019 to join the Unique Devices Identification (UDI) meeting for a presentation of the progress related to future UDI database in EUDAMED. The Draft guidance regarding "Considerations on the control of the Manufacturer's Quality Management System (QMS)" was also discussed followed by a presentation from Germany on Implant Card and interpretation of Art 18 of the Medical Devices Regulation. The Commission presented the final list of UDI devices and data elements.

On 17 and 18 June 2019, HOPE attended a Joint Research Centre workshop on Cybersecurity of Medical Devices in the EU. The Directorate General GROW (Unit.D.4 - Health Technology and Cosmetics, the leading policy DG for MDs, established in spring 2018 a Task-Force on cybersecurity for Medical Devices with the overall mission to develop a guidance document for Medical Devices manufacturers in order to comply with the new Medical Device Regulation, which will become fully applicable on 25 May 2020.

The Joint Research Centre organised this workshop on behalf of DG GROW with participation of the task force members and external experts with the objective to present and critically review the interim results obtained to date by the task force. The participants included thirty experts from Competent Authorities, Notified Bodies, Manufacturers, Academia and independent experts.

To closely follow this issue, **on 29 October 2019, HOPE attended an event jointly organised by the Permanent Representation of the Federal Republic of Germany to the European Union and the trade and industry associations BDI, BVMed, DIHK, MedicalMountains, SPECTARIS and ZVEI**. The event was attended by a variety of stakeholders including representatives from politics, industry, medical associations and patients.

The objective of the meeting was to discuss some questions about its practical implementation that remain unanswered and the difficulties in the delivery and supply of medical devices that could be the result. Several concerns were raised by the participants: the time constraint, the case of up-

classified devices which cannot use Article 120 (the so-called "grace period"), the capacity of the Notified Bodies (NBs) and the EUDAMED.

At the time of the meeting, only 40 of the 56 notified bodies designated for the former MDD (Medical Devices Directive) were seeking application for the MDR and 38 preliminary assessment reports had been received by the Commission. However, there were only 7 functioning NBs which had to manage the application for renewal of about 55000 old certificates and have to deal with certificates for new devices at the same time, creating an overload.

Finally, the issues of the grace period and the loophole that could create the warehousing provisions (Art 120-4) were discussed. But these provisions are only available for already existing Medical Devices and stockpiling is not feasible for medical devices with limited lifetime. The idea to extend to Art 59 'Emergency clause' to more products was mentioned as a possible solution to face these challenges.

On 25 November 2019, the Council of the European Union has 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. With this corrigendum, all Class I devices under the current Directive that would be up-classified under the MDR would be able to make use of the soft-transition and thus have up to 4 additional years, until 26 May 2024, to comply to the new Regulations in full. In addition, devices lawfully placed on the market pursuant to the device Directives prior to 26 May 2020 may continue to be made available on the market or put into service until 27 May 2025, the Regulation says. But the corrigendum corrects this later date to 26 May 2025.

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.

Finally, **on 12 December 2019, HOPE joined the JAMS stakeholder conference of the Joint Action on Market Surveillance of medical devices (JAMS).** The JAMS is aimed to reinforce the market surveillance system for medical devices by improving the coordination of activities by all Member States of the European Union, and ensuring adequate communications and cooperation. The conference gathered representatives from Competent authorities on medical devices, the European Commission and interested stakeholders. The key deliverables and outputs of the Joint Action were presented to the audience.

In parallel, in **November 2018, a large-scale study on implants entitled "The Implant Files" was released** by the ICIJ International Consortium of Investigative Journalists and relayed in several European Media. **HOPE started to draft a Strategic note on the issue, released in 2019.**

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 is 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 have been 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 on the proposal, known as the Cybersecurity Act. On 12 September 2018, the Parliament approved in a plenary session the mandate of the EU Cybersecurity Agency (ENISA) and information and communication technology cybersecurity certification (Cybersecurity Act) and confirmed the decision to enter into interinstitutional negotiations. An agreement was reached during the last trilogue on 10 December 2018. The deal was approved in the ITRE meeting on 14 January 2019 and adopted by the Parliament during the 12 March 2019 plenary with 586 votes to 44 and 36 abstentions. The deal was approved in the ITRE meeting on 14 January 2019 and adopted by Parliament during the 12 March 2019 plenary with 586 votes to 44 and 36 abstentions.

It was signed by the President of the European Parliament and of the Council on 17 April 2019. **The regulation was published on the Official Journal of 7 June 2019 and entered into force on 27 June 2019**. Cybersecurity remains a priority area for further action in the years to come under the new political guidelines for the new European Commission 2019 -2024.

In parallel, in April 2019, The European Union invests through the Connecting Europe Facility (CEF) programme €11.4 million (EU contribution) in projects which seek to strengthen the European Union's capacity and deal more efficiently with cyber-threats and incidents.

Finally, **HOPE spoke at the event on "Cyber Security in the Healthcare Sector" on 9 October 2019 in Brussels**. The discussions focused on current cyber security challenges in healthcare (for hospitals in particular), preparedness and training, and the role of the European Cyber Security Organisation (ECSO) and other initiatives in building cyber resilience. The event was organised under the Finnish Presidency of the EU Council by Jyväskylä University of Applied Sciences (JAMK), European Cyber Security Organisation (ECSO), Regional Council of Central Finland, West Finland European Office.

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 was 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 full application. Besides several initiatives organised, the Commission also published the results of an 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 also that further progress is needed. Although the regulation is directly applicable, Member States have to adapt their current laws in line with the GDPR.

In preparation of a public consultation on the guidelines on data subject rights, the **European Data Protection Board organised on 4 November 2019 in Brussels a stakeholder event “Data Subject Rights**” to get feedback from stakeholders on three elements:

- right of access to personal data;
- right to rectification and right to erasure;
- right to restrict processing and right to object.

Apart from HOPE the participation of health stakeholders was limited to a few representatives of pharmaceutical organisations and consultancies. Most common problematics identified by participants were: the difficulties to reconcile 12 and 15; a general agreement for layers of information but recognition that raw data is not readable. There was a general consensus that 15-1 and 15 3 should be clarified: notion of copy; how data subjects can make their request; is it enough to have email of Data Protection Officers on website; what proof is acceptable; conditions to fulfil more clarification on recipients.

The second session was on the right to rectification and the right to erasure and the specific discussion points were: the feedback from participants was that there is a need for practical guidance to face the lack of knowledge among data subjects, a need to educate. There were comments on: identification and authentication of data subjects; on different responsibility of joint controllers; on the relationship between different rights and how to apply them (right of access and right of rectification and erasure). The need to rectify factual elements is not so clear as far as opinions are concerned. And on the right to erasure, there is an issue of definition; it is not fully clear what it means. There are specific needs for clinical trials and in that case also for controllers outside the EU. In addition, there is a specific concern about minors.

The third session was focused on the right to restrict processing and right to object with several specific discussion points: data subjects need detailed information on the process and legitimate interest should be better defined.

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 engines cases under the GDPR,** which was open 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 transmitted to the European Parliament, to the European Council and to the European Commission.

REUSE OF PUBLIC DATA

The Directive 2003/98/EC on the reuse of public sector information is a core element of the European strategy to open up government data for use in the economy and for reaching societal goals. Revised by Directive 2013/37/EU (PSI Directive) in July 2013, it encourages Member States (MS) to make as much material held by public sector bodies available for reuse as possible to foster transparency, data-based innovation and fair competition.

From September 2017 to December 2017, the European Commission launched a **consultation in the perspective of the review of the PSI Directive.** The European Commission then published the impact assessment in 2018.

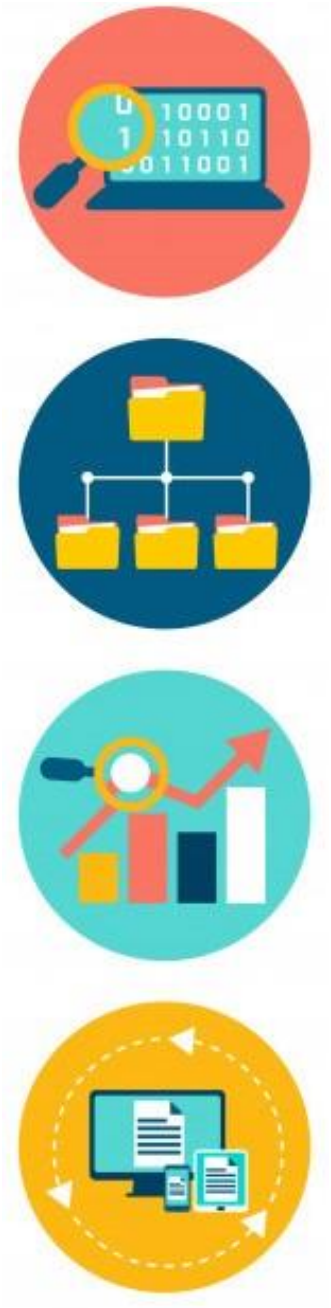
On 22 January 2019, negotiators from the European Parliament, the Council of the EU and the Commission reached an agreement on the revision proposed by the Commission. It was adopted in the ITRE (Industry, Research and Energy) Committee on 19 February 2019.

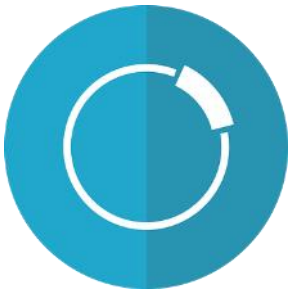
The updated Directive was adopted by the European Parliament on 4 April 2019 and by the Council on 6 June 2019. It was published in the Official Journal of 26 June 2019. **The regulation entered into force on 17 July 2019.**

The new Directive extends the scope of the rules on the reuse of public sector information (PSI) beyond public sector bodies so as to include public undertakings in the transport and utilities sectors.

It also introduces the concept of high-value datasets which are to be made available free of charge through an application programming interface. The text defines six broad categories of high-value datasets: geospatial, earth observation and environment, meteorological, statistics, companies and company ownership, and mobility. The list will be updated through secondary legislation.

The rules will cover publicly funded research data that is already available in public repositories. It will also encourage the dissemination of dynamic data, such as real-time weather or transport data. Overall, public sector data will be available either free of charge or at very low cost. In addition, the reform promotes the use of open data, meaning data in open formats that can be freely used and shared for any purpose.





BLOOD, TISSUES AND CELLS

On 11 October 2019, the Commission published its Evaluation on the EU blood, tissues and cells legislation. This was the first evaluation of the legislation since the adoption of the basic Acts in 2002 (blood) and 2004 (tissues and cells). The evaluation was conducted in line with the Commission's Better Regulation Guidelines and aimed to assess 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 Conference was structured around a series of themes emerging from the evaluation. For each session, the European Commission summarised the findings and a panel of stakeholders made short statements, followed by a moderated discussion with participants. The final session included a panel of leaders of EU and international institutions that discussed future strategies for the field.

The aspects that the Commission tried to look at in the Evaluation are the relevance of the legislation, its coherence with other legislation, its effectiveness, its efficiency and finally the EU added value in the area.

The European Commission underlined that the evaluation has shown the legislation has effectively increased the quality and safety of patients in the EU. Although, some challenges and shortcomings were also identified:

- Some technical provisions are outdated and are not adapted to a dynamic sector with changing risks (technological, epidemiological and societal changes);
- Some citizens are not adequately protected, the focus here was put on donors and on offspring born from donated gametes;
- Oversight provisions do not seem adequate anymore (lack of clarity identified on provision for data reporting, vigilance, effectiveness of inspections and independence of the inspecting authorities);
- The current rules do not allow to keep pace with innovation;
- The provisions of sufficiency are limited, especially in regard with the actual reliance on the US for some elements like plasma in the case of plasma derived medicinal products.

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 raising awareness about its content. Since then, HOPE has been monitorsing the Directive.

On **30 January 2019, the Rapporteur MEP Ivo Belet released its report on the application of patients' rights in cross-border healthcare to which HOPE had contributed.** The report intends to analyse the current shortcomings in the implementation of the Directive and to make recommendations for the improvement of the Directive.

It was followed by an intense European Parliament debate in Strasbourg as the report seemed to put forward that the implementation of the Directive has been sub-optimal, despite having been in place for almost nine years. The report was widely welcomed by the Parliament and was adopted with 512 votes in favour, 32 against, and 62 abstentions.

On 21 May 2019 took place the Cross-Border Healthcare Expert Group Meeting of National Contact Points (NCPS) for Cross-Border Healthcare.

The objective of the meeting was to exchange views on the Commission's 2018 report on the operation of Directive 2011/24/EU and to share experiences on the provision of information to patients, as well as to discuss the outcomes of the European Parliament report of February 2019 and of the Informal Health Council in April 2019. The meeting also addressed the launch of the 2018 data collection exercise as well as the Single Digital Gateway Regulation, its implications for NCPs and the thematic network on "Healthcare in cross-border regions" under the EU Health Policy Platform.

On the implementation of the Directive 2011/24/EU, the main issues raised were amongst others were:

- The role of NCPs in various projects and relevant ongoing work should be spelt out more clearly;
- The interaction of the Directive with the Social Security Regulations still proved difficult to explain to patients;
- Tne NCP representative informed that over and above information campaigns, they are also training healthcare professionals on applicable Guidelines related to the implementation of the Cross-border Healthcare Directive;
- The discussion highlighted that the websites should be looked at from the angle of the patient and become the object of continuous improvement so that the end-user perspective can be enhanced.

The Commission announced that there is a strong agreement amongst the Member States, the Commission and the European Parliament to strengthen information to patients, increase transparency, abolish administrative barriers and support work of NCPs. The European Parliament report endorsed the production and dissemination of a toolbox for NCPs.

EUROPEAN REFERENCE NETWORKS

On 1 March 2017, the newly established European Reference Networks (ERNs) were officially launched. 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 of 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 25 February 2019, possible areas of cooperation between the European Reference Networks and other stakeholders, such as registries or clinical trials, have been explored during the **first meeting between members of the ERNs Working group on Legal & ethical issues and relations with Stakeholders and representatives of the industry and of patients' organisations**.

This meeting represented a first step to analyse how industry may support the ERNs activity and how patients' organisations perspective can be taken on board, which issues are at stake, how to maximize opportunities, which safeguards to ensure transparency and avoid conflicts of interest are to be put in place.

On Friday 26 July 2019, the Commission adopted the Commission Implementing Decision (EU) 2019/1269 amending Decision 2014/287/EU and it will soon launch the call for new members.

It aims to:

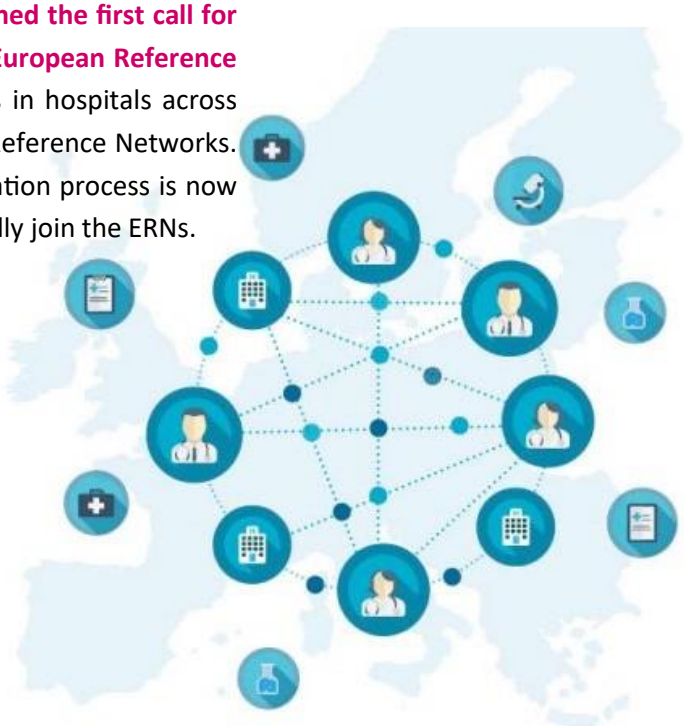
- clarify the role of the Board of Member States in steering the ERNs;
- modify the procedure concerning the application for membership of existing European Reference Networks (ERN); and
- add provisions concerning the establishment of the Clinical Patient Management System (CPMS) and clarifies the applicable 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.

The ERN Board of Member States adopted updated guidance principles to frame collaboration between the ERNs and the industry, through a revision of its 2016 statement on the matter. It also adopted a new statement concerning recommendations and good practices to foster integration of the ERNs in national healthcare systems. These important decisions were taken at the ERN Coordinators and Member State meetings that took place in Brussels on the 24 and 25 June. Finally, the Coordinators designated a new vice-Chair (Prof. Nicoline Hoogerbrugge, ERN GENTURIS), while Prof. Irene Mathijssen (ERN CRANIO) took over from Prof. Franz Schaefer (ERN ERKNET) as Chairperson.

Via its revised statement on cooperation between the ERNs and the industry, the ERN Board of Member States has acknowledged the importance of collaboration between the ERNs and industry, especially in the field of research, whilst at the same time setting clear boundaries to ensure transparency and avoid conflict of interest. Where public funding is not available, sponsorship of single or joint projects or shared funding from more than one stakeholder will be allowed, except in this situation and for these areas: direct allocation of funds to activities related to the management and running of the networks, any type of activity relating to the development of diagnostic and clinical practice guidelines or any other clinical decision-supporting tools, to the development of outcome measures or to the establishment and maintenance of patient registries.

On 1 October 2019, the European Commission has 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 requested to become members of the European Reference Networks. The call closed on the 30 of November and the full evaluation process is now starting to determine which of the applicants, will eventually join the ERNs.



WORK-LIFE BALANCE

On 26 April 2017 the Commission presented its proposal on work-life balance including legislative and non-legislative initiatives. The main points included the enhancement of the existing parental leave scheme by facilitating uptake by women and men with new measures on payment, flexibility and non-transferability. It introduced a proposal for carers' leave and paternity leave and the use of flexible working arrangements to all working parents of children up to 12 and carers with dependent relatives. It promoted non-legislative measures to provide more and better care facilities.

Interinstitutional negotiations started in September 2018. The main issues discussed have been: duration, payment and conditions of the leave arrangements as well as transferability of parental leave.

A provisional agreement between the three institutions was reached in the 6th trilogue in January 2019. On 6 February 2019 EU member States' representatives in the EU Council endorsed the provisional agreement on the Directive.

The European Parliament voted on the provisional agreement in April: 490 in favour, 82 against and 48 abstentions, the Council adopted the proposal and the final act was signed in June 2019. **The Directive entered into force on 1 August 2019 and Member States have until August 2022** to adopt the laws, regulations and administrative provisions necessary to comply with the Directive.

The Work-life Balance Directive introduces a set of legislative actions designed to modernise the existing EU legal and policy frameworks, with the aims of better supporting a work-life balance for parents and carers, encouraging a more equal sharing of parental leave between men and women, and addressing women's underrepresentation in the labour market.

Supporting parental participation in the labour market is also one of the key pillars of the 2013 Recommendation for Investing in Children.

Measures under the Directive include:

- The introduction of paternity leave: under the Directive, fathers must be able to take at least 10 working days of paternity leave around the time of birth of their child, compensated at least at the level of sick pay.
- Ensuring that two out of the four months of parental leave are non-transferable between parents and compensated at a level that is determined by the Member State.
- The introduction of carers' leave: workers providing personal care or support to a relative will be entitled to five days of leave per year.
- Extending the right to request flexible working arrangements to carers and working parents of children up to eight years old.

On January 2020, HOPE released a Strategic Note on the concrete changes that the new Directive will

TRANSPARENT AND PREDICTABLE WORKING CONDITIONS

One of the Commission's actions to implement the European Pillar of Social Rights and more specifically, Principle 5 on 'Secure and Adaptable Employment' and Principle 7 on 'Information about Employment Conditions and Protection in case of Dismissals', was the Commission's proposal for a new Directive for more transparent and predictable working conditions across the EU, launched on 21 December 2017.

The Commission's proposal complemented and modernised existing obligations to inform each worker of his or her working conditions (1991 Written Statement Directive (91/533/EEC)). In addition, the proposal created new minimum standards to ensure that all workers, including those on atypical contracts, benefit from more predictability and clarity as regards their working conditions.

HOPE adopted in June 2018 a Position Paper on the proposal for a Directive on transparent and predictable working conditions in the European Union. This paper explained why, among other aspects, HOPE considers inappropriate to introduce in the EU legislation those minimum rights which would apply to working conditions for all employees regardless of the form of employment.

On 7 February 2019, the European Parliament, the Council and the Commission reached a provisional agreement. **On 13 June 2019, the European Council finally adopted the Directive**.

The new law introduces new minimum rights, as well as new rules on the information to be provided to workers about their working conditions. Its main aim is to respond to labour market challenges triggered by demographic developments, digitalisation and new forms of employment.

The Directive applies to all individuals working more than 3 hours per week over four weeks (i.e. over 12 hours per month). Certain groups of workers may be excluded from some of the provisions, e.g. civil servants, armed forces, emergency services or law enforcement services.

The Directive requires employers to inform workers, as from their first working day and no later than the seventh calendar day, of the essential aspects of the employment relationship, such as:

- the identities of the parties to the relationship and the place and the nature of work
- the initial basic amount of remuneration and the amount of paid leave;
- the duration of the standard working day or week when the work pattern is predictable;
- the identity of the social security institution receiving social security contributions, where this is the responsibility of the employer;
- When the work pattern is entirely or largely unpredictable, employers will also have to inform workers of the reference hours and days within which they may be required to work, the minimum period of advance notice the workers shall receive before the start of work, and the number of guaranteed paid hours.

The Directive sets a number of further minimum rights for workers, including the rights:

- to take up a parallel job with another employer;
- to limit the probationary period to a maximum of 6 months, with longer periods allowed only in case where this is in the interest of the worker or is justified by the nature of the work;
- to request, after at least six months service with the same employer, employment with more predictable and secure working conditions;
- to receive training cost-free, when such training is required by Union or national legislation.

Member States are free to adopt or apply legislation which is more favourable to workers.

The Directive on Transparency and predictability of working conditions was published on 20 June 2019 in the Official Journal. **The transposition in national law should take place before 1 August 2022.**

In May 2019, **HOPE wrote a Strategic Note** to assess which aspect of the final text adopted in plenary session of the European Parliament on 16 April 2019 echoed its 2018 Position Paper.

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.

On that basis 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. The text addresses pharmaceuticals for human as well as for veterinary use. The areas cover all stages of the lifecycle of pharmaceuticals, from design and production to disposal and waste management, in line with the principles of the staff working document of the Commission on Sustainable Products in a Circular Economy. The six areas identified include actions to raise awareness and promote prudent use, improve training and risk assessment, gather monitoring data, incentivise "green design", reduce emissions from manufacturing, reduce waste and improve wastewater treatment.

On 12 November 2019, HOPE took part in a workshop organised by Health Care Without Harm (HCWH) Europe as part of the Safer Pharma programme to look at a multi-stakeholder approach to pharmaceuticals in the environment. The Danish Technological Institute presented the Mermiss project (DK) focusing on environmentally friendly treatment of highly potent pharmaceuticals in hospital wastewater. The idea was to test the policy "the polluter pays" also applying to hospitals. She showed that only 5% of medicines are consumed at the hospital while 95% are consumed in private homes. She also showed an important difference between the pharma waste produced by ambulatory care which is much harmful than in-hospital care. She presented a comparison between two possible ways: water treatment at hospital level and water treatment at municipal level. At hospital level this would require the installation of a whole water treatment system as pharmaceutical treatment can only be the last stage of water treatment which has to go through the conventional treatment first. At municipal level it would mean to add special equipment for pharmaceutical treatment to already existing installations. It appears that the most effective solution would be at municipal level regarding the difference of volume of pharmaceuticals in the water that exists between the two levels.

On 12 December 2019, the European Commission released a fitness check of the Water Framework Directive, its associated Directives, and the Floods Directive which concludes that they are overall fit for purpose, with some room for enhanced effectiveness. Despite improvements in the protection of water bodies and flood risk management, the evaluation points to insufficient level 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 been reached fully yet 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 to improve and to achieve better results.

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, having as a key objective preventing public interventions from distorting the level playing field for operators, mainly focuses on ensuring that SGEI compensation finances genuine SGEIs 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).

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 be deemed not 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.

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) launched in October 2016. HOPE contributed to this consultation by submitting a position. 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 has also been 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. sub-group on joint clinical assessments, sub-group 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 file, following on from last term's rapporteur, MEP Soledad Cabezón Ruiz (S&D, Spain).

The European Council worked in parallel in 2019. At the Employment, Social Policy, Health and Consumer Affairs Council session of 9 December 2019, Ministers took note of a progress report from the Finnish Presidency but no agreement was in view.

EUROPEAN PILAR OF SOCIAL RIGHTS

In 2016, the European Commission launched a public consultation on the European Pillar of Social Rights. The European Pillar of Social Rights 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 contribution 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 get 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.

On 6 December 2018 the EPSCO reached a political agreement on the Commission's proposal for a Council recommendation on access to social protection for all. Member States committed themselves to develop their national plans within two years.

In her political guidelines and her mission letters to Commissioner Nicolas Schmit (Jobs and Social Rights) and Executive Vice-President Valdis Dombrovskis (An Economy that Works for People) **Commission President Ursula von der Leyen foresaw in September 2019 the creation of an Action Plan for the implementation of the social pillar.** This Communication is the first step into this direction in which the new Commissioner explains his plans and planned initiatives that will support the implementation of the social pillar. It also launches a broad discussion with the stakeholders.

On **26 September 2019, the EU Commission released a new public consultation on European Structural Funds support to social inclusion.** The Commission wished to collect opinions on the activities carried out by the EU since 2014 in order to promote social inclusion, combat poverty and any discrimination. These activities were carried out with support from the European Social Fund. The information was collected to assess what had been achieved during the 2014-2018 period. Amongst other subjects, the evaluation assessed whether the persons most in need of assistance were adequately reached (including geographically) and which type of support has been the most effective. The consultation was open to all citizens and organisation until 19 December 2019.

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 relate also to the scope of the regulation, proposing the exclusion of: e-communications services which are not publicly available (home Wifi 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 file, a common Council position was not adopted under the Romanian Presidency, which submitted a progress report to the national ministers in May 2019.

The **Finnish Presidency presented its last compromise proposal on the e-Privacy regulation in November 2019. There was no agreement on the compromise** at the Council Working party on telecom held on 22 November 2019, leaving it to the Croatian Presidency.

Soft Law and Other Initiatives

Besides hard law, HOPE also closely monitors soft law in areas such as standardisation, patient safety, pharmaceuticals (access to medicines, shortages), eHealth, European semester, antimicrobial resistance, vaccines, and the EU health policy forum.

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 in the area of healthcare services has experienced an increase in the number of initiatives. 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 Organisation (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 also have 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 ser-vices throughout Europe. For two years, HOPE with other stakeholders 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 concluded successfully the work of HOPE with other European key stakeholders.

In 2019, HOPE was still actively engaged in discussions about standardisation in healthcare at EU level, warning that this may jeopardise good quality of care.

On **28 October 2019, the European Commission presented its annual EU work programme on European standardisation for 2020** to the other European institutions. The Commission is planning to draw up standards for artificial intelligence. The programme also mentions that the European standardisation organisations should support the implementation of the recommended format for the exchange of European Electronic Health Records by developing state-of-the-art standards to protect health data and ensure the security of network and information systems on which such electronic health record systems rely.

PATIENT SAFETY

Coherently with HOPE mission to improve the healthcare of citizens throughout Europe and high standards of hospital care, over the years HOPE 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) collaborated at several occasions, e.g. HOPE study tours, presentations at the European Parliament and HOPE Agora. Considering the absence of concrete actions carried out 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 common projects in different European countries.

In 2019, two webinars were organised first webinar organised on 11 June 2019 on the TeamSTEPPS pilot-project and on 10 September 2019 on the specific quality audit system from the Vienna Hospital Association (KAV), KAV-Q-Zert.

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 exchange of knowledge and best practices in biosimilars use and uptake.

The EU took 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 the purpose of exporting to a non-EU market where protection has expired or never existed or (during the six months before the SPC expires) for the purpose of 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 being authorised to be placed on the EU market. The aim of SPCs is to avoid that the term of patent protection would in actuality be 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.

The regulation will remove the competitive disadvantages faced by EU-based manufacturers of generics and biosimilars vis-à-vis manufacturers established outside the EU in global markets. The exception will operate only where:

- generics or biosimilars are produced exclusively for export to third countries where protection of the original medicine does not exist or has expired or for stockpiling purposes during the last six months of the validity of the SPC;
- the maker has provided the information required by the regulation to both the authorities of the member state of production and to the holder of the SPC at least three months in advance;
- the maker has duly informed all those involved in the commercialisation of the product;
- the maker has affixed to the packaging of the product the specific logo provided for by the regulation indicating clearly that it is only for export.

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 (voted by the European parliament plenary in April 2019 and formally adopted by the Council in May 2019) has been **published in the Official Journal in June 2019 and is now in force.**

In parallel, **on 10 April 2019, HOPE was invited to 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 out-patient medicinal products. The database is currently only available for national authorities dealing with pricing and reimbursement, and has over 24 European countries participating. The aim is to strengthen the cross-functional cooperation in the field of pricing of medicinal products within the EU/EEA/EFTA in order to enhance patient's access to medicines. Key objectives of the Dialogue Platform are : to establish a sustainable cooperation on information exchange in the field of medicinal product pricing via the discussion of opportunities and challenges of such a cooperation; to further enhance the current functioning of the Euripid database; to monitor the implementation of the Euripid Technical Guidance Document on external reference pricing of medicinal products; to contribute in making transparent prices of medicinal products better work in practice; to investigate suitable methods to measure patients' access to medicinal products in Europe by using the potential of the Euripid database and website.

HOPE was invited to speak on 4 December 2019 at the event organised by the International Association of Mutual Benefit Societies (AIM) **"Fair Prices for Pharmaceuticals – Why and How?"** in the European Parliament hosted by MEP Ismail Ertug (S&D, DE). The meeting dealt with the shortcomings of the current medicines pricing models and their consequences in particular for patients. AIM proposed a concrete alternative for setting a "maximum fair European price calculation model" for innovative medicines, in order to address the issue of affordability of medicines, but also reward and support real innovation.

MEDICINES SHORTAGES

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

In the EU, most medicine shortages are dealt with at national level by national competent authorities. 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. This includes information sharing on alternative medicines that are available in other Member States. The first phase of the pilot ran from April to August 2019 to test the functioning and usefulness of the information exchange via the SPOCs. During this phase, 24 Member States used the SPOC system and circulated 52 notifications of shortages. The task force plans to run a second phase of the pilot in 2020, to test the criteria for identifying cases deserving EU-wide coordinated action and for network alerts of upcoming public communications that could have a high impact on patients.

In May 2019 the Pharmaceutical Group of the European Union (PGEU), representing national associations and professional bodies of community pharmacists in Europe, released a Position Paper on Medicine Shortages calling the EU Institutions for a number of coordinated actions to reduce the burden of shortages on patients, healthcare professionals and supply chain actors.

In **July 2019, EMA and HMA published guidance for marketing authorisation holders on detecting and reporting medicine shortages.** The guidance aims to facilitate the early notification of shortages to national competent authorities, allowing them sufficient time to make contingency arrangements where necessary. In July 2019, EMA and HMA also published guidance for national competent authorities and EMA on good practices in communicating to the public on medicines' availability issues. 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.

On 7 November 2019, EAHP launched its Medicines Shortages Survey. It targets the impact of medicines shortages in the hospital environment. In addition to hospital pharmacists, EAHP is seeking input from patients affected by shortages and all health care professionals working in hospitals. The survey was accessible until 13 January 2020. The 2019 EAHP Medicines Shortages Survey explores issues such as the communication of medicines shortages within hospitals, current management strategies and possible reasons for and the impact on patients. As well as asking how survey participants would like to see medicines shortages handled and/or resolved on the policy level.

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 has 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 European Member States.

HOPE closely monitored the 2019 European Semester and regularly reported on it via its monthly newsletter.

On 27 February 2019, in its annual assessment of the economic and social situation in the Member States, the European Commission stressed the need to promote investment, pursue responsible fiscal policies and implement well-designed reforms.

As a novelty of this February package, the Commission launched a discussion on investment challenges and priorities in the Member States and sets out first ideas as to how EU funds, in particular EU Cohesion Policy funds, can help in the forthcoming programming period 2021-2027. This will also serve to ensure greater coherence between the coordination of economic policies and the use of EU funds, which are a significant part of public investment in several Member States. This new focus is reflected throughout the Country Reports and a new annex on the possible use of future EU Cohesion Policy funds is attached to each Country Report.

In March 2019, the Council adopted a specific recommendation on the economic policies of the euro area. It did so at an earlier stage so that euro-area issues be taken into account when approving the country-specific recommendations. Following the approval of the recommendations, their implementation will be monitored. New recommendations could be proposed by the Commission around May 2020.

On **5 June 2019, the Commission has adopted proposals for country specific recommendations,** including on health and investments in health as part of its ongoing assistance to Member States in implementing their health systems reforms in the light of an ageing population. The Commission recommends that the governments of 16 Member States invest in their national health systems or improve their effectiveness, increase accessibility and strengthen their resilience, with the following recommendations. This year, identifying and addressing investment needs has been a key priority – also with a view to the negotiations about the future Multiannual Financial Framework, the EU's budget for 2021 to 2017.

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 give 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.

The Council adopted the recommendations on 9 July 2019. For the first time and following Greece's exit from its third economic adjustment programme in August 2018, the 2019 CSRs are addressed to all 28 member States.

HOPE Governors discussed in detail the national reports during the 28 October 2019 London Board.

In **December 2019, the European Semester Autumn Package was released by the von der Leyen Commission.** It sets out the economic and employment policy strategy for the EU, placing sustainability and social inclusion at the heart of the EU's economic policymaking, in line with the priorities enshrined in the European Green Deal, the Commission's new growth strategy. The Annual Sustainable Growth Strategy encompasses four interrelated and mutually reinforcing dimensions to addresses long-term challenges:

- environmental sustainability;
- productivity gains;
- fairness; and
- macroeconomic stability.

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:

- HOPE agrees that Europe's health and care systems face serious challenges: ageing, multimorbidity, health (and social) workforce shortages, rising burden of preventable noncommunicable diseases, neuro-degenerative and rare diseases, growing threat from infectious diseases due to increased resistance to antibiotics and new or re-emerging pathogens.
- However, considering differences in epidemiology, wealth, culture and the huge diversity of healthcare system at national and regional level, specificities should be recognised instead of being ignored with a one-size-fits-all approach.
- Public spending on health and long-term care have not been “steadily” rising in EU Member States as the financial and economic crisis showed in several EU member States drastic cuts and disinvestments.
- 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.

Even where it exists, health data often depends on technologies that are not interoperable, thus hindering its wide use. HOPE has been involved in several initiative to create more interoperability such as eStandards and EURO-CAS. But safety comes first.

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

In May 2019, the Directorate-General for Communications Networks, Content and Technology (DG CNECT) published a **series of four reports prepared by the eHealth Stakeholders Subgroups with the participation of HOPE**. The Subgroups are the thematic focus working groups on eHealth. They were established under the mandate of the eHealth Stakeholder Group, an expert contribution to the development of legislation and policy related to eHealth.

One report deals with care continuum (looking into how eHealth tools could play a key role for a better integration of health and social care needs), one addresses citizen and health data (setting out the ambition that every EU citizen should be able to collect, curate, and control relevant health information from multiple sources), one is on reimbursement (taking the view that appropriate criteria should be used to reimburse relevant products, following EU-based guidelines for evidence generation all while taking into account the specificities of digital health products when developing instruments for reimbursement) and one on standards and interoperability (including a set of recommendations to adopt the eStandards roadmap, a Roadmap for allowing collaboration between citizens, healthcare workforce, researchers, vendors and payers drafted as part of a Horizon 2020 call).

The eHealth Stakeholder Group reached the end of its mandate. **A new eHealth Stakeholder Group will carry on the work for 2020-2022. HOPE's application has been accepted** and the first meeting should have taken place on 13 March 2020 but was postponed.

⇒ European Health Data Space

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

On February 2019, the European Commission adopted a Recommendation on a European Electronic Health Record exchange format. The Recommendation supports 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 has been 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. 22 Members States are expected to exchange such health information by 2021. This Recommendation builds on and contributes to the further development of eHDSI, by facilitating the EU-wide interoperability and exchange of comprehensive Electronic Health Records.

On 22 and 23 October 2019, two eHealth Network subgroups met in Brussels to pave the way for the Health national authorities' decision at the upcoming eHealth Network

scheduled end of November on the European Health Data Space. The eHealth Network subgroup on the implementation of the Communication on the digital transformation of health and care met to analyse the recommendations on an electronic health records exchange format (through the so called "Joint Coordination process"), in order to submit a proposal for decision to the eHealth Network. In addition, for the first time, representatives of both Member States and research infrastructures met to see how to best coordinate their actions. The discussion focused then on the set up of a European Health Data Space.

The eHealth subgroup on semantics met for the first time and established its rules of coordination. Germany and the European Commission were designated as co-chairs, whereas the Netherlands as a rapporteur. The Sub-group main responsibility was to define a common understanding of clinical concepts used in health data. Participants agreed on a common strategy which will be proposed to the eHealth Network for its decision end of November 2019, and decided on its working methods and plan.

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 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 ensuring the wide use and deployment of digital technologies across the economy and society, in order 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 has also proposed to fund new digital infrastructure in the EU in 2021-2017 with a renewed Connecting Europe Facility.

On **25 July 2019, the Commission has opened a consultation on the orientation of the first two years of its proposed Digital Europe programme**. The inputs received will help the Commission finalise the Orientations for Digital Europe, of which a draft can be viewed online. These will then shape the work programmes and calls for proposals for the programme's first two years (2021-2022).

ARTIFICIAL INTELLIGENCE

In April 2018, The European Commission put forward a European approach to Artificial Intelligence (AI) and Robotics. It deals with technological, ethical, legal and socio-economic aspects to boost 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 the elaboration of recommendations on future-related policy development and on ethical, legal and societal issues related to AI, including socio-economic challenges.

On 19 February 2019, the ENVI Committee Health Working Group organised a workshop on robots in healthcare. HOPE took part in this workshop which purpose was to inform participants as well as ENVI members about the current status and potential applications of robotic and artificial intelligence in healthcare.

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" while the next steps to bring the Guidelines forward were presented at the Digital Day 2019 event, under the presence of the Commission's Vice President Andrus Ansip and Commissioner Mariya Gabriel.

HOPE contributed with feedback on the Guidelines first draft, and the AI HLEG published a summary to indicate how the contributors comments were taken into account.

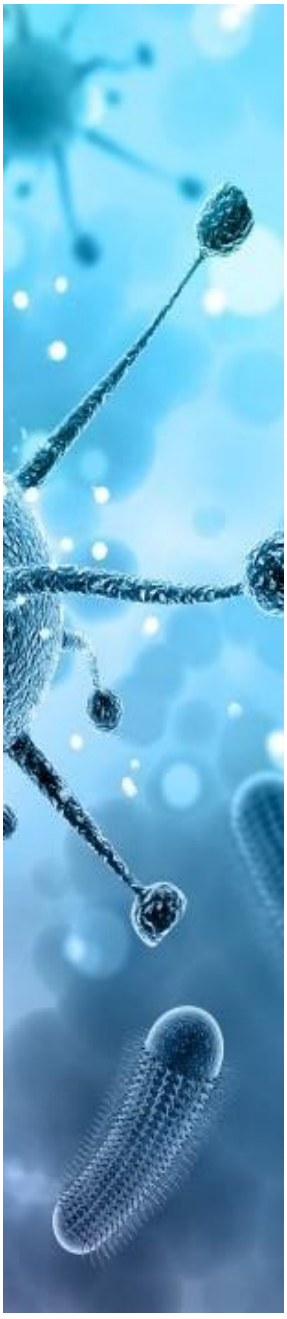
In June 2019, the European Commission has launched the pilot phase of the ethics guidelines for trustworthy AI, as the High-Level Expert Group on Artificial Intelligence released its policy recommendations.

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.**

This plan proposes joint actions for closer and more efficient cooperation between Member States, Norway, Switzerland and the Commission in four key areas: increasing investment, making more data available, fostering talent and ensuring trust. Stronger coordination is essential for Europe to become the world-leading region for developing and deploying cutting-edge, ethical and secure AI:

- Maximise investments through partnerships;
- Create European data spaces;
- Nurture talent, skills and life-long learning;
- Develop ethical and trustworthy AI.

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.

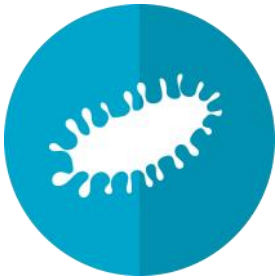
HOPE joined the Joint Action on Antimicrobial Resistance and Healthcare Associated Infections (JAMRAI) launched in September 2017. JAMRAI is a collaborative project built on existing works and initiatives by Member States as well as international organisations (OECD, ECDC, WHO Europe, OIE and FAO). INSERM (France) is responsible for overall coordination of the project, which involves 44 partners and 38 collaborating stakeholders. Its overarching objective is to support EU Member States develop and implement 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 important improvements and resources for its implementation at the national level. It was the result of an intense collaborative drafting and revision process by the Thematic Network on Antimicrobial Resistance.

On **12 June 2019 the European Commission released a progress report on the Implementation of the EU One Health Action Plan against AMR**. On 13 and 14 June 2019, during the Employment, Social Policy, Health and Consumer Affairs Council, Health ministers adopted Council Conclusions on combatting antimicrobial resistance. The conclusions reaffirm that the issue of AMR is a top priority for the EU. According to the Council, Member States should be supported in their efforts to combat AMR, but they also need to do more at national level - develop new antimicrobials, reduce the use of antibiotics and increase understanding of AMR-related issues by the public and health professionals.

On **20 September 2019, HOPE participated in the AMR stakeholder network meeting,** led by the European Public Health Alliance (EPHA). The objective of the

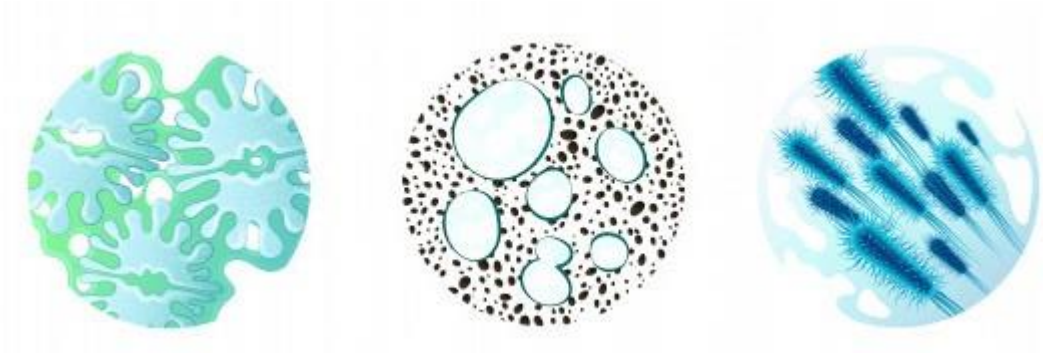
network is to contribute to discussions on Antimicrobial Resistance, an urgent cross-border threat to public health which can only be tackled through a multi-sectoral 'One Health' approach. Following a joint Call to Action, the network seeks to build consensus on key priorities for the implementation of the EU One Health Action Plan on AMR, including advocating for more European leadership and increased support and resources for Member States to implement their AMR National Action Plans.

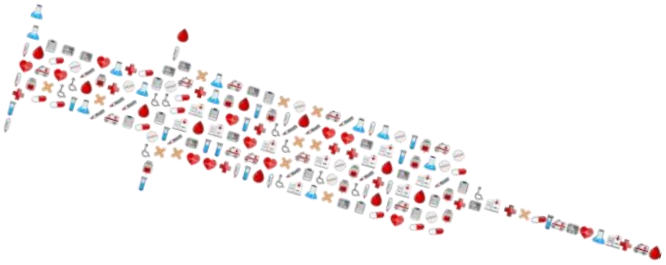


HOPE also collaborates with the European Centre for Disease Prevention and Control (ECDC) to review activities carried out and material disseminated as part of the European Antibiotic Awareness Day (EAAD) campaign. Since 2008, the ECDC has been coordinating activities as part of EAAD, which takes place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

On **18 November 2019, the EU-level launch event celebrating the 12th anniversary of the European Antibiotic Awareness Day (EAAD) initiative took place in Stockholm**. This year, together with its annual update on antibiotic resistance and antibiotic consumption surveillance data from EU/EEA countries, the European Centre for Diseases Control (ECDC) released the report on the "Survey of healthcare workers' knowledge and attitudes about antibiotics and antibiotic resistance, EU/EEA, 2019", which include stratification of results by country, profession and setting. HOPE supported the initiative by disseminating information and EAAD promotional material via its network.

On **21 November 2019, a new MEP Interest Group on Antimicrobial Resistance (AMR) was launched** to help address this global health threat under a multi-sectoral 'One Health' approach integrating its human, animal, and environmental components. The European Court of Auditors' Special Report on EU Action on AMR released earlier in November 2019 concluded that to date, the European Commission's support to strengthen national policies resulted in little progress in reducing AMR. This demonstrates the need for a dedicated parliamentary group to help ensure that more concerted action is taken at EU and national level to tackle AMR within a 'One Health' perspective.





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 **4 March 2019, HOPE attended a meeting organised by the European Commission on Vaccination**. After the event, the Commission sent out a follow-up to the participants in order to suggest a way forward which set the scene of a Coalition on Vaccination:

- The European Commission put at the disposal of the Coalition Members a dedicated space on the EU Health Policy Platform to facilitate communication and collaboration.
- It finalised and open for endorsement the declaration of the coalition, including the comments made by stakeholders.
- It encouraged the stakeholders to make a commitment as Members of the Coalition suggesting an activity that could contribute to achieve the goals included in the Council Recommendation and the Commission Communication.

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 actions through 2022.

On 12 September 2019, the European Commission and the World Health Organisation (WHO) were co-hosting the **world's first Global Vaccination Summit in Brussels.** The aim was to accelerate global action to stop the spread of vaccine-preventable diseases, and advocate against the spread of vaccine misinformation worldwide. At this occasion, European associations of healthcare professionals have established the Coalition for Vaccination to commit to delivering accurate information to the public, combating myths and exchanging best practices. The Coalition is based on the 2018 EU Council Recommendation on strengthened cooperation against vaccine-preventable diseases. 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. This Global Vaccination Summit lead to the publication of a document: "Ten Actions Toward Vaccination For All".**

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 common training and joint 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 and 2019.

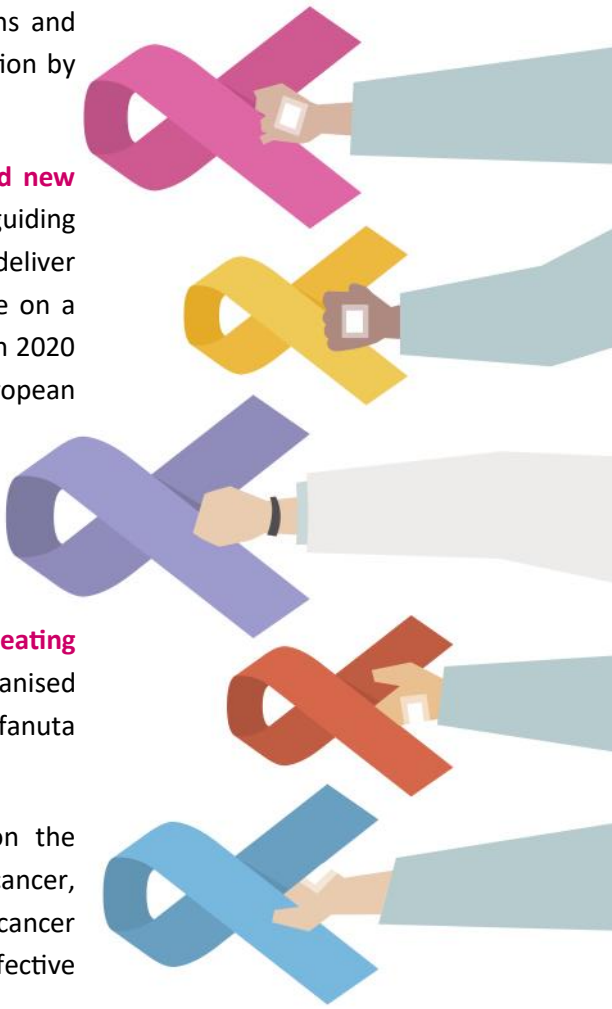
In **March 2019 the Commission released the Staff Working Document "Good practices to support the protection of public spaces".** The good practices cover vulnerability assessments and planning, awareness and training, physical protection, including work on detection technology and security by design and coordination and cooperation between public and private stakeholders.

In May 2019 the Urban Agenda for the EU Partnership on Security in Public Spaces published an Orientation Paper, outlining the Partnership's thematic orientation and working approach. The Partnership commits to respond to some key objectives and outlines three concrete priorities are outlined: Urban planning and design 'to create safer cities', technologies for smart and safe cities and managing security and sharing public space.

The European Commission DG HOME invited HOPE for the **EU Operators' Forum on the protection of public spaces that took place on 6 June 2019**. It brought together representatives of the EU Member States and private operators of public spaces, represented through 14 European associations, covering the hospitality sector, live performances, music and entertainment, amusement parks and attractions, the aviation, railway transport, shopping centres, telecommunication, as well as the private security services and the security equipment manufacturers. The meeting served to share ideas, initiatives and needs on how to take the work forward under the actions proposed in the Commission Staff Working Document "Good practices to support the protection of public spaces" . In the meeting, existing support tools, such as an EU funded awareness raising tool and the EU vulnerability assessment tool, were introduced. Several examples of good practices were presented, as online awareness raising tools and a training programme for private stakeholders, and guidance on “security by design”.

CANCER

The European Commission Initiative on Breast Cancer (ECIBC) works to improve the quality of breast cancer screening, diagnosis and care across Europe. It develops and provides evidence-based recommendations and guidelines in a Quality Assurance scheme to facilitate implementation by breast cancer services in EU Member States.



On **24 October 2019 The Joint Research Centre (JRC) has released new recommendations on breast cancer screening and diagnosis**, guiding policy makers and healthcare professionals to plan, organise, and deliver effective and equitable breast cancer services This initiative will lie on a website that will be completed and available to all Member States in 2020 and then the JRC will start its next big project, namely, the European Commission Initiative on Colorectal Cancer (ECICC).

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.

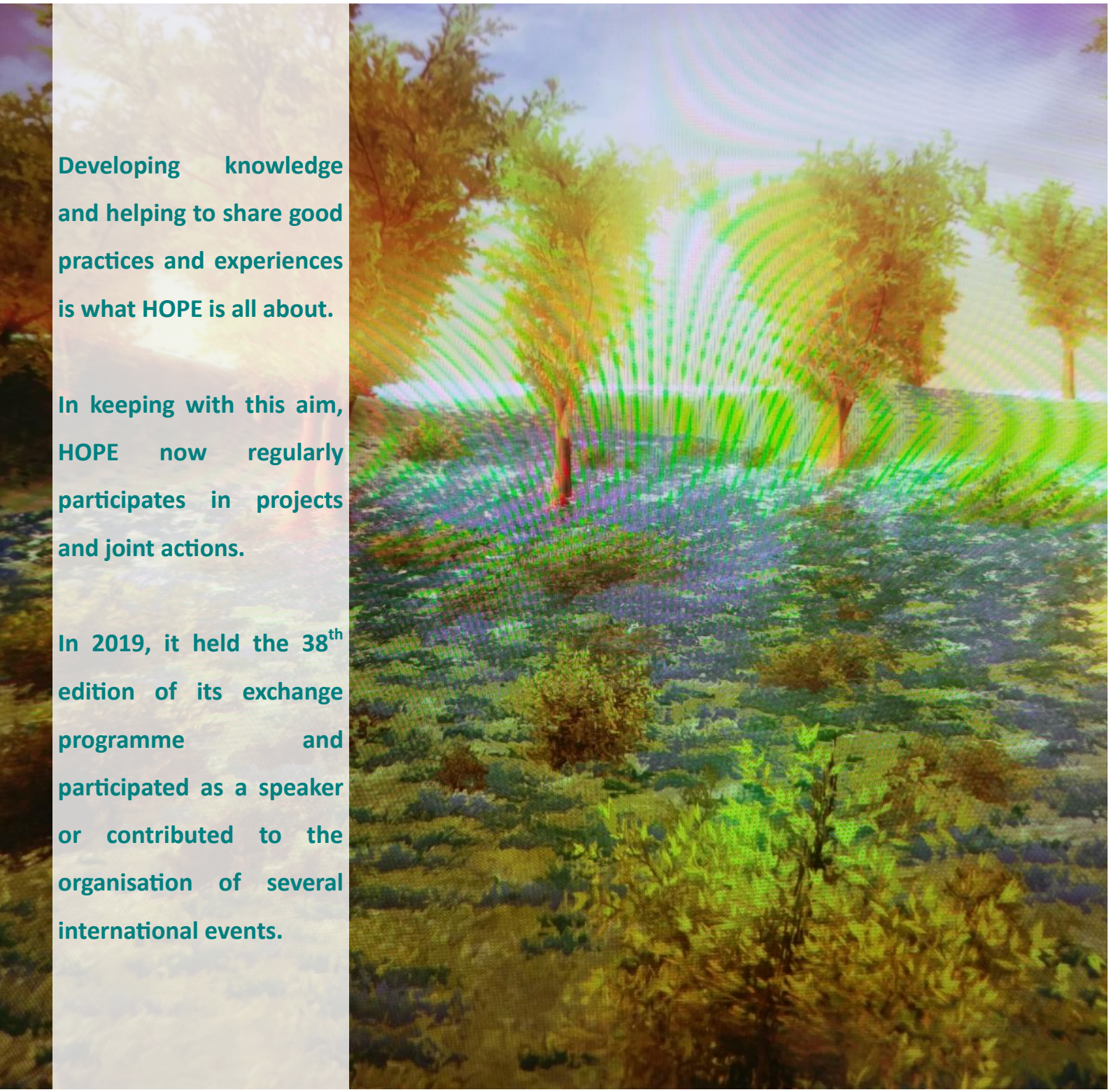
During the event, experts and stakeholders exchanged views on the concrete actions that should be taken to improve the fight against cancer, how to ensure uptake and measure success, and how can the cancer community work together at this critical juncture to ensure an effective future cancer policy that delivers impact for patients across Europe.

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, while the communication and action plan itself is expected towards the end of 2020. A Roadmap and a public consultation were indeed launched on 4 February 2020.

HOPE is involved in iPAAC Joint Action (JA) which aims to developing innovative approaches in cancer control. On 10 December 2019, HOPE attended the 2nd iPAAC Stakeholder Forum (see "projects" for more information about iPAAC).

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 2019, it held the 38th edition of its exchange programme and participated as a speaker or contributed to the organisation of several international events.

HOPE AS A PARTNER – ONGOING PROJECTS

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 on November 2019 and the kick-off meeting took place on the 3 and 4 December 2019 in Madrid.

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 funded by Horizon 2020, the EU Framework Programme for Research and Innovation. 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 ease 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.

EURIPHI—European wide Innovation Procurement in Health and Care

On 31 January 2019, HOPE took part as a partner in the kick-off meeting of EURIPHI in Brussels. EURIPHI is a Coordination and Supporting Action falling under the Horizon 2020 funding programme that kicked-off in Brussels on 31 January 2019. The project aim consists in adopting 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 service providers, 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) team up around the novel approach of Most Economically Advantageous Tendering Value Based Procurement (MEAT) to achieve the following goals:

- establishing a sustainable community of practice using innovative procurement methods and developing legal guidance for efficient cross-border, value-driven procurement with localised decision-making;
- adapting 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;
- developing 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 and its role consists in contributing to the creation of a community of practice; to support actions that enable market readiness for the Europe-wide deployment of cross-border value based PPIs; and, to identify suitable test environment for open-market consultations and learning cases; to raising awareness about the project activities and its results.

On **13 and 14 May 2019, HOPE took part to the EURIPHI consortium meeting, held in Paris.** The two-days event gathered the partners of the consortium to share updates about the progress of the project as well as future actions. Among the points discussed in the agenda, there was the status of the Health Authorities Network and of the Community of Practice. These two hubs will be crucial for the definition of unmet needs and for the adoption of value-based procurement (VBP) for innovation in cross border and integrated care contexts. Interesting results were presented also in the field of VBP for Ventilator Associated Pneumonia (VAP) and chronic diseases in integrated care contexts. The legal framework was also clarified, and the dissemination and communication tools delivered so far presented, including EURIPHI website.

MEDEYE

The MedEye Project has been officially launched on 28 February. HOPE is a partner of this project, funded from the European Union Horizon 2020, the EU Framework Programme for Research and Innovation. HOPE is 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 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 will be 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.

MedEye Technology

iPAAC

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.

On 10 December 2019, HOPE as a collaborating partner attended in Brussels the seminar "iPAAC at mid-term – Challenges and opportunities".

The opening plenary provided an update on iPAAC at mid-way point – reflection on work done thus far by work packages, but also the challenges and opportunities for the next half of the Joint Action.

The Work Package 4 presented the work on the roadmap on Implementation and Sustainability of Cancer Control Actions. Cancer control policy interviews were developed to survey in depth member States to collect their experiences. The end result will be a road map web-based tool to encourage and facilitate mutual learning, with practical examples as well as plan for implementation, including organisational elements.

The Work Package 6 devoted to genomics in cancer control and care is led by Belgian Cancer Centre Sciensano. A large part of its work is on ethical and legal aspects also on genetics screening. The work package 8 on challenges in cancer care focused on pancreatic cancer. The work package 9 on innovative therapies in cancer has already produced clinical practice guidelines and will soon come with reports on horizon scanning systems and real-life monitoring of innovative therapies. The involvement of HOPE was mentioned. The work package 10 on governance of integrated and comprehensive cancer care has developed a set of standards (generic and tumour specific) for the setup of Comprehensive Cancer Centres Networks; HOPE contribution was mentioned.

The breakout Session 1 was devoted to Cancer Information and Registries (WP 7). Roberta de Angelis and Elena Demuru, of the Istituto Superiore di Sanità (Italy) presented advance current registries datasets and better use curent registires datasets, with the potential of population-based registries. Ondrej Majek, Institute of Health Information and Statistics of the Czech Republic, followed with multiple source data integration.

The breakout Session 2 on Cancer Prevention (WP 5) was introduced by Satu Lipponen, Cancer Society of Finland, with surveys on barriers of early diagnosis, report on innovation cancer screening, early detection, prevention. A cross cutting topic has been identified: inequalities.

EU-JAMRAI

HOPE is contributing to the Joint Action on Antimicrobial Resistance and Healthcare Associated Infections (JAMRAI) which was launched on 1 September 2017. 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 will look 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 actions shared by the Member States. EU-JAMRAI aims 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.

On **16 and 17 September 2019, EU-JAMRAI celebrated a successful second Annual Meeting** that assembled 44 partners from 21 countries, European and international organisations as well as stakeholders representing health professionals, industry and civil society.

EUNETHTA

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 is a partner of the EUnetHTA Joint Action 3 (2016-2020) through its Stakeholder Forum. Joint Action 3 aims 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 is 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 was invited on 21 March 2019 to the HTA Network Stakeholder Pool devoted to health providers. The discussion was opened by the Head of Unit of SANTE B4 Health systems, medical products and innovation DG Health and Food Safety, European Commission (EC) and co-chaired by DG SANTE and the representative of European Union of General Practitioners (UEMO).

EUnetHTA was testing and piloting stakeholder involvement in the production of joint assessments and early dialogues. Several elements from this work, e.g. identifying experts, establishing the methods of involvement or the declaration of conflict of interest to ensure transparency will be important input for the practical workings of the future model of HTA cooperation post 2020. The aim is to ensure that EUnetHTA assessments are clinically relevant by eliciting views regarding the condition and available therapies throughout the entire process of the assessment. Conflict of interest often limits the involvement of experts, in highly specialised areas and rare diseases. Ideally experts that are involved should reflect EU and national perspective.

In the discussion there was a general acknowledgement of the efforts of EMA by stakeholders and the benefits of sharing and close cooperation. The importance of the healthcare professionals' experience in the regulatory process was emphasised.

The Chairs thanked for the participants and agreed on the next steps:

- The Stakeholder Pool will continue to work together to propose methods of stakeholder engagement, including key steps and methods of interaction. This would be summarized in a short document including a timeline. The Secretariat will circulate any input received also to the HTA Network members;
- The Finnish representative confirmed that they would welcome the input of health professionals in their future EU Presidency (2nd half of 2019);
- Engage with the European Reference Networks for the call for experts in rare diseases;
- Consider the use of the Agora platform on the EU Health Policy forum and explore if it could be used for other categories in the Pool as well as for disseminating information;
- Reflect on funding opportunities the Commission can provide for training of professionals for improving their understanding of HTA.

The EUnetHTA Executive Board adopted on 26 July 2019 a document entitled "Understanding of EUnetHTA HTA". The EUnetHTA Executive Board agreed that HTA in the context of EUnetHTA activities is understood to be composed of the following elements:

- Assessments should inform decision-making;
- Assessments are not decision-making processes themselves;
- Information should be of relevance to a decision-maker or user of the assessment. Wording which is overly exclusionary has the potential to predetermine decision-making and formulations such as "no conclusions can be drawn" should be avoided;
- Assessments should include the best available evidence at a specific given time point;
- Assessments should specifically formulate a 'summary of findings';
- Summaries should endeavour to use clear and concise scientific language.

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, that 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.

SPHINX toolkit 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. The SPHINX toolkit will enable service providers to specify complete services and sell or advertise these through a secure and easy to use interface.

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 at business as usual and emergency situations across various use case scenarios.

In order to maximize 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 (on-going or finished) in the domain of surveillance, wide zones protection and impact assessment of security systems.

HEALTH WORKFORCE PLANNING AND FORECASTING EXPERT (SEPEN) NETWORK

The "**Support for the health workforce planning and forecasting expert network" 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 to increase their knowledge, improve their tools and achieve 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.

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.

Exchange Programme

HOPE EXCHANGE PROGRAMME – 38TH EDITION

In 2019, the HOPE Exchange Programme reached its 38th edition. It welcomed 123 participants from 23 out of the 30 countries represented in HOPE on the theme **"Evidence-informed Decision-making in Healthcare Management".** From 2 to 4 June 2019, the Association of Health Institutions of Slovenia hosted the HOPE Agora in Ljubljana, Slovenia.

HOPE Agora 2019 Conference in Ljubljana

The participants of the HOPE Exchange Programme discussed the role of different types and sources of evidence. The point of view of researchers, policy-makers, managers and many other stakeholders was also considered. In increasingly complex health systems, the ability to use all types of available evidence to improve decision-making in healthcare is crucial to ensure that citizens are offered the best care possible. Scientific literature is an important source of information. However, decisions are also influenced by local data, stakeholders' positions, cultural factors, etc.

During the two-days conference, the participants talked around 3 modules:

- "Setting the scene: is evidence helpful for management and governance of health institutions?"
- "What can we do to improve evidence-informed decision-making?"
- "Where are we now?"

HOPE Agora 2019 Conference in Ljubljana

The conference was enriched by the presence of high level speakers including: Eva M. Weinreich-Jensen, President of HOPE; Marjan Pintar, Director of the Association of Health Institutions of Slovenia; Aleš Šabeder, Minister of Health of the Republic of Slovenia; Marjan Sušelj, General Director of the Health Insurance Institute of Slovenia; Dorjan Marušič, Minister of Health of the Republic of Slovenia 2010–2011; Petra Došenović Bonča, University of Ljubljana; Dominika Oroszy, University Medical Centre Ljubljana; Peter Pustatičnik, Telekom Slovenije; Tanja Kuchenmüller, WHO Regional Office for Europe; Ellen Nolte, London School of Hygiene & Tropical Medicine; Niek Klazinga, University of Amsterdam; Damir Ivanković, University of Amsterdam; Tanja Španić, Europa Donna Slovenia; Saša Kadivec, University Clinic of Respiratory and Allergic Diseases Golnik; Teodor Žepič, University Medical Centre Ljubljana.

HOPE Agora 2019 Conference in Ljubljana

Conferences

STUDY TOURS

HOPE STUDY TOUR - DIGITAL HEALTH: VIRTUAL HOSPITAL IN HELSINKI

HOPE organised a Study Tour to Helsinki (Finland) on 24 and 25 September 2019 during the Finnish EU-Presidency. The theme was Virtual Hospital 2.0, which produces specialised medical care-related digital healthcare services to citizens, patients and professionals.

Virtual hospital is a joint project between the university hospitals in Finland, and their population responsibility and catchment area covers all Finns. Virtual hospital makes healthcare services available to all Finns regardless of their place of residence and income level, thus improving the equality of citizens. Digital services are especially well suited for monitoring the quality of life, symptoms and lifestyle, and also for living with a long-term illness before and during treatment and in the monitoring stage of the treatment. The services complement the traditional treatment pathways.

The Terveyskylä.fi ('Virtual village') service offers information, advice, self-care, symptom navigators, digital treatment pathways, and tools for citizens, patients and professionals. The service comprises various themed virtual houses, more than 20 houses and services are available for more than 30 groups of patients. The innovation farm offers innovation workshops, piloting, artificial intelligence, IoT, research and researcher's tools. The development of services and changes in operation includes development model, developer network and centres of expertise.

The Study Tour included a site visit to the New Children's Hospital which is focused on demanding specialised health care for children. It provides care for patients from all across Finland and patients range from new-born babies to 15-year-old. In New Children's Hospital, families can stay together and parents are allowed to stay with their child around the clock.

Finland is facing the same challenges as the rest of Europe: an ageing population, a dramatic increase in the number of patients/citizens suffering from chronic diseases, and a rise in health expenditure. Virtual hospital is a way to support an operational change in the health sector instead of digitalising old services or providing new services within the old service framework.

Pictures from participants HOPE Study Tour in Finland

CONFERENCES CO-ORGANISED BY HOPE

A TOUCH OF BRUSSELS FOR NURSES: ESNO -HOPE EVENT

On 20 February 2019, HOPE organised in collaboration with the European Specialised Nurses Organisation (ESNO) prior to the ESNO congress 2019 an "Introduction to Brussels".

The workshop was intended for nurses interested in the European environment from a novice perspective or for those already familiar with a network. They could learn more on the mechanisms and dynamics of the European Union and Europe and how and where to engage. The idea is based on an EPHA project 'A touch of Brussels'. It covered "Europe, how it works in a nutshell for healthcare professionals" and "How it works in context for specialist nurses" presenting the European Commission, agencies and two joint actions (Antimicrobial Resistance; Vaccination) but also Health Workforce initiatives and nurses' engagement.

Several organisations were invited: European Public Health Alliance, European Public Services Union; European Patient Forum; Pharmaceutical Group of the European Union, European Health Management Association and the European Association of Hospital Pharmacists, as well as the representation of pharmaceutical industry in Brussels: Medicines For Europe and EFPIA.

HOPE CEO Pascal Garel presenting at ESNO event "A touch of Brussels for Nurses"

FORUM ANNUAL LECTURE ON ARTIFICIAL INTELLIGENCE

On 18 March 2019 was held the Forum Annual Lecture on Artificial Intelligence by FEAM European Biomedical Policy Forum. The aim was tear from different sectors (patients, healthcare professionals, academia, industry, etc.) about the challenges and opportunities brought by artificial intelligence in healthcare and to identify recommendations and priorities to be addressed by European and national policy-makers.

FEAM Annual Lecture on Artificial Intelligence

19TH INTERNATIONAL CONFERENCE ON INTEGRATED CARE

HOPE joined the organisation of the 19th International Conference on Integrated Care, which took place in San Sebastian, the Basque Region, from 1 to 3 April 2019.

The overarching theme of the 19th International Conference is 'Evaluating and implement models of integrated people-centred services', and will specifically focus on the areas of:

- Integrated health and social care for people at home;
- Engaging and empowering people and communities to become equal partners in care;
- Creating shared cultures, norms and values across organisations, professionals and people;
- Building a stronger integrated primary care;
- Models of care for people;
- Defining measures and outcomes that matter to people;
- Impact of Digital Health.

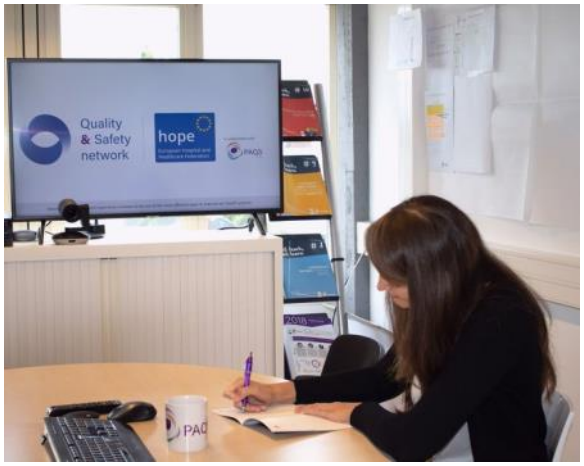
HOPE-PAQS WEBINAR: TEAMSTEPPS

On 11 June 2019, HOPE and PAQS organised a webinar to present the TeamSTEPPS pilot-project which started in 2018 in Belgium. TeamSTEPPS (Team Strategies and Tools to Enhance Performance and Patient Safety) is an evidence-based framework to optimise team performance across the healthcare delivery system.

HOPE-PAQS WEBINAR: VIENNA'S TAILOR-MADE QUALITY AUDIT MODEL

HOPE and PAQS organised their second webinar on 10 September 2019 on the specific quality audit system from the Vienna Hospital Association (KAV), KAV-Q-Zert.

KAV-Q-Zert is a tailor-made audit model that was implemented since January 2018 and by which all clinical departments of the KAV are certified.



HOPE-PAQS Webinar from PAQS office

BREXIT: THE EUROPEAN PARLIAMENT'S ROLE IN PRIORITISING PATIENTS, PUBLIC HEALTH AND HEALTH SECURITY ACROSS EUROPE

On 12 September 2019, HOPE co-organised with several European health-related organisations a joint event at the European Parliament in Brussels. The event was entitled "Brexit: the European Parliament's role in prioritising patients, public health and health security across Europe".

HOPE CEO Pascal Garel speaking at the Brexit event at the European Parliament

EU 2019-2024: HEALTH CHAMPIONS WANTED!

HOPE co-organised a joint post-election event "The EU health debate 2019-2024: Health Champions Wanted!" on 9 October 2019 at the European Parliament. The goal of the event was to raise awareness on the main public health priorities including universal access to high quality and sustainable healthcare, disease prevention, the fight against cross-border healthcare threats and health inequities, as well as a continued supply of medicines for EU citizens. These challenges require urgent EU action and appropriate budgets.

The event, which was co-hosted by MEP Dr Peter Liese (EPP, DE) and Dr Sara Cerdas (S&D, PT), was jointly organised by the International Association of Mutual Benefit Societies (AIM), the Council of European Dentists (CED), the Standing Committee of European Doctors (CPME), the European Medical Students' Association (EMSA), the European Patients Forum (EPF), the European Social Insurance Platform (ESIP), EuroHealthNet, the European Hospital and Healthcare Federation (HOPE) and the Pharmaceutical Group of the European Union (PGEU).

HOPE CEo Pascal Garel speaking at EU 2019-2024: Health Champions Wanted event at the European Parliament

REGENERATIVE MEDICINE: SCIENTIFIC ADVANCES AND REGULATORY FRAMEWORK IN EUROPE

HOPE supported the organisation of FEAM European Biomedical Policy Forum workshop "Regenerative medicine: scientific advances and regulatory framework in Europe". It was held on 27 November 2019 in Brussels.

FEAM European Biomedical Policy Forum on Regenerative Medicines

SOME CONFERENCES WITH HOPE AS A SPEAKER

FT DIGITAL HEALTH SUMMIT - ENHANCING THE IMPACT OF INNOVATION THROUGH COLLABORATION

On 18 June 2019, HOPE President Eva Weinreich-Jensen spoke at the FT Digital Health Summit - Enhancing the Impact of Innovation through Collaboration in Berlin.

Hospitals and health services are under increased pressure from escalating costs and growing demand. The ability to harness digital disruption is key to easing the strain and delivering more adaptable and efficient healthcare. Collaboration and change management can facilitate implementation and help overcome the barriers posed by issues of security, engagement and integration.

Where and how can digital technologies, devices and applications, and the data they produce, have the most meaningful impact? How can they be evaluated to assess their effectiveness in terms of cost savings and enhanced experiences and outcomes for patients? To what extent can innovation promote wellness and relieve the burden on services?

The FT Digital Health Summit, now in its fifth year, aimed at answering these questions and many more as it explored ways to implement digital transformation and improve the impact of innovation. Discussion were meant to delve deep into the constraints and opportunities and consider how patients, hospitals, providers, innovators, investors and regulators can work together to ensure that technology is efficient and consistent in meeting the evolving needs of patients and in sustaining high-value integrated care.

HOPE President Eva Weinreich-Jensen speaking at FT Digital Health Summit

DIGITAL HEALTH SOLUTIONS TO FIGHT PAIN AWARDED AT THE EUROPEAN LEVEL

On 6 November 2019, HOPE took part in the international SIP 2019 Symposium in Brussels “Bringing Pain Policy to the next Decade” where Award Ceremony of the II° Edition of the “EU Civic Prize on Chronic Pain - Collection of good practices” took place. **HOPE CEO Pascal Garel was in the Jury Panel and gave the prize to the winner of the category 'Clinical Practices’.**

The initiative, launched by Active Citizenship Network (ACN), aims to provide evidence of existing good practices in terms of struggle against pain across Europe, encouraging the exchange of experiences among health professionals, healthcare providers, institutions, civic associations and patient advocacy groups.

40 good practices were gathered out of which four were selected as winning best practices. They are all mobile apps and thus demonstrate the growing role of digital health in the treatment of chronic pain.

HOPE CEO Pascal Garel at the European Civic Prize on Chronic Pain

Divided into four categories (patients' empowerment, innovation, professional education, clinical practices), the good practices were evaluated by a pool. Besides a representative of ACN, these representatives came from the European Hospital and Healthcare Federation (HOPE), the European Pain Federation (EFIC), the Sine Dolore European Pain Foundation, the Pain Alliance Europe (PAE), the European Confederation of Care Home Organisations (ECHO), the European Multidisciplinary Network in Pain Research and Education (EMNIPRE), the European Headache and Migraine Alliance (EHMA) and from a retired university professor.

PERSONALISED MEDICINE: EAPM ANNUAL CONGRESS

On 3 and 4 December 2019, HOPE President participated in the third annual conference organised by the European Alliance for Personalised Medicine (EAPM) entitled "Forward together with innovation: the importance of policy making in the era of personalised medicine" in Brussels.

The first day session addressed the issue of the development of an environment allowing for the delivery of better healthcare in the EU Member States. The discussion focused on health data, transnational research, how to ensure the future quality of public health and how to bring innovation into national health systems. The panellists included Marco Marsella (Head of Unit eHealth, Wellbeing & Ageing, European Commission), Indridi Benediktsson (Policy Officer, DG Research, European Commission) and MEP Antonius Manders (EPP, The Netherlands). The debate looked into ways to put the patient at the centre of the policy approach to draw recommendation on personalised medicine. In particular, the European Commission strategy to bring innovation into the healthcare systems was discussed with a focus on: Access, integration, communication of health data; Cross-linking datasets; Interoperability among data, systems and technologies; Cybersecurity and Data Protection; Innovative solutions for prevention, diagnosis, treatment, care; Artificial intelligence, clinical decision support systems; High Performance Computing, blockchains, big data analytics, the Internet of Things, cloud computing.

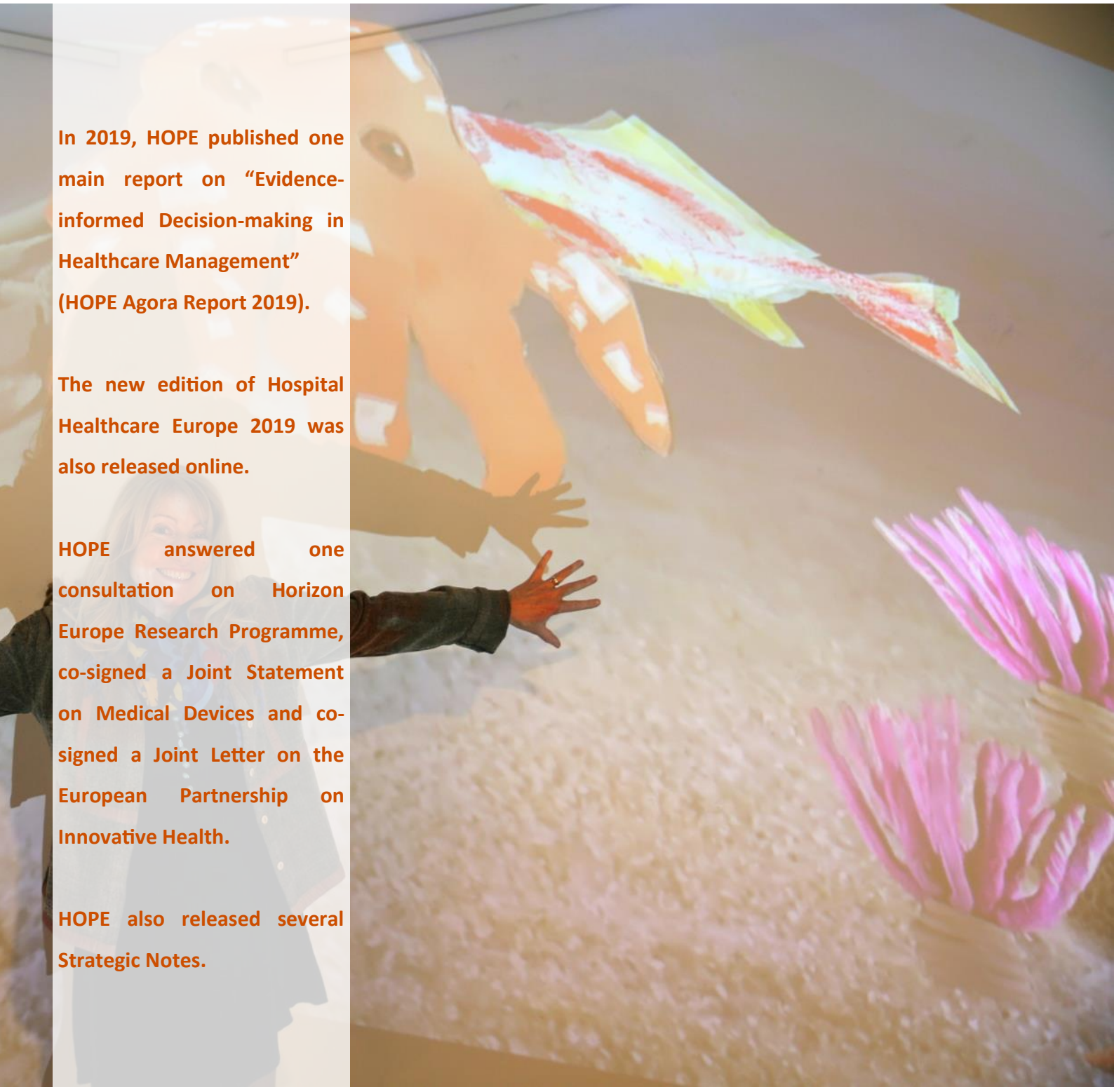
On the evening, the dinner session addressed the challenge of public health genomics integration into personalised medicine. **Speakers included HOPE President Eva M. Weinreich-Jensen, who stressed the need to reconsider the role of hospitals in relation with the challenge of health data sharing, consent and management issues.**

On the second day, the discussions focused on the Orphan Medicines Regulation, cancer research, rare and ultra-rare diseases, biomarkers, molecular diagnostics, HTA and access to medicines. A final session was dedicated to the topics of the 2019-2024 political agenda. MEP Peter Liese (EPP, Germany), MEP Tilly Metz (Greens/European Free Alliance, Luxembourg), MEP Tiemo Wölken (S&D, Germany) and Flora Giorgio (Head of Sector HTA, DG SANTE, European Commission) were among the panellists.

HOPE President Eva Weinreich-Jensen speaking at EAPM Annual Congress diner

Chapter 4

PUBLICATIONS



In 2019, HOPE published one main report on "Evidence-informed Decision-making in Healthcare Management" (HOPE Agora Report 2019).

The new edition of Hospital Healthcare Europe 2019 was also released online.

HOPE answered one consultation on Horizon Europe Research Programme, co-signed a Joint Statement on Medical Devices and co-signed a Joint Letter on the European Partnership on Innovative Health.

HOPE also released several Strategic Notes.

Publications

HOSPITAL HEALTHCARE EUROPE 2019

From 2019, Hospital Healthcare Europe is released only in an electronic version. In October 2019, HOPE released the new issue of Hospital Healthcare Europe. It is an annual publication containing:

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

HOPE AGORA REPORT 2019: EVIDENCE-INFORMED DECISION-MAKING IN HEALTHCARE MANAGEMENT

In September 2019, HOPE released a publication on "Evidence-Informed Decision-Making in Healthcare Management" following the HOPE Agora 2019 which took place from 2 to 4 June 2019, in Ljubljana, Slovenia.

The Association of Health Institutions of Slovenia this 38th edition of the HOPE Exchange Programme that involved 123 participants from 23 out of the 30 countries represented in HOPE. As usual, during the event, the HOPE Exchange Programme participants reported on their 4-week stay abroad with numerous initiatives in different health care settings.

In order to study the use of performance data for institutional management and governance, this year HOPE established a collaboration with the University of Amsterdam and researchers in the Marie Sklodowska Curie Innovative Training Network (ITN) for Healthcare Performance Intelligence Professionals – HealthPros. Prior to the beginning of the Exchange Programme, 2019 participants (as well as previous years' participants) were asked to complete an online questionnaire about the use of performance data in their own professional environments. During the HOPE Exchange Programme, participants were also asked to be observant of the practices in this area in the countries and institutions they will visit and provide brief feedback prior to the Agora. The feedback was provided by sharing notes on the experience, guided by a template with prompting questions and by integrating observations in the country presentations. During the Ljubljana Agora, participants also had an opportunity to learn about preliminary results of the questionnaire and discuss them in detail.

The HOPE Agora on Evidence-Informed Decision-Making in healthcare management then discussed the challenges and opportunities for strengthening the use of evidence in decision-making in healthcare management. The aim was to understand different approaches on decision-making in healthcare employed by managers, researchers, decision-makers, patients and other stakeholders. The end results were exchanges of experience in evidence-informed decision-making implemented by healthcare organisations in European countries.

POSITION PAPERS

HOPE RESPONSE – IMPLEMENTATION STRATEGY OF THE RESEARCH AND INNOVATION FRAMEWORK PROGRAMME HORIZON EUROPE

In September 2019, HOPE responded to a web-open consultation entitled "Orientations towards the Implementation Strategy of the research and innovation framework programme Horizon Europe". The new European Union Framework Programme for Research and Innovation, Horizon Europe, will run from 2021 to 2027. By participating to this questionnaire, HOPE contributed to co-designing the implementation of the future research and innovation programme.

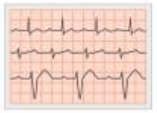
EUROPEAN PARTNERSHIP ON INNOVATIVE HEALTH LETTER FROM 43 ORGANISATIONS

On **13 December 2019, 43 organisations, including HOPE, released a joint letter** to Commissioner for Health and Food Safety, Stella Kyriakides, and to Commissioner for Innovation, Research, Culture, Education and Youth, Mariya Gabriel, and asking them to safeguard the public interest at the core of the European Partnership on Innovative Health.

The initiative was a response to a public consultation launched by five industry organisations (COCIR, EFPIA, Europabio, MedTech Europe and Vaccines Europe) and their draft research agenda. In the letter the 43 organisations highlight their views on the future health partnership in particular the importance of having public interest at the core, improving governance, increasing transparency, open science and the need to discuss sensitive policy issues in multi-stakeholders' platforms.

JOINT STATEMENT ON MEDICAL DEVICES

In 2017, two new Regulations on medical devices and on in-vitro diagnostic medical devices were adopted. These Regulations brought positive evolutions for the safety of medical devices such as the new notification process for notified bodies by the Member States, the new scrutiny mechanism for the certification of medical devices and the setting up of a European database on medical devices (Eudamed). But they are not going far enough for the safety of patients.



On the 25 February 2019, the European Hospital and Healthcare Federation (HOPE), 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 statement on Medical Devices and In Vitro Diagnosis Medical Devices Regulations calling for two things:**

- the timely application of the new rules on medical devices that will allow the evaluation of their adequacy
- a complete transparency concerning high-risk medical devices with public access to Eudamed to ensure traceability, vigilance and surveillance.

ANALYSES - HOPE STRATEGIC NOTES

HOPE POSITION PAPER IMPACT ON THE PROPOSAL ON TRANSPARENT AND PREDICTABLE WORKING CONDITIONS IN THE EU

On 21 December 2017, the European Commission published a proposal for a Directive on transparent and predictable working conditions in the European Union (COM(2017) 797 final). In June 2018, HOPE released a Position Paper drawing attention on some key issues. **In May 2019, HOPE released a Strategic Note showing which elements, among the points raised by HOPE, found echo in the final text adopted** in plenary session of the European Parliament on 16 April 2019.

HOPE STRATEGIC NOTE - IMPLANT FILES

On 25 November 2018, several media worldwide released the results of a large-scale investigation on medical implants: The Implant Files. The investigation was led by the International Consortium of Investigative Journalists (ICIJ) and was carried by 250 journalists from 36 countries including 14 European countries. The aim was to track the harm caused by medical devices to patients and to examine how devices are tested, approved, marketed and monitored.

In March 2019, HOPE released a strategic note making a media overview of the treatment of the enquiry in 5 European countries. It also mentioned the joint position of MedTech Europe – "Medical Device Industry Position on the Implementation of the New Medical Device Regulation" – released on 19 December 2018.

HOPE STRATEGIC NOTE - NEW EUROPEAN COMMISSION

On 16 July 2019, the European Parliament elected Ursula Von der Leyen as the new President of the Commission. After a selection process, the new Commission was approved on 27 November 2019 and entered in office on 1 December.

On 28 November 2019, HOPE released a strategic note presenting the Commissioners that have a sphere of influence that might have major influence on hospital and healthcare services are the following:

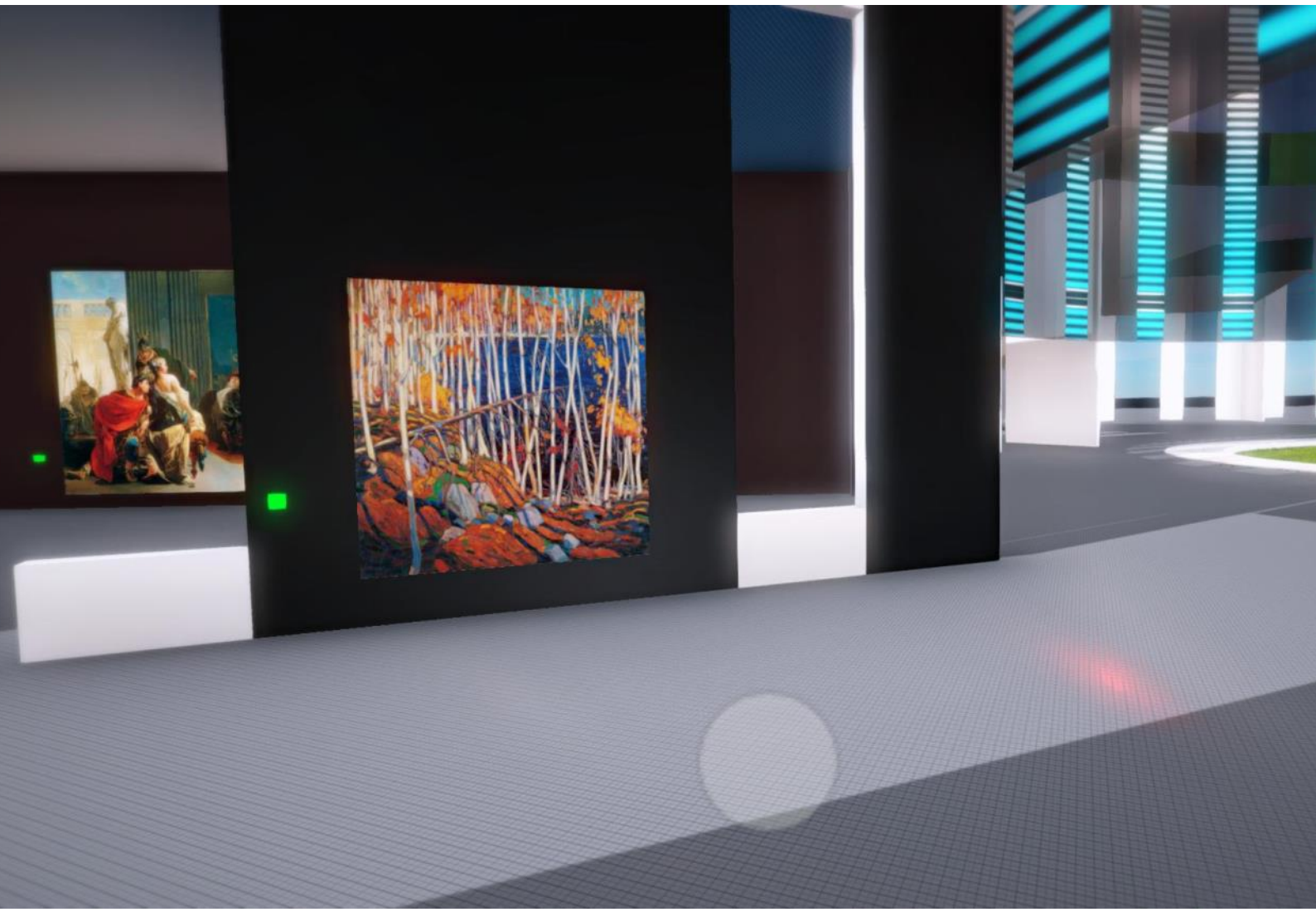
- Health and Food Safety, Stella Kyriakides
- Jobs and Social Rights, Nicolas Schmit
- Innovation and Youth, Mariya Gabriel
- Internal Market, Thierry Breton
- Environment, Oceans and Fisheries, Virginius Sinkevičius
- A Europe fit for Digital Age & Competition Executive Vice-President, Margrethe Vestager
- The European Green Deal & Climate Action Executive Vice-President, Frans Timmermans
- Democracy and Demography Vice-President, Dubravka Šuica

HOPE STRATEGIC NOTE - PATIENT MOBILITY DIRECTIVE 2011-24-EU

In May 2019, HOPE released a strategic note on the impact of the Directive 2011/24/EU on Patient Mobility on the year 2017. Based on questionnaires sent to 30 countries (EU Member States, Norway and Iceland), the data were collected between February 2018 and November 2018. Cyprus and Iceland did not respond and Sweden was not able to complete any data fields.

The strategic note was based on a five points analysis:

- Patient mobility;
- Limitations for patient inflow;
- Healthcare subject to Prior Authorization (PA);
- Healthcare not requiring Prior Authorization (PA);
- Data from the EFTA countries.



General Report on the Activities of the European Hospital and Healthcare Federation 2019

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European Hospital and Healthcare Federation