General Report

on the Activities of the

European Hospital and Healthcare Federation

2018

hope

European Hospital and Healthcare Federation

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General Report on the Activities of the European Hospital and Healthcare Federation — 2018

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Introduction

Last year was a year of change in European health-related policies. On the legislative side, the Commission adopted its legislative initiative on Health Technology Assessment (HTA) on 31 January 2018 and the negotiation between the European Parliament and the Council has been running since.

Several other initiatives gained momentum on the European political agenda. HOPE closely monitored developments and joined discussions about several topics, such as the Falsified Medicines Directive, eHealth, the implementation of the Medical Devices Regulation, the prudent use of antibiotics in healthcare settings, and the European Pillar of Social Rights, to name but a few.

In 2018, European politics were strongly marked by phase II of the Brexit negotiations. In this phase, major implications for the NHS and for health and social care workers both in the UK and the EU27 were at stake. But after the UK parliament rejected May's deal in January 2019, the future of the European Union and its relationship with the United Kingdom remain very uncertain, as some call for an extension of Article 50.

The 2018 HOPE Agora focused on the theme "Improving the quality of healthcare using the experiences and competencies of patients: Are we ready?" and concluded the 37th edition of the HOPE Exchange Programme for healthcare professionals.

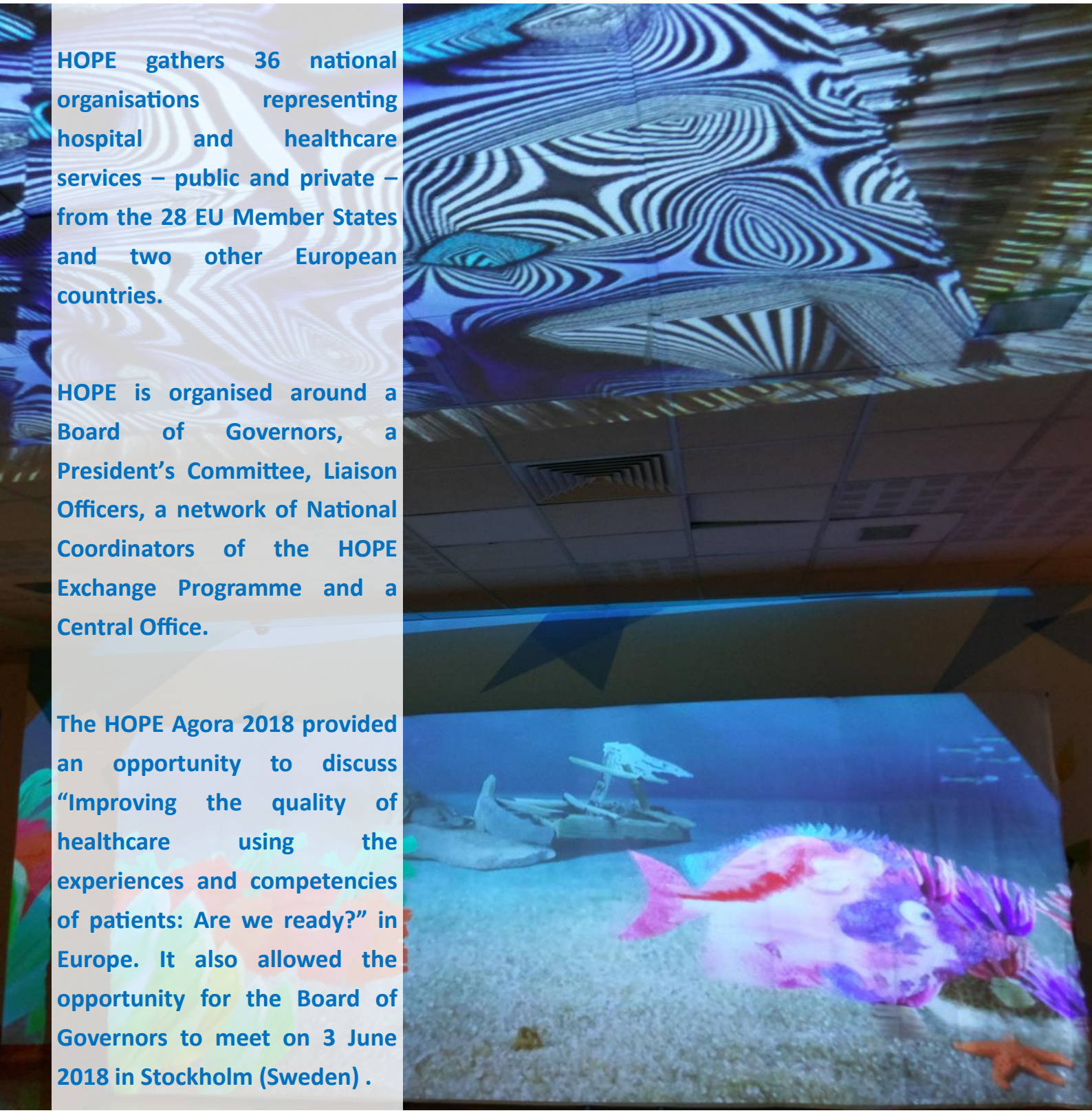
In 2018, HOPE was also active in contributing to the EU non-legislative agenda, mainly through several European projects. The ICT4LiFe and EURO-CAS projects were successfully completed and held their final conferences in Brussels respectively on 18 October and 20 November 2018. Moreover, a project that had started in 2017 further developed its activities in 2018 with HOPE as a partner: in the medication safety project MedEye. The EURIPHI project on value-based procurement was developed and approved in 2018 for a start in 2019.

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 international events.

Finally, HOPE published three comparative reports: Migrants and Refugees' Health; Hospital Groupings; and Capital Investments in the Healthcare Sector. In addition, the main outcomes of the HOPE Exchange Programme were gathered in the HOPE Agora Report 2018, "Improving the quality of healthcare using the competencies and experiences of patients. Are we ready?" published in the autumn.

Chapter 1

LIFE AND GOVERNANCE



HOPE gathers 36 national organisations representing hospital and healthcare services – public and private – from the 28 EU Member States and two other European countries.

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 2018 provided an opportunity to discuss "Improving the quality of healthcare using the experiences and competencies of patients: Are we ready?" in Europe. It also allowed the opportunity for the Board of Governors to meet on 3 June 2018 in Stockholm (Sweden) .

Governance

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

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

The Board of Governors (BoG) is composed of the President and the Governors, one for each European State represented in HOPE. It is the forum for all major policy decisions. The BoG met twice in 2018: on 5 June in Stockholm (Sweden) as part of the HOPE Agora 2018, and on 29 October in Tallinn (Estonia). In Stockholm, one new Governor was nominated for Croatia: Mr. Željko Plazonic.

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. 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 23 April 2018 in Brussels (Belgium) and on 28 September 2018 in Cascais (Portugal) to discuss the Board of Governors' agenda and the meetings of the Liaison Officers, and to decide on the organisation's priorities.

HOPE Board of Governors meeting, Stockholm, June 2018

HOPE Liaison Officers meeting, Venice, November 2018

The network of Liaison Officers was created to enhance activities and the delivery of objectives. In 2018, HOPE Liaison Officers meetings took place three times: on 7 March in Brussels (Belgium), on 3 June in Stockholm (Sweden) and on 22 November in Venice (Italy). At these meetings, Liaison Officers discussed the latest project developments, major EU health topics of the year and the transposition of EU legislation.

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 Stockholm during the Agora and in Venice on 23 November 2018.

Located in Brussels, Belgium, the Central Office is organised and run by the Chief Executive, Mr. Pascal Garel with Health Economist, Ms. Isabella Notarangelo and EU Policies and communication Officer Ms. Laurie Andrieu. HOPE also welcomed in 2018 two EU-Policies Interns: Ms. Giada Tasso and M. Valentin Solimeo. It also received and met several delegations.

GOVERNANCE AT THE END OF 2018

President	Eva Weinreich-Jensen, Denmark
Vice-President	Urmas Sule, Estonia
Chief Executive	Mr. Pascal Garel

GOVERNORS

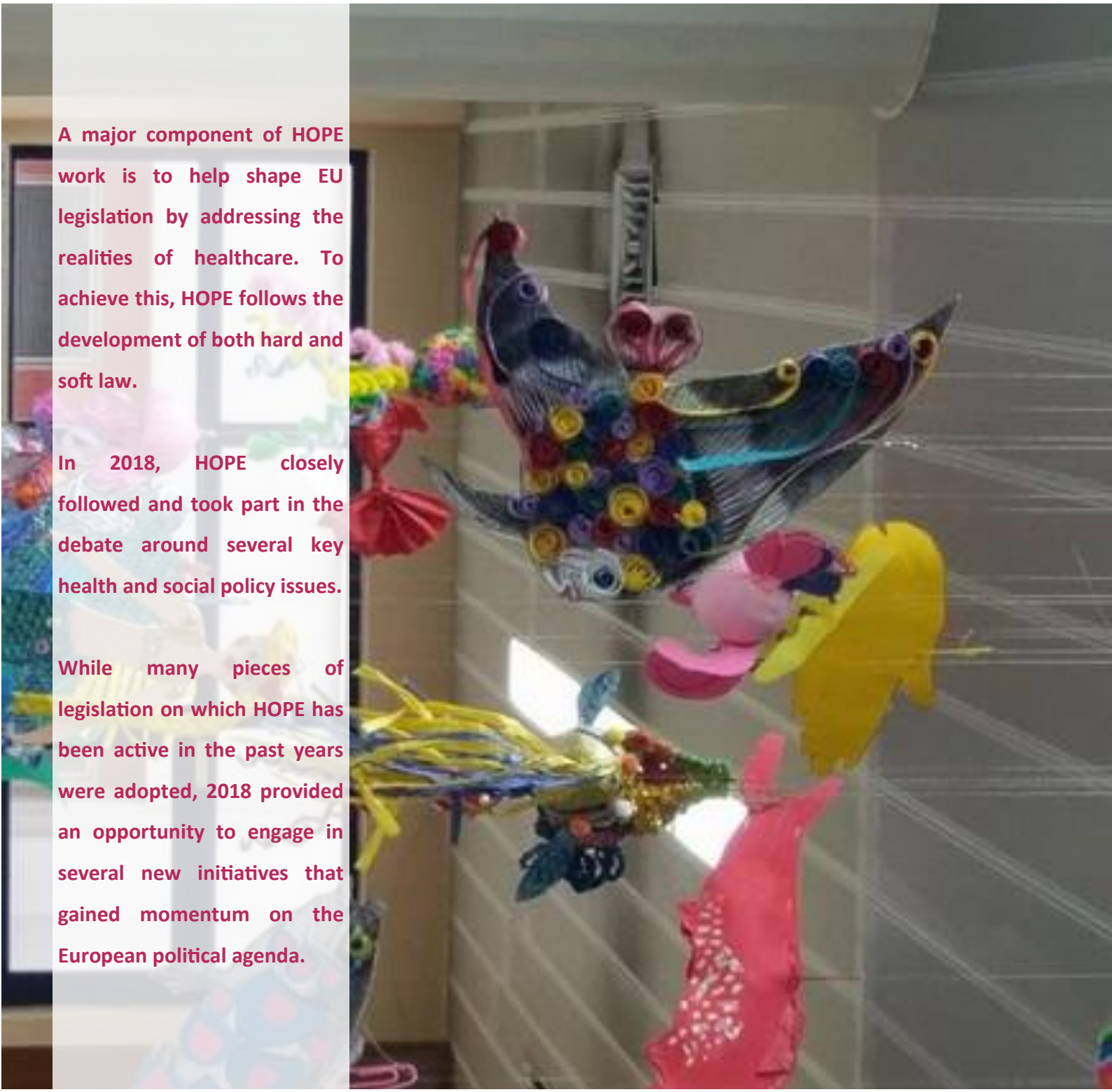
Austria	Nikolaus Koller
Belgium	Willy Heuschen
Bulgaria	Krasimir Grudev
Croatia	Željko Plazonic
Cyprus	Petros Matsas
Czech Republic	Roman Zdarek
Finland	Hannele Hakkinen
France	Zaynad Riet
Germany	Georg Baum
Greece	Yannis Skalkidis
Ireland	Eamonn Fitzgerald
Italy	Domenico Mantoan
Latvia	Jevgenijs Kalejs
Lithuania	Dalis Vaiginas
Luxembourg	Marc Hastert
Malta	Denis Vella Baldacchino
The Netherlands	Sander Gerritsen
Poland	Jaroslaw J. Fedorowski
Portugal	Carlos Pereira Alves
Slovakia	Marián Bencat
Slovenia	Simon Vrhunec
Spain	Sara Pupato Ferrari
Sweden	Erik Svanfeldt
United Kingdom	Niall Dickson

OBSERVER MEMBER:

Switzerland	Bernhard Wegmüller
Serbia	Georgios Konstantinidis

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 2018, HOPE closely followed and took part in the debate around several key health and social policy issues.

While many pieces of legislation on which HOPE has been active in the past years were adopted, 2018 provided an opportunity to engage in several new initiatives that gained momentum on the European political agenda.

HOPE meeting with Commissioner Andriukaitis, January 2018

On 25 January 2018, HOPE President Eva Weinreich-Jensen, Vice-President Urmas Sule and CEO Pascal Garel met Mr. Vytenis Andriukaitis, European Commissioner for Health and Food Safety. The purpose of the meeting was to present the newly elected team, report on the actions taken and list current issues.

The first two items HOPE wanted to raise on 25 January 2018 were already on the agenda of the previous meeting with the Commissioner: Falsified Medicines Directive on which HOPE had raised deep concerns; CEN attempts in healthcare standardisation against which HOPE fought with the leading professional healthcare organisations at European level. HTA, digitalisation, the initiative "State of health", Anti-Microbial Resistance, vaccinations and several other topics were also discussed at this 90-minutes meeting.

Hard Law

Hard law refers to laws that take precedence over national law 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 2018, a central issue on the legislative agenda was Brexit, scheduled for March 2019 and the attempt to draft a deal between EU27 and the United Kingdom. Then, one key health policy, which had been closely followed by HOPE over the past years, reached the end of its implementation process: the General Data Protection Regulation (GDPR) which has been in full force since 25 May 2018. Some other pieces of legislation had been adopted in previous years and were still on the agenda of HOPE, whether because they were still in the implementation process or because they have been reviewed by the Commission: the Medical devices regulations, the Delegated act on the safety features appearing on the packaging of medicinal products for human use (the so-call "Falsified Medicines Directive"), the cybersecurity package, the cross-border healthcare directive and the blood, tissues and cells directives.

In addition, several legislative procedures have taken steps forward such as Health Technology Assessment and several other initiatives have been put on the political agenda on topics of interest to HOPE, like the European pillar of social rights, the re-use of public data 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

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. 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 Commission in October 2015 and published in the EU Official Journal on 9 February 2016.

The delegated act, applicable from February 2019, introduces medicine authentication by means of two safety features: a unique identifier and an anti-tampering device, which will protect patients from the risks of falsified medicines and the consequences of common dispensing errors. It also provides for an end-to-end verification system to ensure authenticity and integrity of medicine packaging at dispensing points for patients, namely in pharmacies and hospitals.

The Regulation responds to what is stated in article 54a of the Directive 2011/62/EU on the community code relating to medicinal products for human use, which requires the Commission to adopt delegated acts regarding various aspects of the safety features for medicinal products for human use.

In January 2018, the Commission submitted a report to the European Parliament and Council giving an overview of the penalties in place in individual EU countries and a qualitative assessment of their effectiveness. The Commission was aided in its assessment by an external study.

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 (NMVOs) 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. This collaboration will aim to facilitate the smooth implementation of the Regulation in European hospitals.

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.

Throughout the year meetings took place on a regular basis (usually monthly): Board of EMVO, stakeholders meeting, project managers' meetings and EFPIA-Medicines for Europe project managers' meeting.

HOPE was invited with other European stakeholders to the afternoon sessions of the 21st expert group meeting (Member States representatives) on the delegated act on safety features for medicinal products for human use taking place in Brussels on 26 June 2018. To start this dialogue between the expert group and the European Medicines Verification Organisation (EMVO) and other European Associations, Directorate General SANTE provided a short update on the outcomes of the morning discussions with Member States: progress on questions and answer documents, presentation of the European Regional Funds as a way to find funding, article 23 concerning wholesalers (as some member states are in the process of launching consultation or even legislation the Commission will collect information). Then several issues were listed: the lack of progress of one of the two IT providers, still relatively low on-boarding, the fees, access to data and hospital preparedness.

During the Employment, Social Policy, Health and Consumer Affairs Council, on 6 and 7 December 2018, the Commission provided information on the implementation of Directive 2011/62/EU on falsified medicinal products that is due to begin on 9 February 2019.

That same month HOPE further developed its report on hospitals readiness gathering the information provided by HOPE Liaison officers and experts on one hand and by European Hospital Pharmacists Association on the other hand. This was presented to the European Commission on 13 December 2018.

MEDICAL DEVICES REGULATIONS

The legislative process started in September 2012, when 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 three years after publication as regards medical devices and five years after publication 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 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.

Additionally, HOPE is also part of the Medical Devices expert group and its Unique Device Identification (UDI) Working Group.

HOPE attended the meeting of the medical devices coordination group (MDCG) that took place in Brussels on 5 March 2018, whose purpose was to update stakeholders on the ongoing implementation work with regard to the two regulations. The MDCG met with the representatives of the competent authorities and the stakeholders who had attended the already existing Medical Devices Expert Group and stakeholder group under the Medical Device Directives. Stakeholders stressed that sufficient time should be given to respond to consultations and that the relevant documents need to be available on the Commission website. They emphasised the need to hold sessions for stakeholders more frequently.

The Commission presented the state of play of the implementing acts. The Implementing Regulation on the codes to be used by notified bodies when applying for designation was smoothly adopted in time by the end of November 2017. Another implementing act on the application for designation as a notified body was dropped due to technical difficulties. The Commission considered that the implementing act on reprocessing of single-use devices was making good progress. Other implementing acts were in preparation, including the one on expert panels and reference laboratories. The implementing act on the so-called Annex XVI products had made good progress regarding the general requirements which are applicable to all six product groups. The Commission presented the state of play of the Eudamed implementation. Much progress has been made for the first set of modules (Actors, UDI/Devices and Certificates), especially for the actor registration and Notified Bodies & Certificates.

HOPE also attended another meeting of the Medical Device Coordination Group (MDCG) and stakeholders organised by Directorate General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW) on 24 September 2018 in Brussels. They addressed the informal consultation held in the summer on the secondary legislation, feedback was requested from the main federations of stakeholders: industry, doctors and hospitals. Only six answers were received, five were positive and only one (HOPE position but the Commission did not name it) was negative. The Commission considers that most elements of HOPE position could not be taken into consideration, as they are included in the regulation.

Several actors have expressed concern on the fact that all the necessary elements of the system and in particular the designation of the Notified Bodies (NBs) could not be achieve on time (before the end of the transition period). They underline the consequences that a disruption to the supply of medical devices could have on public health. Members of the European Parliament Committee on the Environment, Public Health and Food Safety (ENVI) addressed the following concerns and questions to the European Commission in July 2018. Three separate Commission DGs

have a role in the support and coordination of the regulatory system - DG GROW, DG SANTE and DG JRC.

They remind that, as of May 2018, out of 59 existing NBs only 20-30 have applied for re-designation where the Joint Assessment of an NB designation process lasts approximately 18 months. Due to the reduced number of NBs and the challenge of having all NBs ready by May 2020, there could be certification capacity issues. An additional complication is that UK NBs are responsible for certifying a significant number of medical devices. After Brexit, all UK-based NBs may no longer be able to perform conformity assessments in line with EU legislation.

The Chair of the International Medical Device Regulators Forum (IMDRF) Work Group on UDI, which was established in September 2017, **invited HOPE to speak on 12 February 2018 during the international workshop on global use and application of Unique Device Identification (UDI).** IMDRF is a voluntary group of medical device regulators from around the world. It came together to build on the strong foundational work of the Global Harmonisation Task Force on Medical Devices (GHTF) and aims to accelerate international medical device regulatory harmonization and convergence. Pascal Garel, the CEO of HOPE addressed the difficulties of practising traceability in hospitals and referred to the very different practices in each country.

HOPE was invited to join the Meeting of the "European UDI Working Group" on 25 May 2018 for a presentation and discussion on the future unique device identification: Guidance on systems/procedure packs, Guidance on software, Guidance on Unique Devices Identification (UDI) related obligations associated with Article 16 of the Medical Devices Regulation, Guidance on specific device types (contact lenses), Additional considerations on language in the UDI database.

On 5 May 2017, the new Medical Device Regulations were published and they 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.

The **"European UDI Working Group" met on 12 December 2018** in Brussels and presented the progress related to the future UDI database in EUDAMED and discussed draft guidance on the application of UDI rules to device-part of products referred to in Article 1(8), 1(9) and 1(10) of Regulation 745/2017 that set the basic criteria to determine whether and to what extent the relevant legislation on medical devices, medicinal products, human tissue and cells apply to certain products containing a medical device part.

To ease the transition process to the new Regulations, the European Commission's Directorate General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW) launched a web portal in January 2019, providing an extensive source of information on the roles and responsibilities of all these actors.

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.

HOPE was contacted by the Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW) of the European Commission as part of its **communication campaign** on the new Regulations on medical devices (MDR) and in vitro diagnostic medical devices (IVDR). The campaign aims at providing information to key actors and increasing awareness about the new requirements and timelines of these regulations, with the overall objective to avoid any disruption on the market and to prevent any malfunctioning of the healthcare system. The campaign will primarily focus on manufacturers (and notably SMEs), the "procurement world" (e.g. hospitals, Ministries, etc.), authorised representatives, importers, distributors, re-processors of single-use devices, health institutions, healthcare professionals and authorities in third countries. Due to the number of targets and their worldwide distributions, the communication campaign will mainly be performed online, using notably the DG GROW website and existing multiplier networks.

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

As hospitals have been targeted in recent cyberattacks, HOPE is now closely monitoring the EU legislation in this field. 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.

The NIS Directive does this by ensuring:

- Member States preparedness by requiring them to be appropriately equipped, e.g. via a Computer Security Incident Response Team (CSIRT) and a competent national NIS authority;
- Cooperation among all the Member States, by setting up a cooperation group, to support and facilitate strategic cooperation and the exchange of information among Member States. They will also need to set up a CSIRT Network, in order to promote swift and effective operational cooperation on specific cybersecurity incidents and sharing information about risks;
- A culture of security across sectors which are vital for the economy and society and moreover rely heavily on ICTs, such as energy, transport, water, banking, financial market infrastructures, healthcare and digital infrastructure. Businesses in these sectors that are identified by the Member States as operators of essential services will have to take appropriate security measures and to report serious incidents to the relevant national authority. Also, key digital service providers (search engines, cloud computing services and online marketplaces) will have to comply with the security and notification requirements under the new Directive.

In view of the impending deadlines for its transposition into national legislation on 9 May 2018, and for the identification of operators of essential services by 9 November 2018, the **Commission adopted on 13 September 2017 a Communication that aims at supporting Member States in their efforts to implement the Directive** swiftly and coherently across the EU. The "NIS toolkit" provides practical information to Member States, e.g. by presenting best practices from the Member States and by providing explanation and interpretation of specific provisions of the Directive to explain how it should work in practice.

On 13 September 2017 the Commission issued a proposal for a regulation on ENISA, the "EU Cybersecurity Agency", and on Information and Communication Technology cybersecurity certification (''Cybersecurity Act''). The proposed certification framework

will provide EU-wide certification schemes as a comprehensive set of rules, technical requirements, standards and procedures. This will be based on agreement at EU level for the evaluation of the security properties of a specific ICT-based product or service e.g. smart cards.

The certification will attest that ICT products and services that have been certified in accordance with such a scheme comply with specified cybersecurity requirements. The resulting certificate will be recognized in all Member States, making it easier for businesses to trade across borders and for purchasers to understand the security features of the product or service. The schemes proposed in the future European framework will rely as much as possible on international standards as a way to avoid creating trade barriers and ensuring coherence with international initiatives.

The Council decided to consult the EESC on this proposal. As part of its consultative work, the EESC has held a public hearing entitled "Cybersecurity act", which took place on Tuesday, 9 January 2018, at the European Economic and Social Committee (EESC), Brussels. The event offered the opportunity for HOPE to take stock of the emergence of a model of European resilience in the context of attacks hitting citizens, social systems and economic sectors across Member States. The Council Conclusions following the Communication adopted in November 2017 called on the Commission to provide rapidly an impact assessment on possible options and propose by mid-2018 the relevant legal instrument for the implementation of the initiative establishing a Network of Cybersecurity Competence Centres and a European Cybersecurity Research and Competence Centre.

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. The proposal will also upgrade the current European Union Agency for Network and Information Security (ENISA) into a permanent EU agency for cybersecurity.

On 27 March 2018, the committee draft report was published and on 30 April 2018, the amendments tabled in committee were published.

- Certification would be voluntary unless otherwise specified in EU law or member states' law.
- Features covered would include for instance resilience to accidental or malicious data loss or alteration.
- There would be three different assurance levels: basic, substantial or high. For the basic level, it will be possible for manufacturers or service providers to carry out the conformity assessment themselves.

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.

The first trilogue took place on 13 September 2018, the second on 1 October, the third on 5 November, the fourth on 22 November and the fifth on 10 December 2018. An agreement was reached during the last trilogue. 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 Council is expected to adopt it soon.

In relation to the Medical Devices Directive implementation, **HOPE joined the Task-force on cybersecurity created in 2018.** HOPE was invited to the working group to outline the structure of future EU guidance on cybersecurity:

- Cybersecurity requirements scope: what it is/what it is not;
- General principles on cybersecurity (possibly including shared responsibility, intended use, intended environment, state-of the art, information from operators, application of different legislation – such as GPDR and NIS, if deemed applicable);
- Description of risk management (mostly ER 2, 3 and 4), in cybersecurity, notably,
- Clarification that cybersecurity can be intended as reasonably foreseeable misuse
- Lifecycle aspects (including integrating post-market information)
- Consideration of intended use and intended environment of use
- Minimum requirements concerning IT hardware, IT network characteristics and IT security measures (17.2) and communication issues with operators
- Highlight manufacturers' responsibilities vs other operators' responsibilities (how operators can achieve reasonable cybersecurity – classification of security levels – installation/putting into service)

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.

The General Data Protection Regulation replaces the EU data protection directive, which dates back to 1995. The GDPR was adopted in April 2016 as part of a wide-ranging reform package, which also includes a directive on data processing for law enforcement purposes. A set of new rules on e-Privacy is also currently being considered.

The revision of the general data protection Regulation started in 2012 with the publication of the Commission's proposal. HOPE followed very closely the entire legislative process, as data protection rules have an important impact on healthcare services and research.

To influence this legislation, **HOPE collaborated with the Healthcare Coalition on Data Protection** (which represents key stakeholders in the healthcare sector in Europe and in which HOPE has been involved since 2013) and the European Data in Health Research Alliance (EDHRA) bringing together stakeholders from academia, patient and research organisations from across Europe. The latter collaboration was aimed at ensuring that the review of the Data Protection Regulation would not have limited the use of personal data for health research purposes.

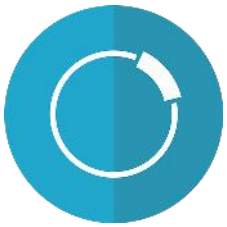
Once the Regulation was adopted, HOPE collaborated with the NHS European Office to share information about its impact on the daily work of hospitals and other healthcare organisations. As a result, the briefing "Protecting and managing personal data: changes on the horizon for hospitals and other health 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.

During HOPE Liaison officers meeting in Brussels in March 2018, Tom Balthazar (Zorgnet-Icuro, Belgium) reported on the work done in this issue in Flanders. Then, during its Board of Governors in Stockholm an exchange of views followed the presentation by Pascale Flamant (CEO of UNICANCER, France).

BLOOD, TISSUES AND CELLS

Since 2017, the Commission has been carrying out an evaluation of the EU blood, tissues and cells legislation. This is the first formal evaluation of this legislation since the basic Acts in 2002 (blood) and 2004 (tissues and cells) were adopted. This evaluation is in line with the Commission's Better Regulation Package and assesses whether the legislation has achieved its original objectives and whether it is still fit for purpose. The evaluation consists of several steps starting with a Roadmap, a study by an external contractor and extensive stakeholders consultation.

The **consultation was launched online on 29 May 2017** and was open until 14 September 2017. Dedicated questionnaires were available for individual citizens and for administrations and organisations, in both cases based on the five assessment criteria: effectiveness, relevance, efficiency, coherence and EU added value. HOPE office prepared answers to the consultation of the Commission. They have not been submitted but could serve as a basis for the position to be taken by HOPE in case there is a proposal of revision of the Directive. Most of the questions and answers are rather technical and would need expertise in each HOPE member organisation.



On **19 April 2018, the Report of the online consultation on Blood, Tissues and Cells was released.** The main findings are that the EU legislation seems to make Blood, Tissues and Cells safer, but needs to keep pace with developments.

The open public consultation evaluating has found most respondents, who included both individual citizens and various groups, such as professional societies, donor and patient organisations and national authorities, consider that the legislation has made blood, tissues and cells safer in the EU.

Most respondents find that the legislation is not up-to-date with scientific, technological, epidemiological or societal developments and that the updating process is too slow and lacks flexibility. They also believe that there are some shortcomings, including:

- Inadequate provisions for the protection of the living donors;
- Lack of requirements to ensure quality of blood, tissues and cells, as opposed to safety;
- Lack of demonstration of safety and efficacy in the recipient;
- Absence of provisions for ensuring sufficiency of supply.

Next steps include further evaluation through an independent study by a contractor, further meetings between the Commission and key stakeholder organisations and the **publication of a Final Evaluation Report by the Commission in 2019.**

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 worked intensely on drafting the Directive and raised awareness about its content. Since then, unlike what is done for most directives, HOPE continued to monitor the directive for long after it adoption.

HOPE was part of the advisory board for the study "Cross-border cooperation: capitalising on existing initiatives for cooperation in cross-border regions" published on 27 March 2018 by the European Commission. The study maps EU-funded cooperation projects for the period 2007 to 2017 in EU and EEA countries and Switzerland; provides insight into opportunities and challenges for cross-border cooperation in healthcare; and offers guidance to local and regional authorities and other parties who are interested in starting a health-related cooperation project.

Directive 2011/24/EU codifies patients' rights to reimbursement for Healthcare received in another EU Member State (MS) and obliges MS to provide information about access to such care through their National Contact Points. In order to assess the impact of the Directive, a questionnaire was sent to all MS in 2015, 2016 and 2017 to collect information on patient mobility in the preceding year. This report, published on 18 July 2018, provides an overview of the data on patient Mobility in 2016, collected from July to November 2017.

On 21 September 2018 the Commission published its report on the implementation. Patients mobility and its financial dimensions within the EU remain relatively low and the Cross-border Healthcare Directive has not resulted in a major budgetary impact on the sustainability of the national health systems. The report also shows that patients are increasingly aware of their rights under the Directive. In the last reporting period (2015-2018), the National Contact Points (NCPs) have been trained and supported interact daily with citizens in a proactive way. The quality of information through dedicated national websites and other means has also improved.

The Directive has created a framework for cooperation between health systems especially in areas of Health Technology Assessment and eHealth. In addition, 24 thematic European Reference Networks (ERNs) for rare, complex and rare prevalence diseases have been established, bringing together more than 900 highly specialised healthcare units located in more than 300 hospitals across the EU. There are now also more than 200 virtual panels on patient cases operating under the ERNs. Overall, in terms of the numbers, cross-border patient mobility within the EU has slightly increased in the last three years, as citizens have more access to information.

HOPE CEO Pascal Garel was invited by Ivo Belet MEP (Vice-coordinator of the EPP Group in ENVI Committee of the EP and the EPP Group rapporteur on the Cross-border Healthcare Directive) **to speak on 17 October 2018 in a European Parliament hearing** on the implementation report on the quality of care and patient safety under the cross-border healthcare directive. The report was intending to analyse the current shortcomings in the implementation of the Cross-Border Healthcare Directive and to make recommendations for the improvement of the directive. This was an opportunity for Pascal Garel, Chief Executive of the European Hospital and Healthcare Federation to present the history of HOPE involvement in and its views on the cross-border care. He went back over the different kind of flows, the continuity of care and the wrong assumptions of the cross-border directive. Concerning digitalisation, he mentioned the position paper adopted by HOPE in June 2018 and concluded with the three digital projects in which HOPE is involved: EURO-CAS, MedEye and ICT4life.

On 30 October 2018, the Draft Report on the implementation of the Cross-Border Healthcare Directive (2018/2108(INI)) by Rapporteur Ivo Belet (EPP) was released and took into consideration several elements suggested by HOPE.

The **European Commission organised a conference 'Enhancing Healthcare Cooperation in Cross-border Regions' on 4 December 2018** in Brussels to present the results of a pioneering mapping study of successful activities and its toolkit for practitioners interested in setting up cross-border cooperation themselves. The Commission estimated that more than one in three Europeans live in a cross-border territory. HOPE reported on several past and present activities in this regard. Cooperation between health services, facilities, providers and authorities has indeed the potential to turn border regions into places of opportunity for better health outcomes, local innovation, jobs, and growth. Aimed principally at professionals in the health and cooperation fields, this compact event showcased good practices and creative solutions in cross-border health cooperation, and the challenges that border regions have encountered and overcome.

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 practice, ERNs will develop new innovative care models, eHealth tools, medical solutions and devices. They will boost research through large clinical studies and contribute to the development of new pharmaceuticals, and they will lead to economies of scale and ensure a more efficient use of costly resources. This will have a positive impact on the sustainability of national healthcare systems, and help tens of thousands of patients in the EU suffering from rare and/or complex diseases and conditions. The ERNs will be supported by European cross-border telemedicine tools and can benefit from a range of EU funding mechanisms such as the "Health Programme", the "Connecting Europe Facility" and the EU research programme "Horizon 2020".

HOPE was invited to speak on 27 February 2018 in the European Parliament during the meeting of the European Parliament interest group on European Patients' Right and Cross-Border Healthcare. Chaired by Stephen McMahon, President of the Irish Patients' Associations, the group was welcomed by MEP Patrizia Toia (Italy). The concept of European Reference Networks was presented by the European Commission Cross-Border Healthcare & eHealth Unit and illustrated by Maurizio Scarpa, Coordinator European Reference Network for Hereditary Metabolic Diseases (MetabERN) and Luca Sangiorgi, Coordinator, European Reference Network on Rare Bone Diseases (ERN BOND). An example of the contribution of patients to ERN was provided by Beatrice De Schepper of the European Huntington Association, as a patient representative in the ERN RND (Rare Neurological Diseases). HOPE CEO Pascal Garel, reported on the work of HOPE in setting up the first seminar for chief executives of hospital leaders and ERNs partners.

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." The Opinions of the Expert Panel on Health support the Commission to identify specific aspects to be considered as well as tangible results that should be achieved to make a real change on health systems reforms and investments at EU level. The Expert Panel concluded that, while ERNs have considerable potential to improve the care of patients with rare diseases across the EU, both through advice on the management of individual patients, as well as through collaboration on research and development of guidelines, it is not yet possible to ascertain the extent to which these goals will be achieved. The Expert Panel also identified several issues which, even at this stage, appeared to need to be addressed, including long-term finan-

cial sustainability and the implementation of effective IT systems.

During the hearing on the report organised in Brussels on 25 September 2018, HOPE CEO congratulated the authors and reminded delegates about HOPE's long involvement in this issue since the early 2000s. He referred to several points raised in the report and in particular referral mechanisms and integration. HOPE had already raised these issues in the early debates that led to the adoption of the directive on cross-border care in which ERNs are included. He also pointed out that Brexit was not mentioned in the report although 6 of the 24 ERN have a UK leader and numerous UK teams are involved in the ERNs.

Health professionals, researchers, patient organisations and policy-makers gathered in Brussels on 21 and 22 November 2018 for the 4th European Reference Networks Conference. HOPE attended and contributed to this event, which featured two full days of presentations and debate, driven by plenary sessions and eight parallel workshops.

Opening the event, Anne Bucher, Director-General of DG SANTE highlighted that more than 250 patients have directly benefited from virtual consultations by the network and this number is expected to grow. The conference focused on the need to consolidate the networks and examined some of the challenges that lie ahead. One of the priorities for 2019 is the integration of ERNs into national health systems. The role of Member States and hospital managers will be central in this regard, and both parties were well represented at the event. Improving the geographic coverage of the networks was a recurring theme: the networks have very strong representation from high GDP countries but less participation among lower GDP Member States. A new call for affiliated members may help to redress the balance.

The potential of ERNs in developing clinical guidelines for rare diseases was under the spotlight. Work is under way to map existing guidelines and to explore how ERNs can help to fill gaps where no guidance is available. The Commission will support this through a tender on the development of clinical practice guidelines which was launched in November 2018 month. Data was also central to a discussion on the role of ERNs in building patient registries for rare diseases.

Several sessions addressed the long-term sustainability of the ERNs. Challenges include funding, awareness among patients and health professionals, support from hospital managers, and the limited human resources available to work on ERN-related initiatives. Given the limited pool of experts in rare diseases, there can be a heavy burden on active ERN leaders. There is also a need to develop an interest and expertise in rare diseases among younger health professionals. There was a strong sense of support for ERNs which are viewed as an example of how European cooperation can add value for vulnerable citizens.

PROPOSED LEGISLATIONS

BREXIT

On 7 December 2017, HOPE (with the support of its NHS Confederation member) and a group of European organisations representing patients, healthcare professionals and the health care industry had called on the EU and UK to prioritise patients in the Brexit negotiations. The document outlined **five priorities,** which the group says will **'determine the risk in Brexit's impact on patients and public health across Europe':**

- Bring about close cooperation between the EU and the UK on the regulation of medicines and medical technologies, to ensure that UK and EU patients will continue to have access to life-saving medicines and medical technologies;
- Establish a common framework for collaboration in research and information sharing between the EU27 and the UK;
- Ensure that there are continued reciprocal healthcare arrangements between the EU and UK;
- Develop strong coordination between the EU and the UK on public health, including in pandemic preparation and disease prevention programmes;
- Ensure EU and UK health professionals continue to benefit from mutually beneficial training and education opportunities, with automatic recognition of qualifications.

At a critical time when both the EU and the UK Government were preparing for phase II of the Article 50 negotiations, a **workshop entitled "Brexit: Prioritising patient safety and public health across Europe" was organised in Brussels** by European stakeholders, including HOPE, on Wednesday 21 February 2018. After a welcome and introduction by Nicola Bedlington of the European Patients Forum presenting the joint statement and the key priorities for patients in the Brexit negotiations, several organisations presenting perspectives on Public Health, Access to medicines and medical technologies, Research and innovation. HOPE Chief executive Pascal Garel presented the issues around Mobility for patients

HOPE and the European health community have warned that time is running out to secure patients' interests in Brexit negotiations. With Phase 2 of the negotiations looming, health groups across Europe have drawn up a list of crucial unanswered questions that must be answered by the EU and UK negotiators to 'put patients first' in the negotiations.

These questions were set out at a meeting of a coalition of European health stakeholders on 21 February 2018 and were released ahead of the European Council meeting on 22 March 2018, where the guidelines for the negotiation of phase 2 were agreed. These focus on how to prioritise patient safety and public health in the Article 50 negotiations on the future relationship between the UK and the EU.

Some of the key questions the coalition sets out are:

- How will a trade agreement ensure sufficient and timely supply of medicines and medical devices for both EU and UK patients?
- In the event of a 'no deal' Brexit, how would the EU27 national governments avoid that public health being affected across the EU?
- How will the UK and the EU come to an agreement to ensure the future drug licensing system does not exacerbate delays in access to the most innovative treatments for patients, both in the UK and across the EU?
- How can EU and UK patients benefit from the pooling of scarce expertise?

On 6 March 2018, HOPE took part in the "Brexit and the NHS" event, organised by MEP Rory Palmer (United-Kingdom, Group of the Progressive Alliance

of Socialists and Democrats) with the UK Shadow Health Secretary Jonathan Ashworth, member of the UK House of Commons. During this speech, Jonathan Ashworth expressed the Labour Party views on how to handle the impact of Brexit on the healthcare sector. He underlined the importance of the collaborative process between the UK and Europe, which in the past led to fundamental medical breakthroughs, and that the Labour Party wish to carry on this fruitful relationship. Many important issues were raised, such as the management of the previously free flow of patients to the only paediatric cardiology structure (Dublin) in the whole island of Ireland; the challenge for foreign doctors leaving for other EU countries whereas they represent a major asset for the NHS; or the importance of quick access to key resources in cases of life-or-death.

On **23 May 2018, HOPE attended the British Medical Association conference "Keeping Europe Healthy: Brexit and the European Medical Profession"** at the European Parliament. The event was hosted by MEP Wajid Khan (S&D, United Kingdom) who pointed out in his opening remarks that Brexit will impact healthcare across Europe and not only the UK. The damages that a badly-shaped Brexit could have on the EU health workforce has to be considered, as well as the need to ensure that patients will not suffer from Brexit.

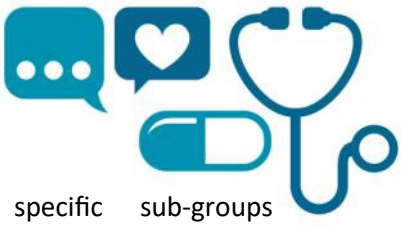
On 27 September 2018, 20 EU-level health organisations, including HOPE, joined forces to highlight the implications of Brexit for healthcare across the continent and organised the **event 'Prioritising patient safety and public health across Europe post-Brexit' at the European Parliament.** They called upon MEPs to follow up on the concerns highlighted at last year's European Parliament ENVI committee hearing in November 2017, urging them to organise a second hearing in order to ensure the preparedness of the EU27 with a view to securing continuity in the supply of medicines post Brexit. The patient's organisation stressed out three main concerns: the trade agreement must ensure the provision of sufficient and timely supply of medicines and medical devices both for EU ad UK patients; partnership on medical research should be pursued and the transition should be progressive enough to avoid impacts on patient safety. The "no deal" would be the worst option from a public health perspective.

On 25 October 2018, the European Journal of Hospital Pharmacy published an **editorial "Brexit and shortages" written by HOPE CEO Pascal Garel.**

It underlines that no agreement was reached between the UK and the EU at the latest European Council Summit on 17 October 2018. Both sides agreed that much work has been done over the last weeks and maintain that a deal is still possible. However, the Ireland/Northern Ireland border remains unresolved despite intense negotiations. Michel Barnier, Chief Brexit Negotiator for the EU, again stressed the need for a legally operational backstop in the Withdrawal Agreement.

On 15 November 2018, the UK and EU published the texts of the **Withdrawal Agreement** setting out the terms of the divorce deal, and the outline political declaration setting out the framework for the future relationship between the EU and the UK. These texts were agreed at negotiators level on 14 November 2018 but subsequently rejected by the UK Parliament.

On 21 November 2018, 15 health organisations, including HOPE, sent a **joint letter to Martin Selmayr, European Commission Secretary General.** The European health community – patients, researchers, pharmaceutical companies – raised its concerns about the lack of contingency measures specific to the continued collaboration on health and asked for an explicit commitment from both parties to long-term cooperation around public health, the regulation and development of medicines and medical technologies, clinical trials and medical research and the European Reference Networks.



HEALTH TECHNOLOGY ASSESSMENT

As defined by the EUNetHTA Joint Action, HTA is "*a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value*". Therefore, 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. HOPE is also part of the stakeholder group provider in the Joint Action for Health Technology Assessment in Europe: EUNetHTA.

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).

Individual EU countries will continue to be responsible for assessing non-clinical (e.g. economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement.

If adopted, the proposal will become applicable three years after it comes into force. Following the date of application, a further three-year period is envisaged to allow for a phase-in approach for Member States to adapt to the new system.

The proposal comes after more than 20 years of voluntary cooperation in this area. Following the adoption of the Cross-border Healthcare Directive (2011/24/EU), a voluntary EU-wide network on HTA composed of national HTA bodies or agencies was established in 2013 to provide strategic and political guidance to the scientific and technical cooperation at EU level.

HOPE was invited to a **roundtable meeting with Commissioner Andriukaitis** along with nine European organisations of health providers on 3 May 2018. Each organisation presented the key points including: the production of joint clinical assessments and the governance, including the involvement of stakeholders. This was an opportunity for HOPE to present the first topics of discussion with its members.

On **5 June 2018, HOPE took part in the discussion "What future for EU cooperation on HTA"** conference in the European Parliament. Hosted by MEP Andrey Kovatchev (PPE, Bulgaria) and organised by the Patient Access Partnership, this meeting gathered key institutional players and stakeholders to deepen the ongoing debates on

HTA. MEPs Biljana Borzan (S&D Croatia), Cristian Silviu Bușoi (EPP, Romania), Lieve Wierinck (ALDE, Belgium), Kateřina Konečná (GUE/NGL, Czech Republic) and Karin Kadenbach (S&D, Austria) welcomed this proposal.

On **9 July 2018, HOPE contributed to the "Way forward for cooperation" stakeholders meeting** organised by the European Commission. Soledad Cabezon Ruiz (ENVI Committee rapporteur for the proposal) stressed the need for a better quality in innovation, scientific evidence and added-value and she called for harmonised criteria among member states for clinically evaluating health technologies. Yet, in the light of the EPSCO (Ministers of social and health affairs) Council meeting held on 22 June, Member States have shown to be sceptical regarding the Commission proposal, they asked for guarantees about transparency as well as their freedom of action and raising concerns about Article 8 of the proposal on the use of Joint Clinical Assessment Reports at Member State Level.

On 13 September 2018, the ENVI Committee at the European Parliament voted in favour of the report drafted by the Rapporteur member MEP Cabezon Ruiz.

On **26 September 2018, HOPE attended the event "Aligning the priorities between the healthcare community and the European Parliament:** Where we are now and the necessary next steps for a regulatory framework for HTA", organised by the European Alliance for Personalised Medicine (EAPM) at the European Parliament. Concerns were raised about:

- The very tight (unrealistic for some) timeframe of the regulation;
- The lack of flexibility of the new system for Member States;
- The availability and access to relevant scientific evidence and the transparency of the data used;
- The remaining uncertainty and ambiguity of some aspects of the proposal;
- The transparency of the procedures that should guarantee the predictability of outcomes and the quality of the outcomes;
- The involvement of some stakeholders (patients and experts) in national settings.

HOPE took part in the **event HTA & Access to Innovative Oncology Drugs in Europe, organised by the European Cancer Patient Coalition (ECPC)** and hosted by Elisabetta Gardini MEP (EPP, Italy) on 25 September 2018 at the European Parliament. The meeting provided an opportunity to highlight the impact of a HTA regulation on the lives of people with cancer.

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.

The European Parliament adopted several amendments that ENVI Committee promoted to address Member State concerns. While still calling for a mandatory system based on nonduplication, the EP provides Member states with greater flexibility to conduct complementary clinical assessments which address national specificities. Moreover, it limited the role of the Commission to an administrative function and extended the transition period to four years for medicinal products and to seven years for medical devices.

At the Employment, Social Policy, Health and Consumer Affairs Council session of 7 December 2018, Ministers took note of a progress report from the Austrian presidency, according to which several delegations 'cannot agree to any degree of mandatory use' of joint clinical assessments. Technical discussions continue under the Romanian presidency, which intends to move the file forward.

EUROPEAN PILAR 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. The pillar's objective is to contribute to social progress by supporting fair and well-functioning labour markets and welfare systems. It sets out 20 principles and rights, divided into three categories: equal opportunities and access to the labour market; dynamic labour markets and fair working conditions, public support /social protection and inclusion.

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" 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.

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.

The European Economic and Social Committee invited HOPE to the **public hearing on "Delivery of essential services in conjunction with the European Pillar of Social Rights"** in Brussels on 3 October 2018.

The rights and principles forming the European Pillar of Social Rights fall into three areas, one of which is social protection and inclusion, which covers all aspects of living conditions in our society. The 20th and final principle of the European Pillar of Social Rights deals with "access to essential services". This principle establishes the right to essential services of good quality and gives a non-comprehensive list of those services which are most important to people's daily lives. However, it raises more questions than it answers.

First of all, the concept of essential services does not exist in the Treaties and therefore has no legal value. Why should a new concept be proposed instead of taking over that of services of general interest which is included in the Treaty as services of non-economic services of general interest (NESGI) and services of general economic interest (SGEI)?

The examples cited by the European Commission to illustrate this principle, namely water, transport, energy, electricity, are SGEIs which are treated by Protocol 26 annexed to the Treaty, which goes beyond the concept of essential services, which speaks of a "right of access to quality services", while the said Protocol also speaks of affordable prices, security, equal treatment, universal access and user rights.

The notion of "essential services" exists with certain international organisations, hence the question whether or not the European Commission intends to be part of a more global framework beyond the EU was raised during the hearing.

TRANSPARENT AND PREDICTABILE 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 complements and modernises existing obligations to inform each worker of his or her working conditions (1991 Written Statement Directive (91/533/EEC)). In addition, the proposal creates new minimum standards to ensure that all workers, including those on atypical contracts, benefit from more predictability and clarity as regards their working conditions.

The Commission estimates that 2 to 3 million additional workers on atypical contracts will be covered and protected by the proposal compared to existing legislation. At the same time, the proposal also puts measures in place to avoid administrative burden on employers, for instance by giving them the possibility to provide the requested information electronically.

More specifically, the Commission aims to reduce the risk of insufficient protection of workers by:

- Aligning the notion of worker to the case-law of the European Court of Justice. Under current rules, definitions may vary and certain categories of workers end up being excluded.
- Bringing within the scope of the Directive forms of employment that are now often excluded.
- Ensuring that workers are provided with an updated and extended information package directly at the start of employment from day one, instead of two months following the starting date as is currently the case.
- Creating new minimum rights, such as the right to greater predictability of work for those working mostly with a variable schedule, the possibility of requesting transition to a more stable form of employment and receive a reply in writing, or the right to mandatory training without deduction from salary.
- Reinforcing the means of enforcement and redress as a last resort to resolve possible disagreements, should dialogue not suffice.

The proposed Directive would need to be implemented by the Member States, either through legislation or by social partners' collective agreements. Fully recognising the importance of social dialogue, social partners would be able to modulate the minimum rights proposed by the Directive as long as its overall level of protection is ensured.

In the Council, the proposal was discussed at the Social Questions Working Party meeting on 6 February 2018. Further discussions followed on 9 March, 15 May and 14 June. Ministers agreed on a general approach to the proposal on 21 June 2018.

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 explains 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.

The JURI Committee voted its report on 27 September and the EMPL Committee of the Parliament voted on the draft report on 18 October 2018. The EMPL Committee of the Parliament voted on the draft report on 18 October 2018. On 26 October 2018, the Committee report was tabled for plenary. On 15 November 2018, the plenary ruled to enter into interinstitutional negotiations.

On 7 February 2019, the European Parliament, the Council and the Commission – reached a provisional agreement. This provisional agreement now has to be formally adopted by both the European Parliament and the Council.

WORK-LIFE BALANCE

On 21 June 2018, the Council agreed its negotiating position (general approach) **on the directive on work-life balance for parents and carers**. The proposal's aim is to improve access to work-life balance arrangements, such as leave and flexible working arrangements for parents and carers. It should boost the take-up of family-related leave by men, which will help increase female labour market participation.

The directive would:

- introduce new minimum standards on paternity leave, with fathers or second parents being able to take at least 10 working days off around the time of the birth of the child, paid at a level defined by the member state concerned.
- update the minimum standard on parental leave, keeping the existing individual right of 4 months but with 2 non-transferable months, with at least 1.5 months to be paid at a level set by the member state concerned.
- introduce an individual right to carers' leave, previously not recognised at EU level.
- extend the right to request flexible working arrangements for parents, until the child is at least 8 years old, and for carers too. Parents and carers could ask, for example, for flexible working hours or arrangements and for the right to work remotely.

On 24 January 2019, the presidency of the Council and the European parliament reached a provisional agreement on some key elements of the proposal for a directive on work-life balance for parents and carers. On 6 February 2019 EU member states' representatives in the EU Council endorsed the provisional agreement on the directive.

WORKING TIME DIRECTIVE

HOPE joined CESI@noon, a lunchtime debate organised by the European Confederation of Independent Trade Unions on 26 September 2018 and entitled "What constitutes working time under EU law?"

This event was devoted to the interpretation of working time legislation and more specifically on **possible impacts of the 'Matzak' ruling by European Court of Justice (CJEU) of February 21 2018. The ruling stated that**, under EU law, stand-by time of a worker at home who is obliged to respond to calls from the employer within a short period must be regarded as 'working time'.

A panel included the lawyer of plaintiff Rudy Matzak, Pierre Joassart; a legal officer from the European Commission, Andrea Grgic; the Vice-President of Avenir Secours and CESI affiliate Alain Laratta; the President of the Luxembourg trade union FGFC and member of CESI Marco Thomé; and the Vice-President of the justice sector of the Spanish trade union CSIF and CESI member Javier Jordán de Urríes.

The moderator, Pierre Baussand, led a discussion that on the different professions that would be impacted by the ruling. It appeared that not only firefighters could expect changes, but also any professions that uses the on-call working time, including the health and social care sector.

The cumulation of working hours when people work for different employers and the exemptions to the EU working time directive in this regard were an unavoidable part of the debates. Delegates also addressed the need to change how voluntary firefighting systems are organised. They acknowledged that voluntary firefighters often accumulate more than 100 hours per week next to their main job, if their on-call time at home is to as working time. How could this possibly be reconciled with legislation?

This also brought up the question of responsibility and pay. How will on-call time be paid? Who is to be held accountable for the breach of the 48 hours per week limit under the EU working time directive, and how will it be possible for local authorities to bear additional staff costs?

E-PRIVACY

In January 2017 the Commission published in an ePrivacy package proposal for a Regulation that concerns healthcare providers. The measures presented by the Commission aim 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 aligns 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 druw 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 Article 13 mentions 'when a phone call is made' but what if no call is made, but the emergency services may be able to track GPS data on a phone to locate an unconscious person, for example.
- Art 13 is about restrictions; the European Commission text was quite helpful as it echoes article 23 (1)(a)-(e) of the GDPR. The most useful exemption from a public health perspective is Art 13 1 (e) The European Parliament has changed this Article in a way that it is now not very clear, but they seem to have taken away the scope to restrict provisions of Art 5-8 of the ePrivacy legislation for public health and social security reasons. This seems good from our perspective to keep this in as we may need to access some metadata (ie location data) from public electronic communications in order to see peak times and locations of A&E services, so we can plan for A&E services etc.

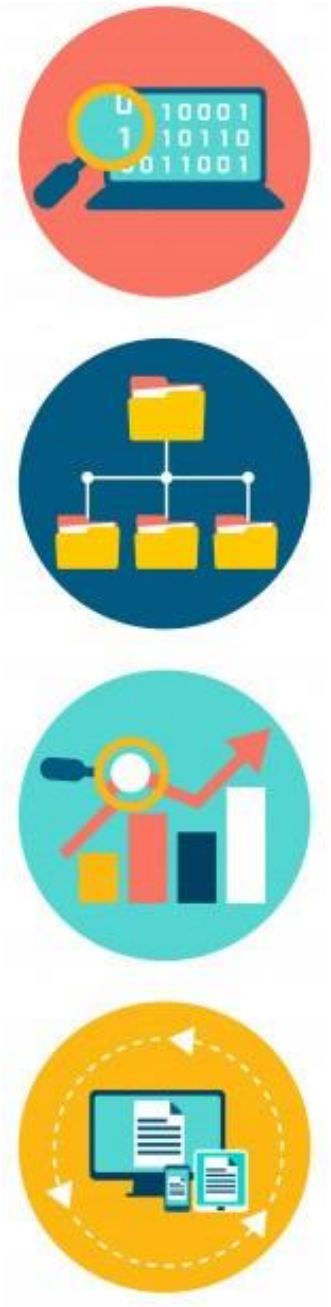
The Austrian EU Presidency adopted a revised text in September, which was discussed in the TELE (telecommunications, transport and energy) configuration at the Council on 27 September 2018. A progress report was presented and an exchange of views took place during the TTE (Transport, Telecommunications and Energy) Council of 4 December 2018. The Austrian presidency proposed amendments seeking to address delegations' concerns and requests for a more flexible regulation.

The new Regulation would not apply to activities such as those concerning national security and defence or e-communications services which are not publicly available; nor to activities of competent authorities for the purposes of the prevention, investigation, or prosecution of crimes. Moreover, the redraft does not apply to content or metadata processed by the end-users after receipt, or by a third party entrusted by them to store or otherwise process them.

The Austrian Presidency has also extended the deadline for entry into application to 24 months. Concerns from civil society about the risks of lowering privacy protection were expressed in different occasions, including in a letter to the Council by several organizations (Joint letter from industries on 28 November 2018; Joint letter from NGO on 3 December 2018).

A common Council position may be adopted under the current Romanian Presidency, after which negotiations with the Parliament could start – most likely after the European Parliament elections in May 2019.

On 23 October 2018 the revision of the Regulation on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data was adopted.



REUSE OF PUBLIC DATA

The Commission is considering the revision of the Directive on reuse of public data adopted in 2003.

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.

As set out in the May 2017 mid-term Review of the Digital Single Market strategy (COM(2017) 228), and in order to fulfil the goals of the strategy in the field of the data economy, the Commission prepared an initiative on accessibility and reuse of public and publicly funded data, and at the same time further explored the issue of privately held data which is of public interest.

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.

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.

Soft Law and Other Initiatives

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

Soft law refers to non-binding instruments, 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 Organization (HSO). Other standardisation bodies in this field include associations of hospitals or medical doctors, quality institutes or private consortia. In recent years, healthcare services standards also have been developed by the **European Committee for Standardisation (CEN)** and its members at European and national levels.

In **2018, HOPE was still actively engaged in discussions about standardisation in healthcare at EU level**, warning that this may jeopardise good quality of care.

Given the importance of this field, the CEN Technical Board decided in March 2016 to establish a Focus Group on Healthcare Services (HSFG) with the aim of exploring how standardisation can support quality, efficiency and safety in complex healthcare services throughout Europe.

The **13 November 2017 meeting of the CEN focus group** did not show any visible change in CEN policy. The activities carried out so far, e.g. the working groups on terminology and criteria, were not referred to anymore. Instead there was a focus on the use of standards in accreditation and certification processes. It seems that there is a strategic decision to continue with the process of defining a framework of action for standards in healthcare services.

One action point which resulted from the meeting is the mapping of 'reference documents' in the area of healthcare services, which shall explicitly exclude "medical/ clinical guidelines and laws and regulations". The objective of the exercise is to have a better overview of existing standardisation activities in the field of healthcare services and subsequently to determine whether and where CEN can add value vis-à-vis other organisations. The expected outcome of the Focus Group is therefore to identify are-

as in which European standards can add value and propose a way forward for addressing them. Moreover, the Focus Group will produce a CEN Guide – a manual for standard writers in healthcare services. The Guide will consolidate current knowledge and lessons-learned from the European Standards developed in this field in order to share this experience with stakeholders.

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. To this end, it is proposed to: have a joint meeting with DG GROW in the second half of February; have an informal roundtable with other stakeholders not yet part of the group. The item is on the agenda of the working party on public health at senior level on 12 February 2018. The CEO explained in Stockholm that a CEN working document was proposing to disband the healthcare services focus group, on the grounds of continued stakeholder opposition and EU lack of support.

The **proposal 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.

ACCESS TO MEDICINES

HOPE worked on expensive medicines by adopting a position paper in 2017, contributing to the OECD consultation and the broader discussion.

The Bulgarian Presidency of the Council of the EU organised in **Sofia on 6 March 2018 a conference on topics related to the accessibility of medicinal products**, their therapeutic effects and the effectiveness of the use of public resources. Participants discussed the need to apply the principle of proportionality in drug delivery, the need to take into account the specificities of EU Member States' drug policies and the possibility of finding a common national and European solution. One of the key messages was that medicinal products are specific commodities and their trade as well as the control over shortages of such products should be regulated through sustainable solutions. Emphasis was placed on finding a balance between the speed of regulatory approval and safety data for new drug therapies with reliable data on the effectiveness of therapies.

The conference was attended by experts from the Member States of the European Union, the World Health Organisation, the Organisation for Economic Cooperation and Development, the European Commission, the European Medicines Agency, the academic community, the industry and non-governmental organisations involved in the healthcare field.

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 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.

Participants included representatives of public authorities, patients' organisations, healthcare professionals, and pharmaceutical companies. They shared their best practices and clinical experiences with biological medicines, including biosimilars and discussed policy choices on the uptake of biosimilars in oncology, sustainable procurement practices, and how to improve the understanding of biosimilars. IQVIA (formerly IMS Health & Quintilles) presented the updated report for 2018 on the impact of biosimilar competition in the EU.

The other documents published on 13 September 2018 are the **translations of the biosimilar guide for healthcare professionals into** Dutch, French, German, Italian, Polish, Portuguese and Spanish. The guide, which was first made available in English in 2017, provides healthcare professionals with comprehensive and easily understandable information on both the science and the regulation underpinning the use of biosimilars.

HOPE joined BEUC (European Consumers Association) and the Permanent Representation of Portugal to the European Union at the **conference "Healthier Solutions for Access to Medicines" organised in Brussels on 23 October 2018**. This conference shed light on what needs to happen to develop truly innovative medicines and keep them affordable. Many people struggle to get the medicines they need. High costs and drug shortages do affect European patients – and are a huge strain on people's budgets and the public purse. An increasing number of new medicines, sold at high prices, do not offer sufficient benefits compared to those which already exist on the market.

The three items of the conference were Health technology has to be truly innovative and effective; role of national and EU public subsidies for research and development; Excessive pricing: competition enforcement and its impact on prices.

It was followed by a panel discussing the initiatives taken since the Dutch Presidency in 2016. A second panel was organised on Health Technology Assessment: Is there an EU way forward?

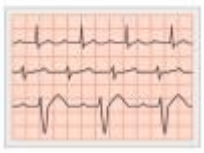
PERSONALISED MEDICINE

HOPE attended the European Alliance for Personalised Medicine (EAPM) annual conference in Brussels on 27 and 28 March 2018: "Personalised Medicine and the Big Data Challenge". High-level speakers and attendees came from a wide range of stakeholder groups including patients, healthcare professionals, academics, industry representatives, politicians and legislators, the media and more. The conference focused on two sets of Council Conclusions in the health arena: the first of these was the Luxembourg conclusions on access to personalised medicine two years ago; the Council Conclusions on Health in the Digital Society - making progress in data-driven innovation in the field of health at the end of 2017.

Among the opportunities identified are those arising from Big Data and improved data analytics capabilities, as well as from personalised medicine, the use of clinical decision support systems by health professionals and use of mobile health tools for individuals to manage their own health and chronic conditions. Medical research and clinical trials are generating unprecedented amounts of Big Data that is moving treatments forward in many disease areas. However, rare diseases present their own challenges, and in this sense the need for cross-border, pan-European collaboration is greater than anywhere else. Big Data can also be put to excellent use by providing an evidence base for other treatments, not least in neurology, alongside public health genomics.

On **27 September 2018, in Estoril (Portugal) during the 27th European Association of Hospital Managers Congress,** HOPE organised a session "Precise medicine for better patient outcomes". It was chaired by HOPE President, Eva M. Weinreich-Jensen with speakers from Denmark (Erik Jylling), Estonia (Andres Metspalu), Belgium (Pascal Verdonck) and France (Guillaume Mercy).

Eva M. Weinreich-Jensen introduced the speakers and explained that the session sought to examine at four different perspectives on the topic of precision medicine: regions, hospital federations, managers, and researchers. To shine a light on the various ways that precise medicine affects how we work and what we need to do to make the most of the new possibilities, in order to make the newest possibilities available to our patients.



There are many considerations for delivering precise personalised medicine/healthcare: a health care system infrastructure (governance), a technology infrastructure (electronic patient record, information systems), a legislative framework (GDPR, Data-ownership), patient consent, patient empowerment (self-management, wearables...), and a digital health strategy. This includes initiatives like: The Virtual Doctor, digital tools for rehabilitation, better citizen control and overview of health data, Digital Pregnancy Journal, digital workflows between different health sector professionals, continuous work on home monitoring, data security and IT, infrastructure optimisation and so on. It needs an infrastructure for personal health and new legislation concerning (among others) genomics data and citizen consent concerning the use of health data.

So, in short, the big picture is that the vast new variety of data and information available – with some of this coming directly from patients' wearables – means that we have a much higher possibility of treating the patients individually. If we – as hospitals - manage to catch the information, work closely with the patients and consider their input valuable, we can get better results. But as simple as it sounds it will challenge the way we usually have been thinking of healthcare and how to deliver it.

Summing the conference up in short: we need to think healthcare and the role of hospitals in a new way, if we want to take advantage of the possibilities precise medicine offers.

HOPE contributed to the 2nd European Alliance for Personalised Medicine Congress which took place from 26 to 28 November 2018 in Milan (Italy).

This event covered a wide range of issues such as lung-cancer screening, prostate cancer, diabetes and pancreatic cancer but also the role of the European Union regions. Hospital chief executive officers debated personalised medicine development down the line.

In some areas, the EU has had a strongly supportive role in healthcare. The resulting coordination, to develop science, to translate innovation, to systemise marketing authorisation requirements for medicines and to facilitate quality testing and trials has shown a positive aspect of the EU and should serve as inspiration and encouragement for more joined-up approaches to tackle new challenges.

The main conclusion is that a key component will be an understanding of the potential for personalised medicine to deliver improved outcomes for European citizens, the challenges that it presents to traditional health systems and the barriers that currently exist. Infrastructure and tools also need to be set up for personalised medicine-enhanced healthcare. This would help generate new diagnostic, therapeutic and preventive approaches from scientific research. It is essential to cooperate and avoid silo-thinking.

HOPE President Eva Weinreich-Jensen was among the panellists of the Presidential Session 'Interfacing with Public Policy Makers'. The panel put forward that the innovative quality of personalised care demands links to other areas of innovation. "*To make the most of personalised medicine, which means to get it to the patients fast, the laws must be clear and modernised, so everybody knows what can and cannot be done. And we need to get a lot of information out to patients, citizens and our staff in order for them to understand what it is all about, what are the options, what are the dilemmas*" said Eva Weinreich-Jensen.

Radical changes in thinking at the highest policy level, in relation to public health generally, will enhance the measurement of value for health interventions and adapt payment systems accordingly. All of this will require agreement on standards, and improvements to regulatory pathways, as well as an appropriate regulatory and medical framework.

HOPE also took part in A joint event entitled "From genomic data to personalised healthcare" organised on 12 December 2018 in Brussels by the United Kingdom and Estonian Permanent Representations to the European Union. The aim was to bring together experts and others involved in health and research policy to discuss the exciting developments in this area, and their potential to transform healthcare.

MEDICINES SHORTAGE

On 7 November 2018HOPE joined the **event organised by the European Association of Hospital Pharmacists (EAHP) to present the results of its 2018 Medicines Shortage Survey**.

According to EAHP, the results of the 2018 Medicines Shortages Survey underline that medicine shortages remain a major problem for patients in European hospitals. Since the publication of EAHP's last survey results in 2014, the percentage of hospital pharmacists reporting shortages to be an issue in terms of delivering the best care to patients has seen a significant increase with 91.8% respondents, compared to 86.2% in 2014. This clearly shows that shortages are a problem faced in hospital pharmacies.

For EHAP, many hospital pharmacists highlighted the need for more timely and accurate information on medicines shortages. The association considers that given that medicines shortages continued to increase over the past four years an inquiry at European level into the primary causes is also needed. After the release of the 2014 results, EAHP already called on without success the European Commission to conduct a high-level investigation to better understand the precise factors that create cross border medicines shortages and to examine its role in bringing nations together to tackle this issue. Given the increase in respondents reporting that shortages are a significant problem in terms of delivering the best care to patients, EAHP urges again the European Commission to commit to work on identifying the root causes of shortages to improve the outcomes for patients in the EU.

The company Amgen supported the preparation of this report. Unfortunately, the survey was limited insofar as few answers were obtained in several countries.

AGEING

In 2012, HOPE joined **the European Innovation Partnership on Active and Healthy Ageing,** which gathers stakeholders from the public and private sectors, across different policy areas.

The partnership's main aim is to increase the average healthy lifespan in the EU by two years by 2020. This will call on three strategies:

- improving the health and quality of life of Europeans with a focus on older people;
- supporting the long-term sustainability and efficiency of health and social care systems;
- enhancing the competitiveness of EU industry through business and expansion into new markets.

Moreover, HOPE has been particularly engaged in the area of ageing and integrated care as leader of the dissemination and exploitation work package of the EU-funded project ICT4Life. More information on this topic is provided in this report in Chapter III (section "Completed Projects").

The **European Innovation Partnership on Active and Healthy Ageing (EIP on AHA)** Conference of Partners (CoP) took place on **27 and 28 February 2018 in Brussels**. The 2-day meeting was open to EIP on AHA partners and dedicated to reviewing the action plans of the Action Groups and the Reference Sites Collaborative Network, and especially how these plans are aligned with the European Commission policy activities, notably the "Transformation of health and care in the Digital Single Market" Communication currently in preparation.

On the 27, the session started by the welcome speech by Commissioner Andriukaitis. The digital transformation of health and care in the Digital Single Market was presented by MEP McGuinness, Vice-President of the European Parliament and Dario Gargiulo, Director General of Campania Region. The focus was put on the role of digital tools to achieve citizen empowerment, better protection of young populations and healthy lifestyle for all, stressing the importance of reducing the digital gaps between regions.

This was followed by two plenary sessions discussing the Partnership achievements and future prospects while the afternoon was dedicated to interoperability of electronic health record systems across borders, data-enabled research process and personalised medicine in active and healthy ageing and the deployment of new digitally-enabled care models.

On the 28, the focus was more practical as the CoP focused on discussions on **co-investment opportunities and capacity building for digital health solutions for Member States and regions.** This was followed by parallel sessions showcasing new tools to support investors decisions, the visibility of market opportunities in Europe and the policy actions needed to scale up digital innovation. The afternoon parallel sessions focused on various topics, from better prescription and adherence to medical plans for the ageing population to falls prevention or integrated care for chronic diseases. The Conference was closed by Miguel Gonzalez-Sancho from DG CONNECT and Dr. Tapani Piha from DG SANTE recommending directions for the Partnership beyond 2020.

The European Innovation Partnership on Active and Healthy Ageing organised the meeting of B3 Action Group on Integrated on 14 November 2018 in Brussels. The participants were welcomed by DG CONNECT, European Commission Filip Domanski, Policy Officer, DG SANTE, and the European Commission. Several new EU funded projects were then presented: Scirocco Exchange (Health Programme); VIGOUR (Health Programme); Digital Health Europe (Coordinated Support Action); EURIPHI (PCP/PPI Value-based Healthcare of which HOPE is a partner). The final Integrated Care Performance Assessment Framework measures and prototype tool were also debated.

The **12 personas and types of digital solutions** which regions and organisations have implemented to support needs were described. A first small group discussion was organised to ratify personas and digital solutions identified. Sylvain Giraud, Head of Unit, DG SANTE, presented the Structural Reform Support Service (SRSS) and its work on Integrated Care and Digital Health.

A second small group discussion presented the digital tools collected and the gap analysis. It identified additional solutions that members are aware of. Members confirmed that there are no current solutions for identified needs or any insufficiently mature solutions.

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 2018 European Semester and regularly reported on it via its monthly newsletter.

On 23 May 2018, the Commission adopted proposals for country specific recommendations, including on health as part of its ongoing assistance to Member States in implementing their health systems reforms in the light of an ageing population and a number of other challenges.

The Commission recommends that the governments of 12 Member States take better care of their national health systems and improve their effectiveness, increase accessibility and strengthen their resilience, with the following specific recommendations: Austria	Ensure the sustainability of the health and long-term care systems.
Bulgaria	In line with the National Health Strategy and its action plan, improve access to health services, including by reducing out-of-pocket payments and addressing shortages of health professionals.
Cyprus	Take measures to ensure that the National Health System becomes fully functional in 2020, as planned.
Finland	Ensure the adoption and implementation of the administrative reform to improve cost-effectiveness and equal access to social and healthcare services.
Ireland	Increase the cost-effectiveness of the healthcare system.
Latvia	Increase the accessibility, quality and cost-effectiveness of the healthcare system.

The **adoption each May 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.

In **November 2018, the European Semester Autumn Package was released**. The 2019 European Semester cycle of economic and social policy coordination begans against a backdrop of sustained but less dynamic growth in a climate of high uncertainty, a lot must be done to support inclusive and sustainable growth and job creation while enhancing the resilience of Member States' economies.

At EU level, this demands taking the decisions to further strengthen the Economic and Monetary Union. At national level, there is a pressing need to use the current growth momentum to build up fiscal buffers and reduce debt.

Investment and structural reforms need to focus even more on boosting productivity and growth potential. These actions will provide the conditions for sustained macro-financial stability and serve the EU's long-term competitiveness. This will, in turn, create the conditions for more and better jobs, greater social fairness and better living standards for Europeans.

The **Annual Growth Survey (AGS),** which sets the general economic and social priorities for the upcoming year, calls on the EU and its Member States to take decisive and concerted policy action to deliver inclusive and sustainable growth. At national level, policy efforts should focus on delivering high-quality investment, and reforms that increase productivity growth, inclusiveness and institutional capacity, while continuing to ensure macro-financial stability and sound public finances. At EU level, the priorities are deepening the Single Market, completing the architecture of the Economic and Monetary Union (EMU) and advancing the principles set out in the European Pillar of Social Rights.

The **draft Joint Employment Report**, which analyses the employment and social situation in Europe, shows continued job creation, decreasing unemployment and an improving social situation across the EU. The Report also includes the findings of the Social Scoreboard, which analyses the performances of the Member States in light of the principles of the European Pillar of Social Rights.

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, 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.

The consultation seeks views on possible actions to address the risks from pharmaceuticals in the environment and also to obtain views and information to support the development of the Commission's strategic approach to pharmaceuticals in the environment. **HOPE answered the consultation in February 2018** and published its answers online. The consultation ran until 21 February 2018.

E-HEALTH

HOPE has been regularly active in eHealth issues first of all as a **member of the eHealth Stakeholder Group (eHSG).** In June 2018, HOPE also released a Position Paper on eHealth.

Established by the Commission in 2012 and renewed in 2016, the eHSG currently comprises 30 European umbrella organisations representing different groups like health professionals and managers, patients and consumers, industry, and standardisation bodies. Its aim is to ensure an informed dialogue with the European Commission and to add value to policy design and implementation. It debated in particular on the European eHealth Digital Service Infrastructure, the health apps.

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. Twelve EU Member States start exchanging patient data on a regular basis: Sweden, Finland, Portugal, Croatia, and Estonia. Five more countries are scheduled to join the network in 2019, and another wave is expected for 2020 with six more countries currently negotiating to join the club. Until now European healthcare systems exchanged digital patient data only in projects, and on a limited scale. They are backed by the Connecting Europe Facility (CEF), a funding programme which promotes growth, jobs and competitiveness in Europe.

A study, written by the health policy and communications agency Incisive Health, concludes that health apps are failing to reach their potential in Europe. **On 29 January 2018, a roundtable in the EU Parliament was organised to discuss this report.** The Report on eHealth, finds that 73% of people across seven major EU countries have never used a health app – and that three quarters of the people that have are 34 years old and younger. However, there is a great deal of appetite across Europe to participate in the healthcare e-revolution. In order to unleash the potential of eHealth, the report identifies the barriers that must now be overcome. More than half of people cite data reliability concerns, data protection concerns and a lack of health system endorsement as the reasons why they would not use health apps.

Therefore, the challenges identified during the roundtable were: firstly, there needs to be a much greater degree of interoperability between the IT used by healthcare systems and eHealth services. And this requires – secondly – a much greater degree of investment in the digital infrastructure of healthcare systems. Thirdly, there needs to be some method of assessing and approving certain, effective eHealth technologies which bring added-value to people. And fourth, these approved healthcare technologies need to be reimbursed by healthcare systems. Finally, to unleash the opportunity of Big Data to drive real improvements in population health, there needs to be common standards governing data flows.

On **26 April 2018, HOPE took part in the eHealth Stakeholder Group meeting** held at the Directorate General for Communications Networks, Content and Technology (DG CONNECT) offices in Brussels. Three priorities were defined to make healthcare in Europe more digital:

- Secure access and exchange of health data,
- Data-based research and personalised medicine
- Digital tools to empower patients

Then, specific issues were presented: the Conference of Partners of the European Innovation Partnership on Active and Health Ageing, the Joint Declaration on Access to 1 million sequenced genomes in the EU by 2022, the Silver Economy Study, key results achieved by the EU funded research and innovation on ICT for Active and Healthy Ageing and finally mHealth policy actions.

The meeting was the opportunity for DG CONNECT to get direct feedbacks from members. On this occasion, the European Consumer Organization (BEUC) raised some concerns and gave recommendations: health data should not be for sale and should only be used for medical research and to improve patients' safety and quality of care. Like many of the stakeholders, they welcomed the Commission Communication but would expect more guarantee concerning the privacy and data protection, the security of the system and the awareness among patients and healthcare professionals.

In the afternoon. some specific issues related to DG SANTE were discussed: the eHealth Network meeting and agenda, the 3rd Joint Action on eHealth, the European Reference Networks, the eHealth Digital Service Infrastructure. Finally, the reports from the working groups on interoperability and standards, new and shifting balances and reimbursement were presented.

On **18 June 2018, HOPE took part in "The digital transformation of healthcare – challenges and opportunities"** conference hosted in the European Parliament by MEP Andrey Kovatchev (EPP, Bulgaria).

EU Commissioner for Digital Economy and Society Mariya Gabriel delivered a keynote speech on eHealth and the new European Commission Communication on eHealth released on 25 April 2018. She highlighted the objective to set up a mechanism for cooperation in order to assemble data and procedures and they discussed the new possibilities for integrated care provided by eHealth.

Kaisa Immonen (European Patients Forum) pointed out the need for empowering patients and in which ways eHealth can fulfil this need, if technology is made accessible in an understandable language and digital health literacy is guaranteed. She said patients are expecting better coordination, a more effective data sharing, patients' access, and a person-centred model. She further noted that patients are more and more in favour of sharing their health data as long as safeguards are in place.

On **21 June 2018, the first meeting of a new Joint Action on e-health** took place in Lisbon, in the context of the 2nd Lisbon eHealth summer week. The Joint Action will contribute to integrate eHealth into health policy and align eHealth investments with health requirements, thus improving healthcare with the use of ICT.

The JA will also support the eHealth network whose aims are to: facilitate the management of chronic diseases and multimorbidity, increase the sustainability and efficiency of the health systems, facilitate personalised care and finally to empower citizens.

Coordinated by the Serviços Partilhados do Ministerio da Saude E.P.E. in Portugal, the Joint Action is a 3-year action with an estimated budget of EUR 4.5 million (including the EU contribution of EUR 2.7 million) and the participation of 20 EU Member States plus Norway and Serbia.

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.

On **12 October 2018, HOPE took part in the 6th eHealth stakeholder (eHSG) group meeting** organised by the Directorate-General for Health and Food Safety and the Directorate-General Communications Network of the European Commission. One of the most pressing concerns regarding the e-Health dimension for healthcare practitioners is the gap between technologists/regulators – the entities responsible for developing the IT systems and how to implement them –and healthcare personnel, as stressed by UEMO (European Union of General Practitioners). According to them, e-Health must support the relation between healthcare professionals and patients.

Then, the EESC opinion on Digital transformation of health and care that was adopted on 19 September 2018 was presented, as well as the European Commission Recommendation on the Technical Specifications for a European electronic health record exchange format. Two documents produced by the eHSG of some of its members were reviewed and commented: 'Proposed Guiding Principles for Reimbursement of Digital Health Products and Solutions' and 'Citizens and Health Data'.

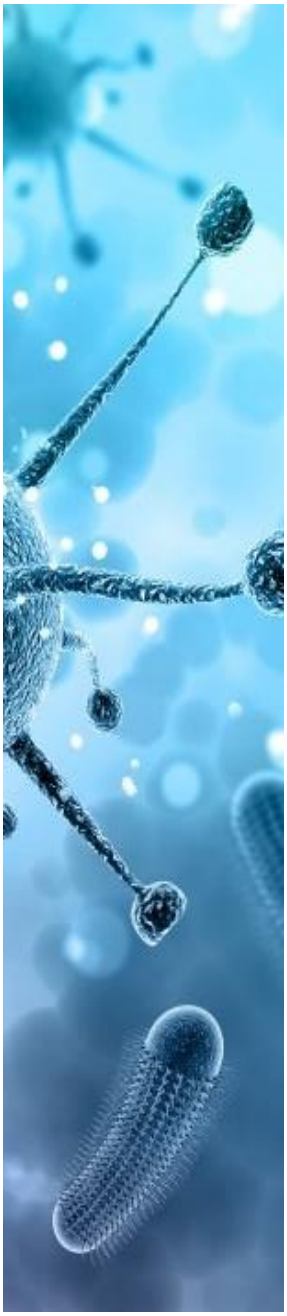
In October 2018, the Netherlands has recently signed the **declaration "Towards access to at least 1 million sequenced genomes in the EU by 2022",** thus becoming the 18th EU Member State to participate in the joint European effort to deliver cross-border access to genomic health data. The Declaration on linking genomic health data across borders is a mechanism of cooperation between the EU signatory countries, which are committed to collaborate on the secure and authorised access to national and regional banks of genetic and other health data.

On **25 October 2018, several European regions gathered to present their experience during a conference entitled "Digital health for all" organised in the Committee of the Regions**. This took place in the context of the European Commission Digital Market Strategy and the publication of the Communication on Digital Transformation of Health and Care in the Digital Single Market in April 2018 and in particular with the discussion on the European electronic health record exchange format. Access to Electronic Health Records was presented with the examples of Clic Salud + in the Andalusian Health Service, in Spain. eHAction was then presented by the Serviços Partilhados Ministerio da Saude, Portugal. Shared Services in Ministry of Health, Portugal, with an electronic health record patient portal, including the possibility for healthcare professional to consult from abroad. The example of the coordinated vaccine card was shown. The third session was on Better data to advance research, disease prevention and personalised health and care with the Northern Ireland Initiative; the Big Data strategy in Catalonia and the Andalusian population health database (BDP).

On **22 November 2018, the European Commission launched a Roadmap on European Electronic Health Record (EHR).** This proposal will make some recommendations on how electronic health records can be accessed and shared more easily in every EU member country.

This aims to make it easier for patients, health professionals or other authorised parties to use health data from different records across the EU – for example, to avoid having to repeat medical tests that have already been carried out in one country.

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.

The new Action Plan extends to innovative approaches, whilst ensuring the continuation of EU actions that are still needed. It focuses on activities with a clear EU added value and, where possible, on measurable and concrete outcomes. These activities have been grouped into three Pillars:

- Supporting Member States and making the EU a place of best practice on AMR;
- Boosting research, development and innovation;
- Shaping the global AMR agenda.

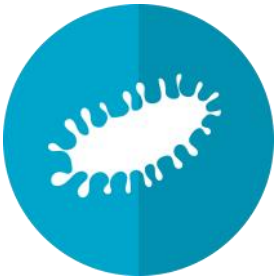
The new plan contains concrete actions with EU added value that the Commission will develop and strengthen as appropriate in the coming years for a more integrated, comprehensive and effective approach to combating AMR.

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 5 February 2018, the EU One-Health Network on AMR, chaired by the European Commission, met for the second time in Brussels. Network members include representatives of chief veterinary officers and chief public health officers from all 28 EU countries, Commission experts and EU agencies.

At the meeting, the Commission presented the state of play of the new EU AMR Action Plan, the EU's strategic approach to pharmaceuticals in the environment, supporting activities in developing countries, and funding opportunities under the Structural Reform Support Service (SRSS). The European Food Safety Authority (EFSA), the European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC) advised on how to use the key outcome indicators for AMR and antimicrobial consumption. In addition, France – the leader of the Joint Action on AMR and health-care associated infections presented its activities.



HOPE was invited as a member to **the Technical Advisory Committee of the European Centre for Diseases Control (ECDC) in Stockholm on 18 and 19 June 2018.** The main aim of the meeting was to discuss the plans for European Antibiotic Awareness Day (EAAD)2018 as well as the strategy and direction from 2019 onwards.

In the past months, ECDC has been performing an analysis of the yearly EAAD evaluations completed since the first EAAD in 2008, with a focus on the national needs and the barriers for the implementation of the campaigns at country level. ECDC is currently also consulting with professional, patient and consumer organisations that support EAAD, and it plans to integrate their feedback as part of a 2 to 5-year working framework for the campaign.

The meeting was also an opportunity to review 2017 activities at EU and at national level, coordinate activities with the European Commission and with WHO/Europe (in the framework of the World Antibiotic Awareness Week) and share best practices (Poland, Croatia and Spain presentations) and discuss preliminary plans for 2018.

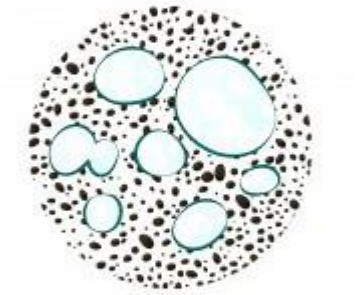
The own **initiative report on "A European One Health Action Plan Against Antimicrobial Resistance" was adopted by the Environment, Public Health and Food Safety (ENVI) Committee** of the European Parliament on 20 June 2018. The report stresses that the correct and prudent use of antimicrobials is essential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

On 6 June 2018, HOPE took part in an event hosted by MEP Fredrick Federley (ALDE, Sweden), organised by the company 3M and entitled "Infection prevention: a sustainable solution to the rise of AMR". The Joint Action on Antimicrobial Resistance and Healthcare-Associated Infection (EU-JAMRAI) as well as successful hand-hygiene prevention campaigns in Belgium hospitals are among the solutions presented during the event.

On 12 September 2018, the members of the European parliament (MEPs) adopted, with 589 votes to 12 and 36 abstentions, the non-binding resolution "One Health Action Plan against Antimicrobial Resistance". MEPs called on the EU Commission and member states to restrict the sale of antibiotics by human and animal health professionals, and to remove any incentives for prescribing them. Firm action should be taken against illegal sales, and sales without prescription of antimicrobials in the EU.

The European Commission should draft an EU priority pathogen list for both humans and animals, clearly setting future R&D priorities. Incentives should be created to stimulate investment in new substances.

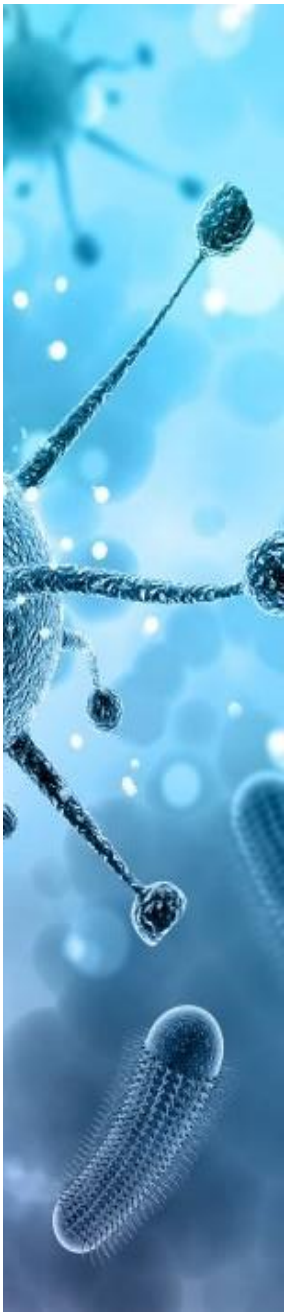
Labels explaining antibiotic use would also enable consumers to make well-informed choices. The Commission should create a single system for labelling, based on animal welfare standards and good animal husbandry practices, say MEPs.



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. As part of the 2017 campaign, the ECDC released a new toolkit for professionals in hospitals and healthcare settings, including hospital managers and administrators.

During the 2018 **European Antibiotic Awareness Day**, HOPE supported the initiative by disseminating information and EAAD promotional material via its network. As every year, HOPE also attended the EU-level stakeholder event, which took place in Brussels on 15 November, and was active on social media and contributed to the debate on Twitter (with the official hashtag #KeepAntibioticsWorking). This year the event marked the 11th anniversary of



this EU-level initiative aimed at raising awareness about the threat to public health of antimicrobial resistance (AMR).

The event, entitled "**One Health to Keep Antibiotics Working**" was moderated by Kate Kelland (Reuters) and opened with a keynote speech by the EU Commissioner for Health and Food Safety, Vytenis Andriukaitis The event was structured by interventions from the audience as well as contributions from several high-level speakers. Moreover, the Commission released the results of a new Eurobarometer study on public knowledge about antibiotics and overall trends in their use. On this occasion, ECDC presented the latest estimates of the health burden of antibiotic resistance, and the new data on the prevalence of healthcare-associated infections and on antimicrobial consumption in acute care hospitals and long-term care facilities in the EU/EEA.

On 26 November 2018, the EU introduced **new and improved rules to step up the fight against antimicrobial resistance and improve the availability and safety of veterinary medicines and medicated feed.** This will be of benefit to animal health and help boost the competitiveness of the EU veterinary pharmaceutical sector. The Council adopted the animal medicines package including two new regulations on:

- veterinary medicinal products
- the manufacture, market approval and use of medicated feed
- and changes to the existing rules laying down procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

At the **G20 meeting of Health Ministers on 4 October 2018** in Argentina, Ministers of Health stated that they were looking forward to the recommendations of the UN Interagency Coordination (IACG) on AMR and they acknowledged the commitment made at the UNGA High-level meeting on ending TB to treat 1.5 million people with multi-drug resistant TB as the first global AMR target.

AMR was also one of the main themes discussed at the **World Health Summit which took place on 14 -16 October 2018** in Berlin. The discussion was quite pharmaceuticals-oriented and highlighted the importance of supporting sustainable investments in antimicrobials R&D and ensuring appropriate access to antimicrobials while tackling excess use and abuse of antibiotics.

VACCINES

Supporting the initiative of HOPE Maltese member, **HOPE has been working on a survey on flu vaccination of healthcare professionals,** a field that lacks comparative elements. The Board of Governors meeting in Tallinn on 29 October 2018 debated about the advisability of going further with the survey's results but for now it has been kept as an internal document.

Several initiatives took place in this field 2018, all followed by HOPE.

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, highlighting the initiative's aims and objectives. A public consultation also ran until 15 March 2018.

In addition, a stakeholder consultation was held to examine the following questions about the EU in this area: How could it act with member states to address current vaccination challenges? How could it reach people who refuse to be vaccinated? How could it boost vaccine research? How could it talk vaccine shortages? How could it communicate more effectively about vaccines? Who are the key players in vaccination? What other suggestions are there for strengthening cooperation?

On **20 March 2018, the European Parliament environment committee adopted a draft resolution** expressing concerns about Europe's insufficient coverage rates and its impact on public health. To address these imbalances, the MEPs call on the European Commission to facilitate a more harmonised schedule for vaccination across the EU and to increase its support to national vaccination initiatives.

They also welcomed plans for EU countries to buy vaccines together, which should make them cheaper. In the draft resolution, MEPs welcomed the Joint Action Plan on Vaccination to fight people's reluctance to be vaccinated. They also proposed several measures to make the evaluation of vaccine safety more transparent and they called for more communication and awareness campaigns to fight false information on vaccination, especially online.

The Pharmaceutical industry (VaccinesEurope) was financed an event on 24 April 2018 in Brussels. The **Steering Group on Influenza Vaccination**, co-chaired by MEP Françoise Grossetête and Prof Thomas Szucs, organised the event called: "The EU Manifesto on Influenza Vaccination – together reducing the

burden of influenza." The keynote speech was delivered by Mr. Xavier Prats Monné, Director-General for Health and Food Safety, European Commission. The event was organised to coincide with European Immunisation Week 2018 to respond to needs outlined in the European Commission's Roadmap to Strengthen Cooperation Against Vaccine Preventable Diseases.

With financial support of the Pharmaceutical Industry EURACTIV organised a "stakeholder forum" on 26 April 2018 to discuss how European citizens could play a greater role in protecting themselves against vaccine preventable diseases. Several questions were raised:

- How to show citizens how vaccination can drive positive life outcomes – direct and indirect benefits?;
- What practices help citizens take more control of their own health?;
- How to optimise public engagement on vaccination in a digital world?
- What role for different stakeholders in implementing life-course vaccination?

Onhe same day, **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 proposal calls for 20 concrete actions by the Commission and Member States, including:

- Developing and implementing national and/or regional vaccination plans by 2020, including a target of at least 95% vaccination coverage for measles;
- Introducing routine checks of vaccination status and regular opportunities to vaccinate across different stages of life, for example in schools and workplaces;
- Presenting options for a common vaccination card that can be shared electronically across borders;
- Establishing a European vaccination information portal by 2019 to provide online objective, transparent and updated evidence on the benefits and safety of vaccines;
- Mitigating the risks of shortages by developing a virtual repository EU

data warehouse with information on vaccine stocks and needs to facilitate voluntary exchange of information on available supplies and shortages of essential vaccines;

- Equipping all healthcare workers with the necessary training to confidently deliver vaccinations and address hesitant behaviours;
- Convening a Coalition for Vaccination to bring together European associations of healthcare workers as well as relevant students' associations in the field, to commit to delivering accurate information to the public, combating myths and exchanging best practice;

- Establishing a European Information Sharing System to gather knowledge and develop guidelines for a core EU vaccination schedule by 2020 with doses and ages that EU Member States agree as being common to all countries;
- Strengthening partnerships and collaboration on vaccination with international partners.

In addition, the Commission will also produce a report on 'The State of Confidence in Vaccines in the EU', to monitor attitudes toward vaccination, in the context of the State of Health in the EU process.

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. By sharing tools for stronger national responses to vaccination challenges, EU-JAV aims at spurring long-lasting European cooperation against vaccine-preventable diseases in the era of the Sustainable Development Goals promoted by the United Nations.

The kick-off meeting brought together the European Commission, health ministries, international policy-makers and organisations, institutes, universities from 20 countries and a wide range of stakeholders, including civil society and manufacturers' representatives, working on vaccination policy and health services.

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. These include efficient mechanisms for interoperability of digital vaccine-related data and robust methods of monitoring immunisation programmes, accurate forecasting of vaccine needs through a concept of repository of vaccine supply and demand data, priority-setting of vaccine research and development,

information-sharing on evidence regarding efficacy, risks and costs of vaccines, as well as best practices and interventions to be improved.

The Joint Action is funded for 3 years with a total budget of €5.8m, including €3.5m from the Health Programme of the European Union. 17 EU Member States are participating as partners, as well as Norway, Serbia, Bosnia and Herzegovina.

On **31 August 2018, the Expert Panel on Effective Ways of Investing in Health** (a multidisciplinary and independent body set up by the commission to advise on matters related to health care modernisation, responsiveness, and sustainability), released a draft opinion on Vaccination Programmes and Health System in Europe.

Also, **three reports were released by the European Commission in October 2018**: The organisation and delivery of vaccination services in the European Union; State of Vaccine confidence in the EU; "Vaccination Programmes and Health Systems" of the Expert Panel on effective ways of investing in Health.

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 Commission is providing €18.5 million from the Internal Security Fund to support transnational projects in this fields. In 2018, a further €100 million from the Urban Innovative Actions supported cities investing in security solutions. The Commission issued new guidance material to help Member States address a wide range of issues related to the protection of public spaces and raising public awareness. The guidance includes technical "security by design" solutions to make public spaces more secure while preserving their open and public nature. The Commission established a Practitioners' Forum and 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 this context, the European Commission launched a new forum to facilitate enhance public-private cooperation on the protection of public places: the so-called EU Operators' Forum. In this forum, stakeholders have obtain available guidance, develop recommendations and share best practice.

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. A first meeting of the Forum took place on 20 December 2017, in which HOPE took part.

HOPE was invited to the **EU Operators' Forum thematic meeting on hospitality organised in Brussels by DG HOME on 26 September 2018.**

An overview was given of the EU work on protection of public spaces and on the threat picture. A session addressed lessons learned from recent attacks on public spaces and various actions taken to mitigate and counter the threat. Examples of good practices in the hospitality sector were provided. This was followed by a discussion to outline ideas and initiatives and to suggest concrete action for the EU to take.

A session provided examples how cooperation between public and private stakeholders could enhance the protection of public spaces in the hospitality sector with an overview of technology and standards development.

On **26 November 2018** HOPE was invited **to the meeting of EU Operators' Forum on the protection of public spaces in Brussels.** It focused on the recommendations to public authorities and private operators regarding the protection of public spaces presented in a document ("non-paper") sent on 13 November 2018.

The meetings showed that many public authorities and businesses have already been strengthening security at venues. The Commission provided forum participants with good practice materials via its CIRCABC platform which serves as the main repository for materials and information.

The meetings also flagged up remaining challenges and gaps. Protection levels are very uneven across the various sectors, and even within the same sectors isignificant differences have been noted. While some sectors have a well-developed security culture, others are only now putting in place more systematic approaches to protecting their venues.

Drawing on the discussions and material provided so far, the non-paper prepared by the Commission has identified good practices for measures that all operators and public authorities should implement to strengthen the security of public spaces. They reflect the basic steps for future work within all relevant sectors.

EU funding has also been made available to better protect public spaces. **The Commission published a call for proposals under the Internal Security Fund** – Police, for protection of public spaces and critical infrastructure against terrorist threats worth over EUR 25 million in 2017. 15 projects were selected, of which seven focus on the protection of public spaces. Another call for proposals was published in October 2018 under the Internal Security Fund - Police with a budget of EUR 9.5 million. It will focus inter-alia on public-private cooperation in the protection of public spaces. In addition, the Commission published a call for proposals with a budget of EUR 100 million in October 2018 under the Urban Innovative Actions initiative as part of the European Regional Development Fund to provide cities with innovative solutions to address urban challenges. Urban security is one of the four priorities of this call. Additionally, EU-funded security research addresses the protection of public spaces in different calls in 2018-2020 with the aim to develop innovative solutions for both the protection of critical urban infrastructures and public spaces, and to improve the collaboration between public authorities, operators and technology developers.

EU HEALTH POLICY FORUM

The **EU Health Policy Forum (EUHPF) was created in 2001 and** gathers today 52 umbrella organisations representing European stakeholders in public health and healthcare. In 2016, the EUHPF changed its format and is now based on three main strands:

- An IT platform, comprising a public webpage and a collaborative platform for registered participants;
- Regular meetings and a biannual summit;
- An annual health award for good practices that promote a healthier EU.

Within the platform, HOPE is a member of the network of EU experts and stakeholders groups on chronic diseases, integrated care and independent living solutions.

HOPE attended the EU Health Policy Platform third annual meeting in Brussels on 12 November 2018. At the event, Vytenis Andriukaitis, the European Commissioner for Health and Food Safety, announced the winners of the 2018 EU Health Award for Non-Governmental Organisations Working to Prevent Tobacco Use.

- The first prize of €20,000 was awarded to the Irish Cancer Society for the innovative social dimension of their campaign;
- The second prize of €15,000 was awarded to "Education Against Tobacco" from Germany for a well-structured and well-studied initiative;
- The third prize of €10,000 was awarded to the "Youth Network No Excuse" from Slovenia for their strong policy and advocacy component and young leadership.

Delegates had the opportunity to discuss a wide range of topics such as the role of stakeholders in EU health policy. Discussions were kicked off by Commissioner Andriukaitis who underlined the key role of stakeholders in helping the EC to define policy, especially health policy. He stressed the importance of having public health present in the next European elections and the need for civil society to actively campaign on health issues to be put on the top of the agenda.

John F. Ryan, Director Public Health, Country Knowledge and Crisis Management (DG SANTE) outlined how new tools such as the EU Policy Platform have changed policy development.

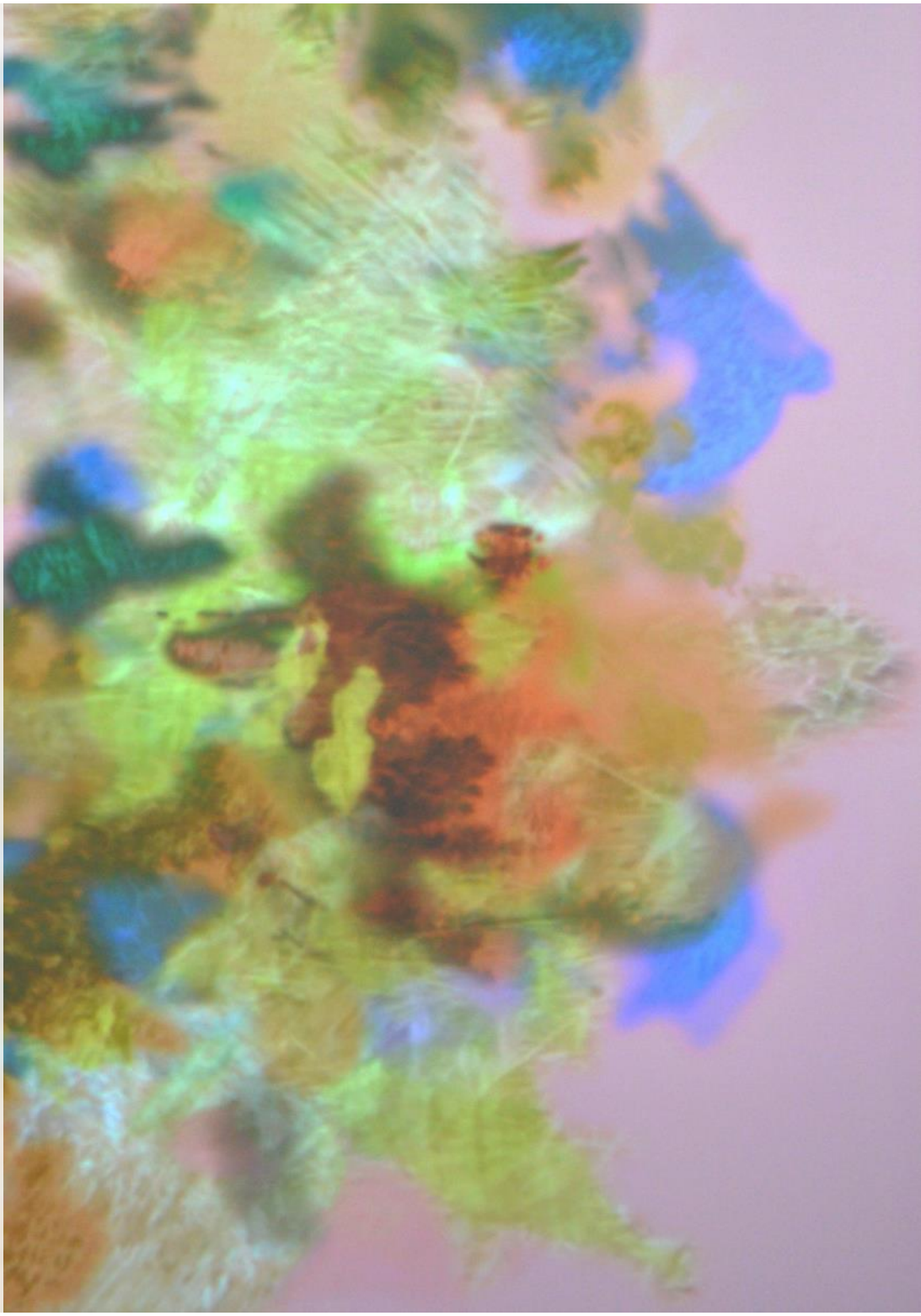
There were suggestions on how to make the Platform more user-friendly, to be as inclusive as possible to people with different associability or linguistic needs. The EC believes that providing more information about the work the EC will do (i.e., EC work programme) could be a path to explore to further involve stakeholders.

The 2018 Joint Statements prepared by the Thematic Networks under the EU Health Policy Platform were also presented, and the potential topics for the 2019 Thematic Networks cycle were announced.

The meeting was concluded by the presentation of the of the **Best Practice Portal for best practice sharing**. Participants are encouraged to submit practices, which would then be evaluated based on criteria that have been adopted by the Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases. If the submitted practices meet a threshold, they would be seen as “best” and shared on the Best Practice Portal. If a group of member state is interested in a particular practice, DG SANTE would assist in finding the right EU funding to support transferring this particular best practice to those member states that are interested in adopting it.

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 2018, it held the 37th edition of its Exchange Programme and participated as a speaker or contributed to the organisation of several international events.

HOPE AS A PARTNER – COMPLETED PROJECTS

ICT SERVICES FOR LIFE IMPROVEMENT FOR THE ELDERLY - ICT4LIFE

In 2018, HOPE was deeply involved in implementing ICT4Life project activities as **leader of the Work Package on Dissemination and Exploitation of project results.** The project ended in December 2018.

Financed by Horizon 2020, the EU Framework Programme for Research and Innovation, ICT4Life was a three-year project that kicked-off in Madrid on 19 January 2016 to provide new services for integrated care employing user -friendly ICT tools. The ultimate aim was to improve quality of life and autonomy at home for patients with Parkinson disease, Alzheimer and other dementias, and to support their caregivers too. To reach this goal, ICT4Life brought together nine partners representing academia, industry and end users' groups, all committed to improving patients' lives and advancing Europe leadership role in personalised services for integrated care.

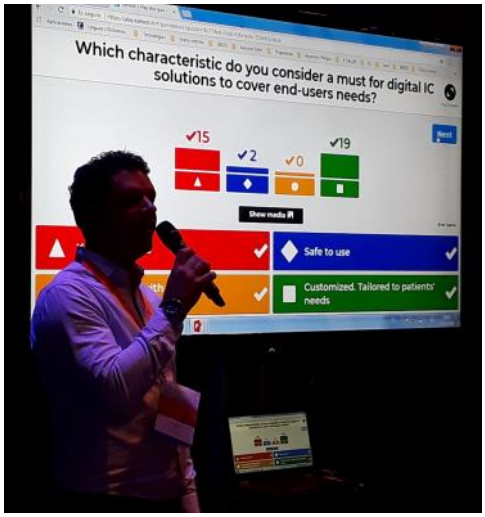
On **18 and 19 January 2018, HOPE took part in the ICT4Life Consortium meeting in Maastricht.** The meeting aimed to coordinate partners' work and review testing results to prepare for the pilot phase. During the two-day meeting, ICT4Life consortium agreed on the pilot final roadmap ahead of imminent launch of the pilots in three sites in France, Spain, and Hungary in order to test and fine-tune the technology. The pilots will consider three scenarios and will take place in a rehabilitation centre (Madrid), in three-day care centres (Madrid, Pécs and Paris) and at six patients' homes (Madrid, Pécs and Paris). At the meeting, consortium members were filmed as part of the official ICT4Life promotional video soon to be released.

ICT4Life Consortium Meeting in Maastricht

On 26 February 2018, HOPE and AGE Platform Europe organised a joint workshop entitled "Taking up the digital shift in healthcare" in Brussels**,** on market-ready innovations in eHealth in the frame of the EU-funded projects ICT4Life, FrailSafe and I-Prognosis. The workshop was kindly hosted by Occitanie Europe and moderated by Sergio Ferreira, project coordinator for Innolabs. In the eve of the Conference of Partners of the European Innovation Partnership on Active and Healthy Ageing, the workshop's topic of discussion was: What are the most promising routes to

ICT4Life Brussels eHealth Workshop

ICT4Life Consortium Meeting in Budapest



ICIC18 in Utrecht

take up the digital shift in healthcare? The three EU-funded projects showed how they are pioneering the healthcare systems of tomorrow and discussed the challenges of digitalised healthcare and how to support companies in bringing innovation to the market.

On 25 May 2018, HOPE presented ICT4Life project. A cluster of five H2020 projects -ICT4Life, Polycare, CONNECARE, ProACT and CAREGIVERSPRO-MMD- presented together a panel on "Digital health and ICT tools for the future: what's the added value for integrated care?" at the 18th International Conference on Integrated Care "Value for People and Populations: Investing in Integrated Care" in Utrecht (The Netherlands) from 23 to 25 May 2018. The event was organised by the International Foundation of Integrated Care (IFIC) in partnership with RIVM and Vilans with the support of HOPE.

ICT4Life Final Conference Brussels

On **20 and 21 June 2018, HOPE took part in the ICT4Life Consortium Meeting in Budapest, Hungary.** The event was hosted by the consortium partner Netis Informatics Ltd. ICT4Life partners shared the results of the first pilots which had been running for about three months in Spain, France and Hungary.

As leader of the project dissemination activities, **HOPE organised the ICT4Life Final Conference in Brussels on 18 October 2018.** It showed a diverse audience how the platform which has been developed responds to the needs of integrated care systems and provides tailored solutions for diverse regional contexts. A specific session presented the pilots and the strategic approach based on end-users' feedback. The event gathered experts from other EU-funded projects to discuss the challenges faced by digital health innovators when exploiting H2020 projects results on the real market.

ICT4Life Final Conference Brussels

The event was divided into three sessions each focusing on a specific aspect of the platform and its context of emergence. The first session dealt with the challenges of integrated care in the EU. The second session explored how end-users contribute to digital health innovations. In this session, three experts from Brussels -based organisations presented the perspectives of patients, carers and healthcare professional perspectives. Finally, the third session addressed how to bring the results of EU-funded initiatives into the real world.

The day before the final conference, a consortium meeting convened in Brussels with its 17 members. The main aim was to prepare the conference.

EURO-CAS

The EURO-CAS project, financed by Horizon 2020, the EU Framework Programme for Research and Innovation, **was launched in Vienna on 26 January 2017.** HOPE is involved in the project as a partner and contributes to the project's dissemination and communication activities.

The aim of the project was to foster the testing of **ICT solution interoperability against identified eHealth standards and profiles defined in the eHealth European Interoperability Framework (eEIF).** The key deliverable is a sustainable Conformity Assessment Scheme (CAS) for Europe. EURO-CAS is committed to putting in place an operational CAS based on ISO/IEC 17025 that will meet the interoperability requirements of European eHealth projects as well as national and regional eHealth programs. This will allow stakeholders to test the interoperability capabilities of products and services for a single digital market in eHealth in Europe in line with the Digital Agenda for Europe and based on international profiles and standards.

The key deliverable is a sustainable Conformity Assessment Scheme (CAS) for Europe

HOPE was a member of the EURO-CAS multidisciplinary consortium composed of organisations focused on implementing international standards, industry stakeholders and healthcare providers. The consortium will review existing interoperability CAS, collect the requirements and needs at cross border, national/regional levels, establish the CAS for Europe with implementation guidelines and governance, propose business models for the CAS for Europe, validate results and plan national/regional adoption, inform and educate eHealth stakeholders and motivate industry and projects to participate in a European accreditation process. The CAS for Europe will provide a comprehensive framework to complete the eEIF and which is aligned with the international CAS. Its flexibility will allow better sustainability and harmonisation at European, national and regional levels.

Connectathon 2018 The Hague

HOPE Chief executive spoke at the roundtable organised by EURO-CAS during the Connectathon (The Hague, The Netherlands) on 19 April 2018. Connectathon is a five-day 'connectivity marathon' for testing the interoperability of health information systems. It is a unique opportunity for vendors to test the interoperability of their products in a structured and rigorous environment with peer vendors. Attended by stakeholders of different kinds (healthcare professionals, IT specialists and vendors), the roundtable fielded the question, "The conformity assessment scheme for Europe: what is in it for me?" On 20 April the 3rd EURO-CAS validation workshop also took place in The Hague.

Connectathon 2018 The Hague

HOPE participated in the EURO-CAS Project 4th validation workshop hosted by Agence eSanté in Luxembourg on 12 September 2018. It started with a roundtable on the topic of deployment and future sustainment of CASforEU. The partners expressed how they could contribute to maintaining CASforEU after the end of the project and what could be the follow-up actions. The workshop also assessed the 8 country workshops that were organised as these offered essential participant feed for the development of CASforEU.

On **21 November 2018, the EURO-CAS Project hosted its final conference in Brussels**. There, the Conformity Assessment Scheme for Europe (CASforEU) was presented along with the next steps for its adoption across Europe and the benefits for stakeholders, including patients, healthcare professionals, vendors, procurers, healthcare providers and national/regional health authorities

EURO-CAS Final Conference Brussels

The healthcare provider perspective was presented by HOPE CEO Pascal Garel. He presented the complexity of hospitals and healthcare services as well as the disruptive forces which are changing and redefining healthcare systems. Moderated by Petra Wilson (PCHAlliance), the first session presented the user perspective on the opportunities and challenges in the care process such as obtaining the right information at the right time or the increasing number of players and components (human, devices, systems).

HOPE AS A PARTNER – ONGOING PROJECTS

MEDEYE

MedEye is an innovative medication verification suite that scans, detects, and verifies medication at the bedside

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 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.

MedEye Technology

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.

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

As a collaborating partner, HOPE was invited on 20 September 2018 to the first iPAAC stakeholder forum organised in Brussels to present the Joint Action and its Work Packages and introduce the key deliverable, i.e. the Roadmap on Implementation and Sustainability of Cancer Control Actions. 44 partners from 24 EU countries participated.

The **first session looked at "Genomics in cancer control and care** – the way forward" (Work Package 6) with an introduction by Marc Van den Bulcke, Sciensano. This work is linked to the previous joint action CANCON and the note on personalised medicines adopted by the Member states. It is developing practical guidance for member states to deal with "direct to consumer", education and training on genomics for health professionals.

The **second session was on "Innovative therapies in cancer"** (Work Package 9) presented by Muriel Dahan, French National Cancer Institute. This work package works on multiple innovations and in particular innovative immunotherapies and biomarkers associated with them dealing with the challenges associated with car-T cells. The aim is to map existing guidelines and reference frameworks, identify and validate predictive biomarkers for response, resistance or toxicity, and identify tools for real life monitoring of innovative treatments. In addition, work package 5 involves an EU-wide survey into the perception of attitudes toward prevention and screening. Work package 10 focuses on governance of integrated care and comprehensive cancer care. Its aim is to develop practical instruments.

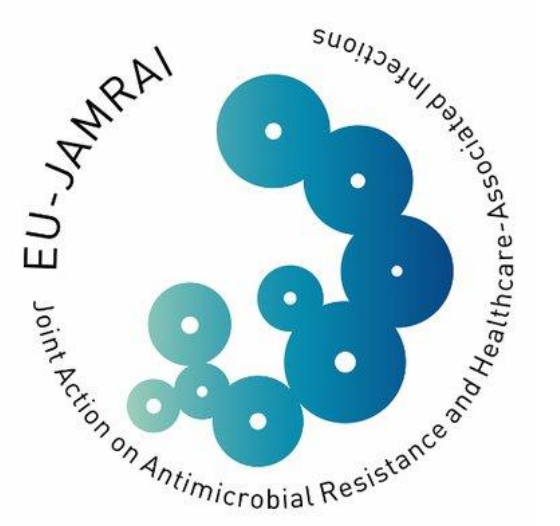
Expectations and remarks from the Commission side concluded the day. Future joint actions should show they have an impact on people. DG RTD and DG SANCO will co-manage the research activities. A steering group will prioritise new policies and then organise the transfer of good practices for the benefit of member states. There is already a best practice portal at pilot level with simple criteria than there is an evaluation. Its aim is to both inform people about best practices and transfer such practices. Work will be carried out on implementation possibilities beyond the pilots.

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 **9 November 2018 in Vienna**, European policy-makers, key international organisations, industry representatives, civil society and healthcare professionals were invited for the 1st EU-JAMRAI Stakeholders Forum to discuss the global challenges and developments in the AMR field. EU -JAMRAI first annual meeting took place on 7-8 November 2018 in Vienna, Austria.



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 (20416-2020) 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 AS AN ADVISOR

ORPHANET

HOPE is a member of the Orphanet International Advisory Board. The body provides recommendations and advises the Orphanet Management Board on the overall strategy of the project.

Orphanet is a resource gathering and improving knowledge on rare diseases so as to improve diagnosis, care and treatment. It aims to provide high-quality information on rare diseases, and ensure equal access to knowledge for all stakeholders. Orphanet also maintains the Orphanet rare disease nomenclature (ORPHAnumber), essential in improving the visibility of rare diseases in health and research information systems.

Orphanet was established in 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.

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.

JOINT PROGRAMMING INITIATIVE

HOPE was a member in 2018 of the Joint Programming Initiative "More Years, Better Lives – The Potential and Challenges of Demographic Change," a new approach to enhance coordination and collaboration between European and national research programmes related to demographic change. It was set up by a group of member states in 2010.

Areas affected by demographic change cover research fields and policy topics ranging from health to social welfare, education & learning, work & productivity to housing, urban & rural development and mobility. The JPI "More Years, Better Lives" therefore follows a transnational, multidisciplinary approach bringing together research programmes and researchers from various disciplines in order to provide solutions for the upcoming challenges and make use of the potential of societal change in Europe. Currently 15 European countries plus Canada and Israel are participating.

The aim of Joint Programming is to making better use of Europe's limited R&D funds. Joint Programming targets national public research and European programmes first and foremost.

Exchange Programme

HOPE EXCHANGE PROGRAMME – 37TH EDITION

In 2018, the HOPE Exchange Programme reached its 37th edition. It welcomed 135 healthcare professionals from 24 European countries and focused on the theme "Improving the quality of healthcare using the experiences and competencies of patients: Are we ready?".

From 3 to 5 June 2018, the Swedish Association of Local Authorities and Regions (SALAR) hosted the HOPE Agora 2018 in Stockholm. The focus was on patient involvement as a tool for improving healthcare. The participants in the HOPE exchange programme showed how the quality and efficiency of healthcare can be improved by using the experiences and competencies of patients and their relatives. Participants also examined the factors helping or hinding patient involvement in healthcare.

During the two-day conference, the 2018 HOPE Exchange Programme participants presented the main findings and lessons learned during their stay in their host country. The conference was enriched by the presence of high-level speakers, inclusing: Hans Karlsson, Director of SALAR Health and Social Care Division; Cristin Lind, Neha Sharma and Hans Lindqvist, Patient Partnership Facilitators at QRC Stockholm; Ida Björkman, Postdoctoral Fellow at University of Gothenburg Centre for Person-centred Care (GPCC); Sofie Zetterström, Deputy CEO of Inera; Sara Tunheden, Project Manager at SALAR; Åsa Steinsaphir, User Involvement Coordinator at North Stockholm Psychiatry.

HOPE Agora 2018 Conference in Stockholm

HOPE Agora 2018 World Café in Stockholm

HOPE Agora 2018 Conference in Stockholm

HOPE Agora 2018 Conference in Stockholm

Conferences

STUDY TOURS

HOPE STUDY TOUR - THE DANISH WAY IN QUALITY AND HEALTH CARE

On 10 and 11 April 2018, the Danish Regions organised in Copenhagen a HOPE Study Tour on the Danish way in quality and healthcare.

The participants learned about working methods and projects that help define and address the current challenges. Discussions took place in an open-forum format which is the heart of the HOPE Study Tours.

A large group of 37 people from 11 countries participated in the Study Tour. The packed agenda featured a brief introduction of Denmark's free and equal access healthcare system, mega trends and visions in healthcare, and visits to Rigshospitalet in Copenhagen (Rigshospitalet) and the Local Government Denmark. During these visits, delegates learned about the work undertaken on quality at local, regional and national levels. Even the dinner was with a point, as Meyers House of Food (Meyers) gave an insight into how they work with quality from farm to table.

HOPE Study Tour : The Danish way in quality and healthcare

HOPE Study Tour : The Danish way in quality and healthcare

HOPE Study Tour : The Danish way in quality and healthcare

CONFERENCES CO-ORGANISED BY HOPE

TAKE UP THE DIGITAL SHIFT: EHEALTH WORKSHOP

On 26 February 2018, HOPE and AGE Platform Europe organised a workshop on market-ready innovations in eHealth under the EU-funded projects ICT4Life, FrailSafe and I-Prognosis. The workshop was kindly hosted by Occitanie Europe and moderated by Sergio Ferreira, project coordinator for Innolabs.

On the eve of the Conference of Partners of the European Innovation Partnership on Active and Healthy Ageing, the workshop's topic of discussion was: What are the most promising routes to take up the digital shift in healthcare?

The three EU-funded projects showed how they are pioneering the healthcare systems of tomorrow and discussed the challenges of digitalised healthcare and how to support companies in bringing innovation to the market.

Mr. Sánchez-Rico de Heras , ICT4Life Project Coordinator at "Take up the digital shift " Workshop in Brussels

ANNUAL LECTURE ON "BIOMEDICAL AND HEALTH RESEARCH: DEVELOPING A VISION FOR EUROPE"

Horizon Europe, the 9th EU Framework Programme for Research and Innovation, was under discussion in 2018. To contribute to this debate, the FEAM European Biomedical Policy Forum of which HOPE is a member held an annual lecture on 21 March 2018 in Brussels (Belgium) dedicated to the topic: "Biomedical and health research: developing a vision for Europe."

The event brought together policy-makers and high -level representatives from across different biomedical sectors to present their vision for the future of biomedical and health research. Topics discussed were: thematic priorities for future research; linkage with the United Nations Sustainable Development Goals; research missions; current gaps in support; and how to improve coordination and consolidation of research programmes across Europe.

FEAM Forum 2018

9TH EUROPEAN CONFERENCE ON RARE DISEASES & ORPHAN PRODUCTS (ECRD) 2018

The 9th edition of the European Conference on Rare Diseases & Orphan Products (ECRD) took place from 10 to 12 May in Vienna, Austria. HOPE was an official partner of this event -the largest multi-stakeholder rare disease gathering in Europe in 2018, organised by EURORDIS-Rare Diseases Europe, a non-profit alliance of over 700 rare disease patient organisations from more than 60 countries, and co-organised by Orphanet and the DIA.

ECRD - the European Conference on Rare Diseases & Orphan Products 2018

18TH INTERNATIONAL CONFERENCE ON INTEGRATED CARE

HOPE took part in the 18th International Conference on Integrated Care "Value for People and Populations: Investing in Integrated Care" in Utrecht (The Netherlands) from 23 to 25 May 2018. The event was organised by the International Foundation of Integrated Care (IFIC) in partnership with RIVM and Vilans with the support of HOPE. On 25 May 2018, HOPE presented ICT4Life project. A cluster of five H2020 projects - ICT4Life, Polycare, CONNECARE, ProACT and CAREGIVERSPRO-MMD- presented together a panel on "Digital health and ICT tools for the future: what's the added value for integrated care?".

Isabella Notarangelo presenting ICT4Life at ICIC18

26TH INTERNATIONAL CONFERENCE ON HEALTH PROMOTING HOSPITALS AND HEALTH SERVICES

The annual International Conference on Health Promoting hospitals and Health Services (HPH) is a forum on health promotion in and by health services for health practitioners, consultants, scientists and politicians. The 2018 edition was held in Bologna (Italy) from 6 to 8 June 2018 and focused on "Health promotion strategies to achieve change: evidence-based policies and practices". HOPE is member of the HPH Conference Scientific Committee and co-organised the event.

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

On 27 September 2018, 20 EU-level health organisations, including HOPE, joined forces to highlight the implications of Brexit for healthcare across the continent and organised the event 'Prioritising patient safety and public health across Europe post-Brexit' at the European Parliament.

'Prioritising patient safety and public health across Europe post-Brexit' at the European Parliament

ICT4LIFE FINAL CONFERENCE: MEETING THE CHALLENGES OF DIGITAL HEALTH INNOVATION FOR INTEGRATED CARE IN THE EU

HOPE organised ICT4Life Final Conference in Brussels on 18 October 2018. It showed a diverse audience how the platform which has been developed responds to needs of integrated care systems and provides tailored solutions for diverse regional contexts. A specific session presented the pilots and the strategic approach based on end-users' feedback. The event gathered experts from other EU-funded projects to discuss the challenges faced by digital health innovators when exploiting H2020 projects results on real market .

HOPE CEO Pascal Garel speaking at ICT4Life Final Conference

The event was divided in three different sessions each focusing on a specific aspect of the platform and its context of emergence. The first session dealt with the challenges of integrated care in the EU and addressed issues like the new roles and skills for healthcare professionals, the specific needs linked with integrated care for brain disorders in Europe and the H2020 EU-funded projects response to these challenges. The second session explored how end-users contribute to digital health innovations. In this session, three experts from Brussels-based organisations presented respectively the patients, the carers and the healthcare professional perspectives and three ICT4Life partners showed how ICT4Life could answer to the very needs of these actors.

Morning session at ICT4Life Final Conference

Finally, the third session addressed how to bring EU funded initiatives results into the real world and started with a presentation of ICT4Life Fieldwork and how it developed tailored solutions in diverse regional contexts. A presentation was then given about ICT4Life exploitation and the development of a strategic approach based on iterative testing and end users' feedback. Lastly, the conference addressed the exploitation challenges of H2020 project results from an SME perspective.

Afternoon session at ICT4Life Final Conference

The day before the final conference, a consortium meeting convened in Brussels with its 17 members. The main aim was to prepare the conference.

Coffee break at ICT4Life Final Conference

VACCINATION CHALLENGES AND EU COOPERATION. WHAT IS THE WAY FORWARD? - FEAM WORKSHOP

On 19 November 2018 in Brussels, HOPE co-organised a workshop on "Vaccination challenges and EU cooperation. What is the way forward?" as part of the Federation of European Academies of Medicine (FEAM) forum.

Hosted by Jean-Michel Foidart, Perpetual secretary, Belgian Royal Academy of Medicine (ARMB) the workshop started by the question "How can European countries improve vaccination in the wake of the measles outbreak?" providing views from academia: George Griffin, President, Federation of European Academies of Medicine (FEAM), Jos van der Meer, past President, European Academies' Science Advisory Council (EASAC)

How can vaccination levels be improved through better public dialogue? was the first session with impulse presentations by: Mike Catchpole, Chief Scientist, European Centre for Disease Prevention and Control (ECDC) who spoke about the trend from deferential to referential societies; Siff Malue Nielsen, Communications Consultant, WHO Regional Office for Europe who presented the Tailoring Harmonised Programmes; Heidi Larson, Professor of Anthropology, Risk and Decision Science, London School of Hygiene and Tropical Medicine who presented the Vaccination confidence survey; Paolo Villari, Professor, Department of Public Health and Infectious Diseases of Sapienza University of Rome, Representing the Institute Pasteur of Italy who spoke about the consequences of austerity on vaccinations.

Workshop on "Vaccination challenges and EU cooperation. What is the way forward?"

The second session was on "Vaccination and EU policies: How to strengthen cooperation at EU level?" with impulse presentations by: Martin Seychell, Deputy Director General for Health, European Commission, DG SANTE; Heike Galbraith, External Affairs Working Group Chair, Vaccines Europe; Geneviève Chêne, Coordinator of the EU Joint Action on Vaccination (INSERM) and Mariano Votta, Director, Active Citizenship Network.

The concluding remarks were delivered by Pierre Coulie, Member of the Belgian Royal Academy of Medicine (ARMB).

EURO-CAS FINAL CONFERENCE

On 21 November 2018, the EURO-CAS Project hosted its final conference in Brussels. During the conference, the Conformity Assessment Scheme for Europe (CASforEU) was presented along with the next steps for its adoption and implementation across Europe and the benefits for stakeholders, including patients, healthcare professionals, vendors, procurers, healthcare providers and national/ regional health authorities.

HOPE CEO Pascal Garel speaking at EUROCAS Final Conference

7TH INTERNATIONAL CONGRESS OF HOSPITALS – CITIZEN INVOLVEMENT AND ACCOUNTABILITY IN THE NATIONAL HEALTH SERVICE

APDH organised the 7th International Congress of Hospitals – "Citizen Involvement and accountability in the National Health Service", from 21 to 23 November in Lisbon, Portugal.

The Portuguese Association for Hospital Development (APDH) is a non-profit association, and it has collective (hospitals) and individual members from all over the country. As the representative of HOPE and IHF (International Hospital Federation) in Portugal, its basic goals are to encourage cooperation between the Portuguese hospital institutions and the foreign ones, in order to promote and develop innovation in the hospital management sector.

HOPE President Eva M. Weinreich-Jensen presenting at 7th International Congress of Hospitals

CONDUCTING CHANGE IN PSYCHIATRY AND MENTAL HEALTH

The ADESM (French Association of Mental Health Institutions) organised from 21 to 23 November 2018 in Marseille (France) a conference "Conducting Change in Psychiatry and Mental Health" with the support of HOPE.

As health systems in European countries have to deal with converging trends in different ways and at different speeds, the congress looked closely at this phenomenon and its causes and influence. It also examined disruptive scientific progress and medical knowledge in psychiatry and the larger field of neuroscience.

Conference "Conducting Change in Psychiatry and Mental Health"

SOME CONFERENCES WITH HOPE AS A SPEAKER

EUROPEAN REFERENCE NETWORKS

HOPE was invited to speak on 27 February 2018 in the European Parliament during the meeting of the European Parliament interest group on European Patients' Right and Cross-Border Healthcare. Chaired by Stephen McMahon, President of the Irish Patients' Associations, the group was welcomed by MEP Patrizia Toia (Italy).

The concept of European Reference Networks was presented by the European Commission Cross-Border Healthcare & eHealth Unit and illustrated by Maurizio Scarpa, Coordinator European Reference Network for Hereditary Metabolic Diseases (MetabERN) and Luca Sangiorgi, Coordinator, European Reference Network on Rare Bone Diseases (ERN BOND). An example of how patients contribute to ERN was provided by Beatrice De Schepper of the European Huntington Association, as a patient representative in the ERN RND (Rare Neurological Diseases).

HOPE CEO Pascal Garel, reported on HOPE's work in setting up the first seminar for chief executives of hospital leaders and ENR partners.

EURO-CAS ROUNDTABLE AT CONNECTATHON

HOPE CEO spoke at the round table organised by EURO-CAS (during the Connectathon (The Hague, The Netherlands) on 19 April 2018. Connectathon is a five-day 'connectivity marathon' for testing the interoperability of health information systems. It is a unique opportunity for vendors to test the interoperability of their products in a structured and rigorous environment with peer vendors.

Attended by stakeholders of different kinds (healthcare professionals, IT specialists and vendors), the roundtable fielded the question "The conformity assessment scheme for Europe: what is in it for me?".

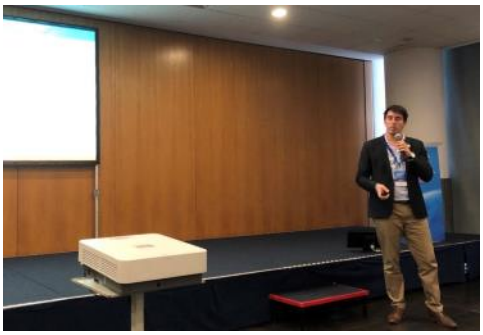
PERSONALISED MEDICINE – HOPE SESSION - EUROPEAN ASSOCIATION OF HOSPITAL MANAGERS CONGRESS

On 27 September 2018, in Estoril (Portugal) during the 27th European Association of Hospital Managers Congress, HOPE organised a session "Precise medicine for better patient outcomes", chaired by HOPE President, Eva M. Weinreich-Jensen with speakers from Denmark (Erik Jylling), Estonia (Andres Metspalu), Belgium (Pascal Verdonck) and France (Guillaume Mercy).

Eva M. Weinreich-Jensen introduced the speakers and explained that the session was wanted to bring forth four different perspectives on the topic of precision medicine: regions, hospital federations, managers, and researchers. To shine a light on the various ways that precise medicine affects how we work and what we need to do to make the most of the new possibilities, in order to make the newest possibilities available to our patients.

EAHM 27th Congress

HOPE session "Precise medicine for better patient outcomes" at EAHM Congress



HOPE session "Precise medicine for better patient outcomes" at EAHM Congress

There are many considerations for delivering precise personalised medicine/ healthcare: a healthcare system infrastructure (governance), a technology infrastructure (electronic patient record, information systems), a legislative framework (GDPR, Data-ownership), patient consent, patient empowerment (self -management, wearables...), and a digital health strategy. This includes initiatives like: The Virtual Doctor, digital tools for rehabilitation, better citizen control and overview over health data, Digital Pregnancy Journal, digital workflows between different health sector professionals, continuous work on home monitoring, data security and IT, infrastructure optimisation and so on. It needs an infrastructure for personal health and new legislation concerning (among others) genomics data and citizen consent concerning the use of health data.

So, in short, the big picture is that the vast new variety of data and information available – with some of this coming directly from patients' wearables – means that we have a much higher possibility of treating the patients individually. If we – as hospitals - manage to catch the information, work closely with the patients and consider their input valuable, we can get better results. But as simple as it sounds it will challenge the way we usually have been thinking of healthcare and how to deliver it.

Summing the conference up: we need to think healthcare and the role of hospitals in a new way, if we want to take advantage of the possibilities precise medicine offers. Even if citizens are ready to share the data, we must be ready to get their consent, opinion and have the infrastructure ready to manage the huge amount of data that are possibly accessible, not just for patient treatments but for research purposes, too. And that we take both hospital managers, hospital staff, hospital federations, patients, citizens and many more to succeed with that.

CROSS-BORDER HEALTHCARE DIRECTIVE - EPP GROUP HEARING

HOPE CEO was invited by Ivo Belet MEP (Vice-coordinator of the EPP Group in ENVI Committee of the EP and the EPP Group rapporteur on the Cross-border Healthcare Directive) to speak on 17 October 2018 in a European Parliament hearing on the implementation report on the quality of care and patient safety under the cross-border healthcare directive. The report looks at the current shortcomings in the implementation of the Cross-Border Healthcare Directive and makes recommendations for the improvement of the directive.

This was an opportunity for Pascal Garel, Chief Executive of the European Hospital and Healthcare Federation to present the history of HOPE involvement in and its views on the cross-border care. He went back on the different kind of flows, the continuity of care and the wrong assumptions about the cross-border directive. With regards to digitalization, he mentioned the position paper adopted by HOPE in June 2018 and concluded with the three digital projects in which HOPE is involved: EURO-CAS, MedEye and ICT4life.

HOPE CEO Pascal Garel

EUROPEAN CONGRESS ON PERSONALISED MEDICINE MILAN 2018

HOPE contributed to the 2nd European Alliance for Personalised Medicine Congress which took place from 26 to 28 November 2018 in Milan (Italy).

This event covered a wide range of issues such as lung-cancer screening, prostate cancer, diabetes and pancreatic cancer but also the role of the European Union regions. Hospital chief executive officers debated personalised medicine development down the line.

In some areas, the EU has had a strongly supportive role in healthcare. The resulting coordination to develop science, translate innovation, systemise marketing authorisation requirements for medicines and facilitate quality testing and trials has shown a positive aspect of the EU and should serve as inspiration and encouragement for more joined-up approaches to tackle new challenges.

The main conclusion is that a key component will be an understanding of the potential for personalised medicine to deliver improved outcomes for European citizens, the challenges that it presents to traditional health systems and the barriers that currently exist. Infrastructure and tools also need to be set up for personalised medicine-enhanced healthcare. This would help generate new diagnostic, therapeutic and preventive approaches from scientific research. It is essential to cooperate and avoid silo-thinking.

HOPE President Eva Weinreich-Jensen was among the panellists of the Presidential Session 'Interfacing with Public Policy Makers' that gave attendees the viewpoint that the innovative quality of personalised care demands links to other areas of innovation. "To make the most of personalised medicine, which means to get it to the patients fast, the laws must be clear and modernized, so everybody knows what can and cannot be done. And we need to get a lot of information out to patients, citizens and our staff in order for them to understand what it is all about, what are the options, what are the dilemmas" said Eva Weinreich-Jensen.

Radical changes in thinking at the highest policy level, in relation to public health generally, will enhance the measurement of value for health interventions and adapt payment systems accordingly. All of this will require agreement on standards, and improvements to regulatory pathways, as well as an appropriate regulatory and medical framework.

Chapter 4

PUBLICATIONS

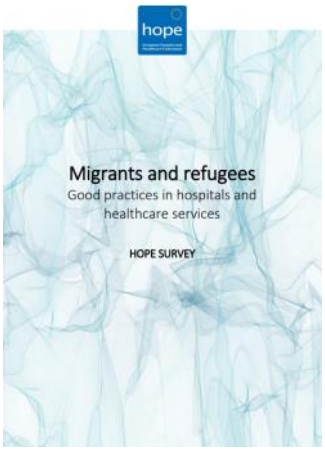
In 2018, HOPE published four main Reports on the following topics: Migrants and refugees' health, capital investments and grouping in the healthcare sector.

HOPE also released the report "Improving the quality of healthcare using the competencies and experiences of patients. Are we ready?" (HOPE Agora Report 2018).

HOPE adopted four position papers, on e-health, e-Privacy, health technology assessment (HTA), and on transparent and predictable working conditions. Four strategic notes were conducted as well: on Brexit, on the EU enlargement, on falsified medicines and on positions of stakeholders on HTA.

Publications

MIGRANTS AND REFUGEES: GOOD PRACTICES IN HOSPITALS AND HEALTHCARE SERVICES



In March 2018, HOPE released a publication on "Migrants and refugees: Good practices in hospitals and healthcare services". Taking into account different projects launched by the European Union or the WHO (World Health Organisation), the report seeks to identify the good practices and innovations that have emerged in the field of migrants' and refugees' health in the European Union.

The increasing mobility and diversity of the population strongly affect healthcare services and hospitals: people on the move face greater health risks, suffer from conditions not commonly found in Europe and have different expectations about health services. Access to adequate healthcare is further complicated by language barriers and migrants often being socially disadvantaged. Although health services are used to accommodating cultural diversity, European hospitals are facing new challenges. HOPE and its members have been discussing this topic for many years. In the recent context of intensified migratory pressure on some EU countries, it seemed essential to collaborate and share good practices and knowledge relating to the specific health needs of migrants. The HOPE Board of Governors has recently urged members to review and list good practices. The publication is the result of this work.

GROUPINGS IN THE HEALTHCARE SECTOR

In April 2018, HOPE released a publication on "Grouping in the healthcare sector" which aims to analyse different types of grouping: hospital grouping, network of professionals, network of healthcare and social care institutions and public institutions providing services to healthcare institutions.

With the growing pressure to deliver higher quality of care at lower cost, while reducing clinical activity levels in hospitals, European countries are testing and using various methods. Hospital and healthcare groupings are one of them. They could aim at reducing operation expenses, increasing revenue or re-configuring service delivery. Quality improvement and acquisition of new skills and technologies are also rationales that have led to the hospital and healthcare groupings. HOPE has been collecting the information available on this complex topic with its members. This report provides a summary of the most recent information available about groupings in the healthcare sector in Europe.

CAPITAL INVESTMENT IN HOSPITALS AND HEALTHCARE SERVICES

In July 2018, HOPE released a publication on "Capital investment in hospitals and healthcare services".

The 2007 financial and economic crisis has affected the European healthcare systems in various ways. In HOPE's report entitled "The Crisis, Hospitals and Healthcare" published in April 2011, several HOPE members mentioned investment being postponed or even abandoned. More recently the report by the High-Level Task Force on Investing in Social Infrastructure in Europe mentioned a huge investment gap in healthcare.

The database "A System of Health Account 2011" (SHA) provides information on investment through the Gross Fixed Capital Formation. This is presented in the first part of this report.

But to get a better picture, HOPE decided to collect existing information and to complement it by producing a questionnaire to collect not only figures but also information about capital investment procedures in hospital and healthcare services. The answers presented in the second part of the report were provided by HOPE Liaison Officers and their colleagues.

HOPE AGORA REPORT 2018: IMPROVING THE QUALITY OF HEALTHCARE USING THE COMPETENCIES AND EXPERIENCES OF PATIENTS. ARE WE READY?

In October 2018, HOPE released a publication on "Improving the quality of healthcare using the competencies and experiences of patients. Are we ready?."

The HOPE Agora 2018 took place in Stockholm on 3-5 June 2018. It was hosted by the Swedish Association of Local Authorities and Regions (SALAR) and focused on the "Improving the quality of healthcare using the competencies and experiences of patients. Are we ready?" and more specifically on patient involvement as a tool for improving healthcare.

The Agora concluded the 37th edition of the HOPE Exchange Programme. This edition welcomed more than 140 health professionals from 22 European countries. During the Agora, HOPE Exchange participants reported on their 4-week stay abroad. For their presentations, they showed how the quality and efficiency of healthcare can be improved by using the experiences and competencies of patients and their relatives. They also looked at the factors helping or hindering patient involvement in healthcare. They were asked to identify examples within their host country's healthcare system that are inspiring for meeting the challenges they face at home. There were numerous initiatives in a range of settings to be discovered, providing significant scope for knowledge transfer.

POSITION PAPERS

HOPE POSITION PAPER ON THE PROPOSAL FOR A REGULATION ON HEALTH TECHNOLOGY ASSESSMENT

On 31 January 2018, the European Commission proposed a regulation COM (2018) 51 on health technology assessment (HTA) and amending Directive 2011/24/EU. HOPE participated in the preparatory public consultation and has been active as a stakeholder in the EUnetHTA three successive joint actions. HOPE welcomes the fundamental concern of the EU Commission to promote cooperation between the member states in the field of health technology assessment.

In June 2018 HOPE adopted a Position Paper on the proposal for a regulation on Health Technology Assessment. By increasing scientific exchanges and improving research transparency, significant synergies can be achieved, including the avoidance of unnecessary duplication and waste of resources. HOPE attaches particular importance to sustainability for high-quality patient care, which also includes safe access to new technologies. In this respect, HOPE welcomes the proposal's objectives. However, as there is no consensus among HOPE members on these mandatory assessments, HOPE refrains from having an opinion on this aspect. HOPE welcomes the separation made in the proposal between the clinical assessment at EU level and the non-clinical assessment at the national level, insofar as the member states wish to carry out further examination in their respective healthcare systems.

HOPE POSITION PAPER ON THE PROPOSAL FOR A DIRECTIVE ON TRANSPARENT AND PREDICTABLE WORKING CONDITIONS IN THE EUROPEAN UNION

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). To summarise, the proposal for a Directive suggests minimum rights to apply to working conditions for all employees regardless of the form of employment.

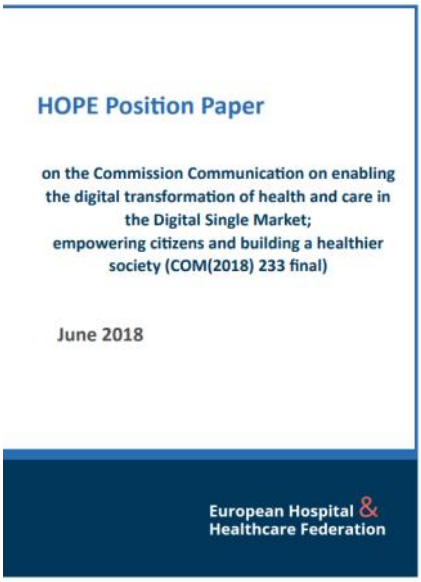
In June 2018, HOPE adopted a Position Paper on the proposal for a directive on transparent and predictable working conditions in the European Union.

In particular, HOPE finds it inappropriate to introduce minimum rights which would apply to working conditions for all employees regardless of the form of employment.

HOPE POSITION PAPER ON THE COMMISSION COMMUNICATION ON EHEALTH

On 25 April 2018, the European Commission published a Communication to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society (COM(2018) 233 final).

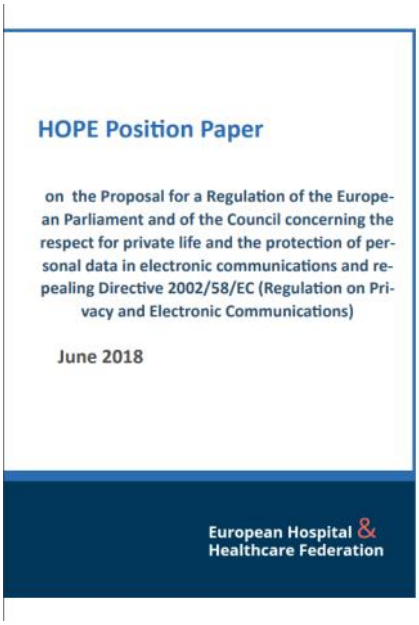
- In June 2018 HOPE adopted a Position Paper on the Commission Communication on eHealth welcoming this Communication but asked to further clarify several elements:
- HOPE agrees that Europe's health and care systems face serious challenges: ageing, multimorbidity, health (and social) workforce shortages, 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 recognized instead of being ignored with a one-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 the goal. The aim of hospital and healthcare services is to provide high-quality care and cure, not to help setting 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 with 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 matters first.



HOPE POSITION PAPER ON E-PRIVACY

On 10 January 2017, the European Commission adopted a proposal for a Regulation of the European Parliament and of the Council concerning the respect for private life and the protection of personal data in electronic communications and repealing Directive 2002/58/EC (Regulation on Privacy and Electronic Communications) COM(2017) 10 final in order to provide a high level of privacy protection for users of electronic communications services and a level playing field for all market players.

The proposal reviews the ePrivacy Directive, set out in the DSM Strategy objectives and ensuring consistency with the GDPR. The ePrivacy Directive had been designed to ensure the protection of fundamental rights and freedoms, in particular the respect for private life, confidentiality of communications and the protection of personal data in the electronic communications sector. It should also guarantee the free movement of electronic communications data, equipment and services in the European Union. It should implement in the EU secondary law the fundamental right to the respect for private life, with regard to communications, as enshrined in Article 7 of the Charter of Fundamental Rights of the European Union ("Charter").



In June 2018 HOPE adopted a Position Paper on e-Privacy and welcomes this initiative while identifying several issues related to healthcare:

- Public networks will need to comply with the new legislation;
- Healthcare providers contacting 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 Article 13 mentions ‘when a phone call is made’ but what if no call is made, but the emergency services may be able to track GPS data on a phone to locate an unconscious person, for example.
- Art 13 is about restrictions, the European Commission text was quite helpful as it echoes article 23 (1)(a)-(e) of the GDPR. The most useful exemption from a public health perspective is Art 13 1 (e) The European Parliament has changed this Article in a way that it is now not very clear, but they seem to have taken away the scope to restrict provisions of Art 5-8 of the ePrivacy legislation for public health and social security reasons. This seems good from our perspective to keep this in as we may need to access some metadata (ie location data) from public electronic communications in order to see peak times and locations of A&E services, so we can plan for A&E services etc.

ANALYSES - HOPE STRATEGIC NOTES

FALSIFIED MEDICINES DIRECTIVE AND HEALTHCARE INSTITUTIONS PACKAGE – HOPE STRATEGIC NOTE

In October 2018, HOPE released a Strategic note for its members entitled "Falsified Medicines Directive and Healthcare Institutions Package". In order to secure the legal supply chain of medicinal products, the Falsified Medicines Directive 2011/62/EU and the Commission Delegated Regulation (EU) 2016/161 have introduced a new end-to-end verification system for medicinal products subject to prescription. This includes mandatory safety features and a repository that stores information on each individual pack.

POSITIONS OF EU STAKEHOLDERS ON HEALTH TECHNOLOGY ASSESSMENT– HOPE STRATEGIC NOTE

In September 2018, HOPE released a Strategic note for its members on the Positions of EU stakeholders on Health Technology Assessment. It relates to the scope of the regulation, the mandatory or voluntary cooperation and opinions on the ENVI Committee draft report released on 4 May 2017.

EU ENLARGEMENT – STATUS OF THE WESTERN BALKANS COUNTRIES – HOPE STRATEGIC NOTE

In September 2018 HOPE released a Strategic note for its members on EU Enlargement and the status of the Western Balkans countries (Albania, Bosnia and Herzegovina, Kosovo, Macedonia, Montenegro and Serbia).

WHAT COULD BREXIT MEAN FOR HOSPITALS ACROSS EUROPE? – HOPE STRATEGIC NOTE

In April 2018 HOPE released a Strategic note for its members entitled "What could BREXIT mean for hospitals across Europe?". HOPE has been working with a group of European health organisations (patients, healthcare professionals, researchers and industry) to ensure that issues relating to public health and patient safety are highlighted during the negotiation process, and that both parties recognise the issues at stake for patients. Brexit has a potential impact on European hospitals.

General Report on the Activities of the European Hospital and Healthcare Federation 2018

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European Hospital and Healthcare Federation