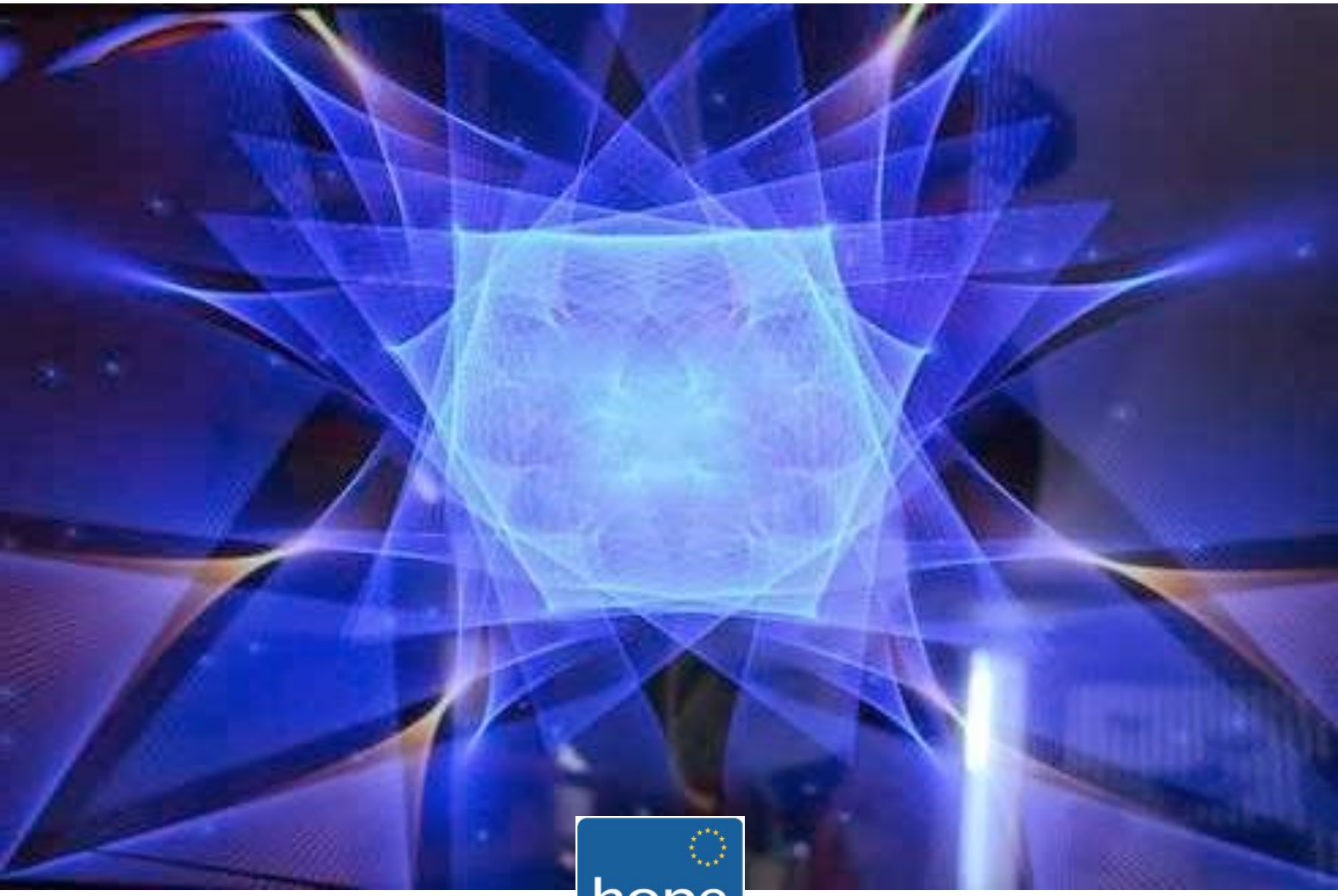
General Report

on the Activities of the

European Hospital and Healthcare Federation

2017



hope

European Hospital and Healthcare Federation

Photo credit:

Cover and chapter illustrations: © Art dans la Cité

ILLUMINART is an intereactive and innovative device proposed by Art dans la Cité.
It allows the projection of artworks in hospitals to improve patients' well-being.
Patients can choose and interact with the content projected.

Front page: Light composition by Santiago Torres
Illustration Chapter 1: Le poulpe
Illustration Chapter 2: Exhibition at HPI Athens
Illustration Chapter 3: The animated movie, Virtual Aquarium
Illustration Chapter 4: Atelier couleur 5 (web)
Back page: Exhibition at HPI Athens(2)

Images and vectors in this publication are either free for use or created by Freepik.com and Pixabay.com.

General Report on the Activities of the European Hospital and Healthcare Federation — 2017

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

General Report

on the Activities of the

European Hospital and Healthcare Federation

2017

Contents

Chapter 3

Chapter 4

Introduction

The year 2017 marked an intense period of negotiation in European politics, articulated around the so-called Brexit decision. The remaining 27 EU Member States have now agreed to move to phase II of the negotiations, despite the uncertainty on the future of the European Union and its integration process. In this new phase, major implications on the NHS and on health and social care workers both in the UK are at stake.

Last year was also a year of change in European health-related policies. While much legislation of interest to HOPE was adopted (e.g. Regulations on medical devices, data protection and falsified medicines), several new initiatives gained momentum on the European political agenda. HOPE closely monitored developments and joined discussions around several topics, such as the Falsified Medicines Directive, Digitalization, the prudent use of antibiotics in healthcare settings, Health Technology Assessment, and the European Pillar of Social Rights, to name but a few. The 2017 HOPE Agora focused on the theme "Organisational innovation in hospitals and healthcare" and closed the 36th edition of the HOPE Exchange Programme for healthcare professionals.

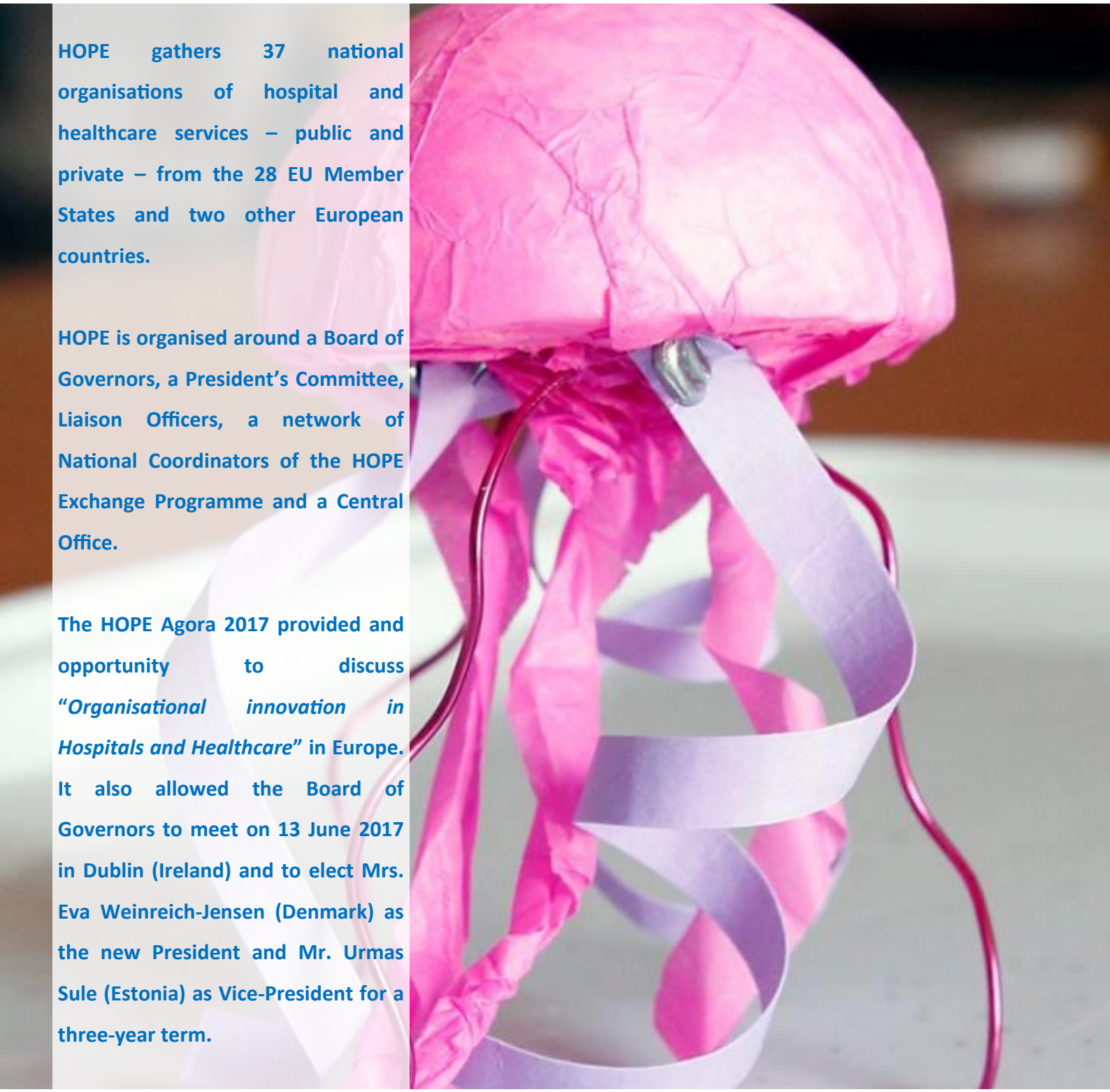
In 2017, HOPE was active in contributing to the EU non-legislative agenda, mainly through several European projects. The eStandards project was successfully completed and held its final conference in Brussels on 26 and 27 June. Moreover, two projects that had started in 2016 further developed in 2017 their activities with HOPE as a partner – ICT4Life and EURO-CAS. Early 2017, the MedEye proposal kicked-off.

Consistent with HOPE mission to facilitate cross-border exchange of good practices among its members, HOPE participated as a speaker or helped organise several international events.

Finally, as every year, HOPE published its official Reference Book "Hospital Healthcare Europe" and published the main outcomes of the HOPE Exchange Programme in the HOPE Agora Report 2017. The Board in Governors meeting in Dublin adopted its vision of the future, a comprehensive document that covers all the challenges hospitals and healthcare services are facing today and will in the future.

Chapter 1

LIFE AND GOVERNANCE



HOPE gathers 37 national organisations of 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 2017 provided and opportunity to discuss "*Organisational innovation in Hospitals and Healthcare*" in Europe. It also allowed the Board of Governors to meet on 13 June 2017 in Dublin (Ireland) and to elect Mrs. Eva Weinreich-Jensen (Denmark) as the new President and Mr. Urmas Sule (Estonia) as Vice-President for a three-year term.

Governance

HOPE gathers 37 national organisations of hospital and healthcare services — public and 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 2017: on 13 June in Dublin (Ireland) as part of the HOPE Agora 2017, and on 15 November in Düsseldorf (Germany). In Dublin, Mrs. Eva Weinreich-Jensen (Denmark) was elected for a three-year term as the new President. The Vice-President is Mr. Urmas Sule, the Estonian Governor, elected as well for a three-year term.

In Dublin, the following Governors were nominated: for the United Kingdom, Mr. Niall Dickson; for Spain, Mrs. Sara Pupato Ferrari. The Board of Governors accepted in Düsseldorf three new Governors: for Bulgaria, Mr. Krasimir Grudev; for France, Mrs. Zaynab Riet; for The Netherlands, Mr. Sander Gerritsen.

The President's Committee (PsC) consists of the President, the Vice-President and three Governors: the two former President 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, co-ordinates the work of the Liaison Officers, acts in the name of HOPE, and authorises legal representation. The PsC met on 11 May in Brussels and on 9 October in Brussels to discuss the Board of Governors' agenda and the meetings of the Liaison Officers, and to decide on the organisation's priority activities.

Governance

The network of Liaison Officers was created to enhance activities and the delivery of objectives. In 2017, HOPE Liaison Officers meetings took place twice: on 26 April in Brussels and on 23 November in Cyprus. 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 Dublin during the Agora and on 24 November in Cyprus.

Located in Brussels, Belgium, the Central Office is organised and run by the Chief Executive, Mr. Pascal Garel with as Health Economist, Ms. Isabella Notarangelo and Ms. Laurie Andrieu, EU Policies and communication Officer, replacing Ms. Valentina Lisi who worked until December 2017. HOPE also welcomed an EU-Policies Intern: Ms. Mathilde Gabriel. It also received and met several delegations.

HOPE Board of Governors in Dublin (Ireland) on 13 June 2017

From right to left : Mr. Pascal GAREL (HOPE Chief Executive), Mrs. Eva M. WEINREICH-JENSEN (HOPE President – Denmark), Mrs. Dr. Sara C. PUPATO FERRARI (former HOPE President 2014-2017 – Spain), Mr. Urmas SULE (HOPE Vice-President – Estonia).

GOVERNANCE AT THE END OF 2017

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	Ružica Palic Kramaric
Cyprus	Dr. 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 2017, 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, 2017 provided an opportunity to engage in several new initiatives that gained momentum on the European political agenda.

Hard Law

Hard law refers to laws that take precedence over national law and are binding on national authorities. This consists of EU Regulations, Directives and Decisions.

HOPE intervenes at three different stages in the decision-making process: when the first discussions take place, when a proposal is adopted by the Commission, and finally when the legislation is adopted and enters the transposition process. This means different types of involvement for HOPE Central Office and HOPE Members.

In 2017, several key health policies which were closely followed by HOPE over the past years reached the end of their political and/or legislative process. Among others, the medical devices regulations and the cybersecurity package. Some other pieces of legislation had been adopted in previous years but were also on the agenda the Delegated act on the safety features appearing on the packaging of medicinal products for human use, the public procurement directive, the general data protection regulation, the clinical trial directive and the blood, tissues and cells directives.

However, new legislative procedures have started and several initiatives have been put on the political agenda on topics of interest to HOPE, such as Health Technology Assessment, and the European Pillar of Social Rights. 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

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 are 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.

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 have been largely welcomed by stakeholders and the public. Increased safeguards against counterfeit devices and traceability will be guaranteed 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 document summarising the main provisions of the coming legislation, with emphasis on the changes that will extensively influence hospital activities.

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

On 6 September 2017, HOPE took part to the meeting of the Medical Devices Expert Group (MDEG) to discuss the International Medical Devices Regulators Forum (IMDRF) activities. The International Medical Device Regulators Forum (IMDRF) was conceived in February 2011 as a forum to discuss future directions in medical device regulatory harmonization. This meeting was the opportunity to discuss the new work items and developments of IMDRF, like how to improve the quality of international medical device standards for regulatory use or Medical Device Adverse Event Terminology.

On 18 October 2017, the second Competent Authorities for Medical Devices (CAMD)/Commission Stakeholder meeting took place in Brussels to which HOPE participated. The European Commission and the CAMD provided an opening address highlighting that this second Stakeholder meeting closes phase 1 of the preparations for the implementation of the Regulation. Phase 1 has been useful in identifying the major priorities to overcome in the coming days, months and years, with some of these activities having been already started. The European Commission and the CAMD want to work together with stakeholders to share responsibilities in view to deal effectively with the challenges and issues ahead.






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.

FALSIFIED MEDICINES

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 put the Commission under the obligation to adopt delegated acts regarding various aspects of the safety features for medicinal products for human use.

HOPE followed closely the drafting of the delegated act, with particular attention on how the medicines verification system at the point of dispending 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 considers HOPE position 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 a smooth implementation of the Regulation in European hospitals.

A meeting was hold on 26 September 2017 between HOPE and the European Association of Hospital Pharmacists (EAHP), which results were later presented on 25 October EMVO Board meeting. The meeting allowed to precise the aim of the EMVO Hospital Platform which is to act as a think tank in order to elaborate an EMVO action plan/strategy for the hospital integration. Some main issues concerning hospital integration were identified as well as actions to put in place. The method was further designed and especially the list of PMMR 2.0 “hospital” indicators as well as the cooperation of HOPE and EAHP Brussels offices to work on a strategy for the integration of hospital expertise in NMVOs. The governance was designed as follow: The Hospital Platform acts within the framework of EMVO. Meetings of the Hospital Platform are thus open to both EMVO Stakeholders and members of HOPE and EAHP. HOPE/EAHP Brussels offices run the secretariat activities of the platform.

HOPE took part to the Conference "Safer Europe without falsified medicine" in Tallinn on 8-9 November 2017.

During the conference it was agreed by most of the speakers that all stakeholders should act and cooperate together to run the new system after 14 months. It was pointed out that this is a Pan-European project and strong involvement and cooperation of all supply chain stakeholders on European and national level is needed.

The biggest challenge to the stakeholders is to connect approximately 2 500 manufacturing companies to the European Medicines Verification System (EMVS), establish national systems in 32 countries, connect many thousands of pharmacies and wholesalers and serialise all appropriate pharmaceutical packs.

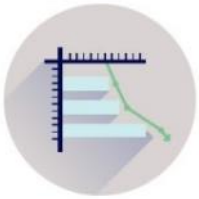
Different stakeholders brought out their main challenges. Community pharmacies have to upgrade the pharmacy software and products libraries, new scanners and procedures are needed along with training of the pharmacy employees. Continuous cooperation of supply chain partners and the National Competent Authorities is needed. Wholesalers pointed out that the consolidated data on wholesalers distribution authorization holders is lacking in EU and it is difficult to find out which organisations have to be connected to the repository system. Manufacturers of medicinal products and other stakeholders would welcome a joint response from European Commission and the NCAs on the various coding and labelling issues which should be solved as soon as possible to allow serialisation activities. HOPE strongly advocated that hospitals should be involved in the NMVOs, both for the contractual and technical on-boarding. The awareness of hospitals about the safety feature project was unfortunately still somewhat limited, communication strategies should be defined that have to include the NMVOs and the NCAs.

The best practices of the Member States on issues and solutions should be shared. NCAs have to play their role by raising awareness and supporting the implementation process. The coding requirements and regulatory pathways to implement the safety features should be in place in all Member States as soon as possible. Alignment across countries has to be achieved.

PUBLIC PROCUREMENT

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

HOPE was then invited to the multi-stakeholders' meeting on pharmaceuticals organised by the European Commission Directorate General (DG) GROW on 12 September 2017. The first item presented was on the EU procurement legislation in the health sector. DG GROW perceives public procurement as a strategic instrument for growth, contributing to more financially sustainable and innovative healthcare systems. Its main objective is to open the market for competition and equal treatment.



Since 2014, in addition to its usual legal work, new activities were given to the public procurement Directorate in DG GROW considering that the health sector represents 30% of all contract notices in European directorate on tenders and is a substantial part of public procurement procedures. A survey has been done showing low publication number of contract award notices for medicinal products, lack of competition, other problems and legal irregularities (discrimination in tender specifications, award criteria not linked to the procurement, and corruption). DG GROW considers there is a need for further professionalization in the application of public procurement rules. A best practice in supporting this goal was presented: the French PHARE project supports training by the central purchasing body RESAH to contracting authorities.

On 3 October 2017, the Commission has put forward an initiative to carry out procurement more efficiently and in a sustainable manner, while making full use of digital technologies to simplify and accelerate procedures.

The initiative in which HOPE has been involved has four main strands:

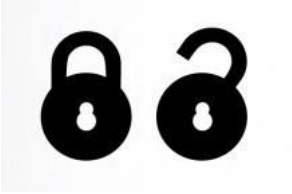
- Definition of priority areas for improvement – Member States are encouraged to develop a strategic approach to procurement policies, focusing on six priorities: greater uptake of innovative, green and social criteria in awarding public contracts; professionalisation of public buyers; improving access by SMEs to procurement markets in the EU and by EU companies in third countries; increasing transparency, integrity and quality of procurement data; digitisation of procurement processes; and more cooperation among public buyers across the EU.

- Voluntary ex-ante assessment of large infrastructure projects – Complex projects can go wrong right from the beginning if the project managers do not fully grasp the complex rules that apply to large-scale procurement. The Commission will set up a helpdesk that can answer specific questions at an early stage related to projects with an estimated value over €250 million. For projects of high importance for the Member

State concerned or with a total estimated value above €500 million, relevant authorities can ask the Commission to check the complete procurement plan for compatibility with the EU procurement legislation, significantly reducing uncertainties and the risk of delays and legal challenges. The mechanism is voluntary, the Commission's advice is non-binding, and information will be handled subject to strict confidentiality requirements.

- Recommendation on professionalisation of public buyers – The Commission recommends steps to be taken by Member States to ensure that public buyers have the business skills, technical knowledge and procedural understanding needed to comply with the rules and make sure that taxpayers get the best goods and services for their money. The Commission will facilitate the exchange of good practices and innovative approaches.

- Consultation on stimulating innovation through public procurement – on the same day the Commission launched a consultation to collect feedback from stakeholders on how to stimulate innovation through the procurement of goods and services. Procurement of innovation may concern the outcomes of innovation as well as innovative ways of purchasing. The consultation is open until 31 December and will feed into future guidance for public authorities, addressing issues such as how to set a strategy, organise support for innovation procurement or use innovation-friendly procurement tools.



CYBERSECURITY

In the recent attacks, hospitals have been targeted. HOPE is then closely monitoring the EU legislation in this field. A Directive on security of network and information systems (the NIS Directive) was adopted by the European Parliament on 6 July 2016 and entered into force in August 2016. Member States have 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 provides legal measures to boost the overall level of cybersecurity in the EU by ensuring:

- Member States preparedness by requiring them to be appropriately equipped, e.g. via a Computer Security Incident Response Team (CSIRT) and a

- Cooperation among all the Member States, by setting up a cooperation group, in order to support and facilitate strategic cooperation and the exchange of information among Member States. They will also need to set 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 notify 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 (by 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.

DATA PROTECTION REGULATION

The General Data Protection Regulation was formally adopted in April 2016 and published in the EU Official Journal on 4 May 2016.

The revision of the general data protection Regulation started in 2012 with the publication of the Commission's proposal. The aim was to strengthen current EU data protection rules and to ensure a more harmonized approach to data protection and privacy across the European Union. 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 its impact on the daily work of hospitals and other healthcare organisations. As a result, the briefing "Protecting and managing personal data: changes on the horizon for hospitals and other health and care organisations" was released in May 2017. It provides recommendations for national and EU implementers on how to prepare for a smooth transition to the new law.

The deadline for implementation is May 2019 and this is posing the question of a need or not to exchange within HOPE on implementation. It was concluded that this item is worth looking for national feedback to be shared.

To follow the specific issues in the clinical trials filed, HOPE co-organised the FEAM Forum workshop "Use of data in cross-border biomedical research: what are the challenges ahead for Europe?" on 20 November 2017 where some specific actions were discussed by stakeholders:

- Forming a cross Directorate General (DG) multi-stakeholder group to monitor the implementation of GDPR in the field of research;
- Establishing incentives for harmonisation of national implementation measures and/or consider European Union law to produce a fully harmonised framework in some areas of research (e.g. areas of likely EU consensus);
- Issuing a call (with associated funding opportunities) to analyse whether the right balance is being struck between privacy and research interests in GDPR implementation (similar to ICREL);
- Monitoring and analysing the costs and other impacts of GDPR implementation in research.

- Biomedical research and healthcare are increasingly data-intensive, and the potential benefits of big data are significant and varied (improved diagnosis and treatment, improved patient safety, better health outcomes, better performance of healthcare systems and increased efficiency and effectiveness in research and development).

Although, considerations including technical, legal and systemic challenges arose. Technical barriers such as a lack of interoperability limit the flow of data between countries and systems. One of the most fundamental challenges is the need to build and maintain public trust about the responsible collection, sharing and use of personal data. At present, individuals are generally supportive of data sharing as long as they can trust that appropriate safeguards are in place. But all stakeholders must play their part in preserving public trust and demonstrating the benefits of sharing and using personal data.

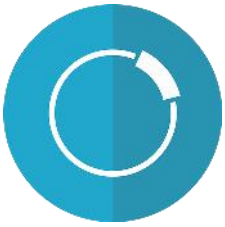
A specific set of challenges arises from the European General Data Protection Regulation (GDPR). Technical challenges include ambiguity about terminology, definitions, roles and responsibilities and there are specific problems arising from inconsistencies in the treatment of consent and lack of clarity about the legal basis for the further processing of data. These challenges are compounded by the fact that the GDPR leaves significant room for interpretation of its many provisions at the national level. This means that, unless a high degree of harmonisation is achieved in the interpretation of the GDPR, there may be a proliferation of national standards, requirements and legislation which may prove to be a significant barrier to effective cross-border research in Europe. The picture is complicated still further by the existence and applicability of several other regulations, laws, conventions and codes to biomedical research.

BLOOD, TISSUES AND CELLS

The Commission is currently carrying out an evaluation of the EU blood and tissues and cells legislation. This is the first formal evaluation of this legislation since the adoption of the basic Acts in 2002 (blood) and 2004 (tissues and cells). This evaluation is in line with the Commission's Better Regulation Package and aims to assess whether the legislation

has achieved its original objectives and whether it is still fit for purpose. The evaluation will consist of several steps starting with a Roadmap and including a study by an external contractor and extensive consultation of stakeholders. The final evaluation report is expected to be published by the end of 2018.

An Online Public Consultation was launched on 29 May 2017 and ran until 14 September. The consultation is now closed. Submissions were received from 158 organisations and 43 citizens. A summary of the outcome, together with the individual submissions (consent permitting), will be published here in April 2018. A Stakeholder Event was held on 20 September 2017 in Brussels. The event attracted a high level of interest with over 200 stakeholders attending.



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. Most of the questions and answers are rather technical and will need expertise in each HOPE member organisation.

EUROPEAN REFERENCE NETWORKS

On 1 March 2017, the newly established European Reference Networks (ERNs) were officially launched. HOPE attended the two-day conference held in Vilnius, Lithuania, where more than 600 participants, mainly ERN coordinators and members, met to celebrate the approval of the first 24 European Reference Networks (ERN) in the EU.

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 diseases requiring a particular concentration of highly specialised healthcare in medical domains where the expertise is rare.

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, which will have a positive impact on the sustainability of national healthcare systems, and for 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 co-organised with the Commission a workshop devoted to the European Reference Networks taking place on 16 and 17 November 2017 in Rotterdam Erasmus Medical Centre. Most healthcare providers are enthusiastic about ERNs but there is some concern about the workload that may be involved. Hospital boards are key players in the success of the ERNs and its members. The hospital environment and how ERNs members' work and activities are integrated in the organisation and working procedures of each hospital is the backbone of the ERN system.

Many hospital board members are already being active players in the implementation process of the ERNs and have developed active strategies and action to support their healthcare providers and in particular their coordinating role. This workshop gathered all the players involved in the ERN implementation: Patients, healthcare providers, ERN coordinators, Member States representatives and Hospital board members. The overall goal would be in the end to establish a trust relation between all involved players for the better effectiveness and sustainability and of the ERNs. The main aim is to create a discussion and reflection space to exchange views of the main players involved in the ERNs implementation and to analyse key issues, challenges and opportunities of the ERNs in relation with the hospital management and support to the ERNs.

PROPOSED LEGISLATIONS

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 health care, 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. The number of replies submitted is 249, mainly from administrations, organisations and associations (150), citizens (63) and SMEs (36). 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). The release of the proposal was planned for December 2017 but it was delayed. Thanks to leaks, HOPE was able to work on the text before its official publication to prepare a position. 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. Member States will be able to use common HTA tools, methodologies and procedures across the EU, working together in four main areas: on joint clinical assessments focusing on the most innovative health technologies with the most potential impact for patients; on joint scientific consultations whereby developers can seek advice from HTA authorities; on identification of emerging health technologies to identify promising technologies early; and on continuing voluntary cooperation in other 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 in 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.

The proposal will now be discussed by the European Parliament and the Council of Ministers. If adopted, it will become applicable three years after it enters 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 is now working on a position on the basis of its members' position.

EUROPEAN PILAR OF SOCIAL RIGHTS

On 17 November 2017, the European Pillar of social rights was proclaimed and signed by the Council of the EU, the European Parliament and the Commission during the Gothenburg Social Summit for fair jobs and growth. The Social Pillar is intended to drive forward a social Europe for all European citizen. It aims at strengthening the social acquis and delivering more effective rights to citizens. It focuses on employment and social aspects and ensuring that the European social model is fit for the challenges of the 21st century. The objective of the Pillar 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 labour market,
- dynamic labour markets and fair working conditions,
- public support /social protection and inclusion.

On 8 March 2016, the European Commission launched a public consultation on the European Pillar of Social Rights that ended 31 December 2016. 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 principles proposed do not replace existing rights, but offer a way to assess and, in the future, approximate for the better the performance of national employment and social policies. 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 as part of a deeper and fairer Economic and Monetary Union.

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

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 initiative was announced in April 2017 together with the European Pillar of Social Rights. It is part of the 2018 Commission Work Programme and followed a two-stage consultation of social partners. The social partners did not enter into negotiations to propose their own agreement. Therefore, the Commission decided to take action in line with the Treaty on the Functioning of the European Union. The initiative also responds to the Resolutions of the European Parliament of 19 January 2017 on a European Pillar of the Social Rights, requesting a framework Directive on decent working conditions in all forms of employment, and of 4 July 2017 on working conditions and precarious employment, calling for a revision of the 1991 Directive to take account of new forms of employment.

E-PRIVACY

In January 2017 the Commission has published in an ePrivacy package including a 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 to process communication data and reinforce 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.

HOPE identified 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.

REUSE OF PUBLIC DATA

The Commission is considering the revision of the Directive on re-use of public data adopted in 2003.

The Commission is launching a public consultation in view of reviewing the directive on the re-use of public sector information (PSI Directive). As foreseen 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 is preparing an initiative on accessibility and re-use of public and publicly funded data, and is at the same time further exploring the issue of privately held data which are of public interest.

The Directive 2003/98/EC on the re-use 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 re-use as possible to foster transparency, data-based innovation and fair competition.

Soft Law and Other Initiatives

Besides hard law, HOPE also closely monitors soft law in areas such as standardization, access to medicines, patient safety, eHealth, European semester, antimicrobial resistance, vaccines, or 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.

STANDARDIZATION

Standardization 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 standardized by private, semi-private and public organizations that can be of national, European and international nature. International examples include Joint Commission International (JCI) and Health Standards Organization (HSO). Other standardization 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 Standardization (CEN) and its members at European and national levels. In 2017, HOPE was actively engaged in discussions around 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 standardization can support quality, efficiency and safety in complex healthcare services throughout Europe. The third meeting of the group took place on 13 November 2017 at CEN-CENELEC Meeting Centre in Brussels.

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 areas 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-learnt from the developed European Standards in this field in order to share this experience with interested stakeholders.

To raise awareness for the opposition to CEN, it was agreed with the European stakeholders to systematically reach out to other stakeholders, attachés and the Commission.

ACCESS TO MEDICINES

The issue of access to medicines is of crucial importance for the more than 10 million EU citizens affected by cancer. Several factors affect this issue, from regulatory standards to funding systems, and it produces big inequalities between countries. HOPE has then worked on expensive medicines by adopting a position paper, contributing to the OECD consultation and monitor the biosimilars development.

In January 2017 HOPE officially adopted the position paper "Expensive medicines: hospitals are concerned". This document calls for greater attention to the consequences that several "innovative" medicines can bring about in hospital activities. HOPE advocated that expensive medicinal products pose new challenges influencing hospitals' financing models and organisation, also potentially leading to treatment rationing, unethical and ineffective from a public health perspective.

The Position Paper provides an overview of the current situation at European level – welcoming the Council conclusions of the 17 June 2016 – and calls for greater voluntary cooperation, by Member States, between relevant authorities and payers. Finally, it sets out recommendations on possible actions at hospital and healthcare services level.

On 2 March 2017, the European Parliament voted to adopt the non-legislative report "EU options for improving access to medicines 2016/2057 (INI)". Even if it does not introduce any new binding rules on the topic, it makes several calls for action aimed at different institutions, both at EU and national levels, to address the most urgent problems in the issue of access to medicines.

On 8 May 2017, six southern member states (Malta, Cyprus, Greece, Italy, Spain, and Portugal) signed the Valletta Declaration, aiming to enhance their cooperation and jointly negotiate with the pharmaceutical industry on drug pricing. The following day, EU health ministers met with the CEOs and heads of Europe-based pharmaceutical companies to discuss about how to improve the overall sustainability of healthcare as well as access to treatment for patients.

In addition, member states were encouraged to explore strategies to jointly negotiate prices with the pharma industry and urged them to exchange information in the phase preceding the launch of negotiations with drug makers. Similar agreements have already been made by several EU countries; Benelux with Austria (Beneluxa), Bulgaria and Romania as well as Visegrád, with Croatia and Lithuania (Visegrad +2).

HOPE provided its contribution to the OECD online consultation on access to innovative therapies.

The consultation is part of an OECD initiative proposed by the French Ministry of Health aiming at promoting an international and high-level dialogue between stakeholders on access to innovative pharmaceuticals and sustainability of pharmaceutical spending.

The initiative was endorsed by OECD member countries and by Health Ministers at the G7 Health Ministerial meeting in Kobe, on 11-12 September 2016. The overall objective is to improve patient access to innovative treatments and ensure the sustainability of health spending as well as continued innovation that meets patient needs

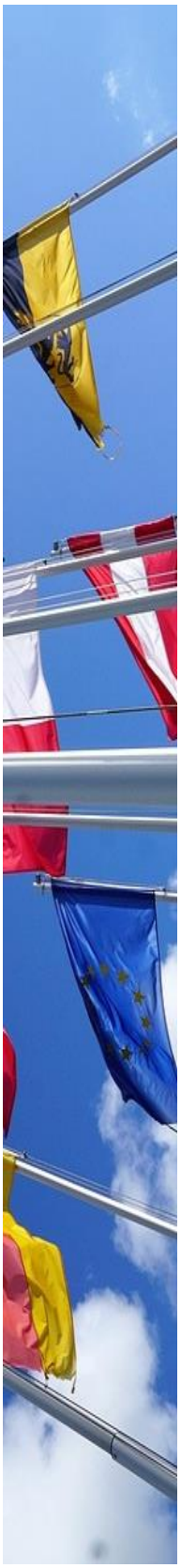
On 5 May 2017, HOPE co-organised the Stakeholder event on Biosimilar Medicinal Products organised in Brussels under the leadership of the European.

This yearly event is aiming at increasing knowledge about biosimilars and foster take up of these products with a view to ultimately improve access to medicines and sustainability of healthcare systems, while at the same time respecting freedom of choice of healthcare professionals.

During the event the "Information guide for healthcare professionals" was presented. The guidelines were prepared jointly by the European Medicines Agency (EMA) and the European, with the support of EU scientific experts and organisations from across the EU representing doctors, nurses, pharmacists and patients. The objective of the guide is to provide healthcare professionals with reference information on both the science and regulation underpinning the use of biosimilars. Additionally, the main findings of the Quintiles MS report 2017 were presented during the event. The report, first published in 2015, shows a consistent average price reduction in therapy areas where biosimilars have been introduced. Increased biosimilar competition affects not only the price for the directly comparable product but for the whole product class. In some cases, the biosimilar version of a product ends up not getting sold. Even then it is likely to eventually be an essential step to a competitive environment, leading to lower prices.

The 2017 event focused on healthcare professionals because of the important role they play in procurement processes and ensuring take up through switching from biological reference medicinal products to biosimilars medicines.

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 2017 European Semester and regularly reported on it via its monthly newsletter.

On 27 January 2017, the Economic and Financial affairs Council (ECOFIN) considered growth prospects and macroeconomic imbalances under the 'European Semester', the EU's annual policy monitoring process. It adopted conclusions on two key aspects:

- the Commission's annual growth survey;
- the 'alert mechanism report', the starting point for the annual macroeconomic imbalances procedure

The Annual Growth Survey is the first step of the European Semester process. With the Conclusion adopted in January 2017, the Council broadly shared the Commission's analysis and agreed on the broad priority policy areas outlined in the report, namely:

- boosting investment;
- pursuing structural reforms;
- implementing responsible fiscal policies.

Health issues have been mentioned in relation to population ageing and technological development or access to cost-effective public and healthcare services.

On 22 February 2017, the European Commission released the European Semester Winter Package. The winter package shifts the attention from the political priorities set for 2017 at EU level with the publication of the Annual Growth Survey 2017 to the national progress made in implementing structural reforms.

The Commission also released the Country Reports, which are analytical documents providing an overview of the economic and social challenges in the EU. They also provide information regarding the progress made in each Member State in the implementation of the Country-Specific Recommendations issued in spring 2016.

The publication of the Country Reports in February is part of the Juncker Commission's efforts to streamline and strengthen the European Semester. The changes were introduced to give more time for dialogue between the Commission and the Member States as well as to improve dialogue with stakeholders at all levels. 2017 reports also reflect the greater focus on employment and social considerations that the Commission is bringing into the European Semester.

Some focus has been put on the healthcare sector during the release of the Winter Package. Moreover, the Communication on the main findings and results of the Country Reports 2017 addresses the need for implementing reform in the healthcare sector as a way to achieve responsible fiscal policies and safeguard the quality of public finances. Reference is made to healthcare systems as an element contributing to the population's health, economic prosperity and social cohesion.

Envisaged reforms of the sector involve: ensuring access to timely and good-quality healthcare for all; shifting from in-patient to outpatient care; investing in health promotion, primary care and integrated care; improving the governance of the systems; using medicines more rationally; using Health Technology Assessment, more centralised public procurement and e-health and health information tools.

In March 2017 HOPE published a Strategic note "European Semester Winter Package: Commission analysis of healthcare systems reforms in EU Countries". On 3 March 2017, the Employment, Social Policy, Health and Consumer Affairs (EPSCO) Council of the European Union hold a debate on the European Semester 2017.

The Council adopted conclusions 6885/17 on the 2017 annual growth survey and joint employment report, dealing with priorities for action in the areas of employment and social policies.

The document clearly supports a different approach to healthcare systems reforms from the one promoted by the European Commission in its European Semester Documents. The Council stresses the importance of improving access to high-quality services and implementing health prevention policies, only marginally touching upon the Commission's mantra on the need to improve fiscal sustainability of healthcare systems.

PATIENT SAFETY

HOPE has long been active on patient safety and quality of care and continued in 2017 to push the European political agenda on increased and continuous collaboration on this thematic field.

HOPE as member of the Expert Group on Patient Safety, was informed that the Commission has decided to discontinue the expert group.

The Commission has instead set up a new mechanism, the Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases (the Steering Group on Promotion and Prevention in short), to maximise joint efforts with the EU Member States for reaching the nine voluntary targets of the World Health Organisation (WHO) by 2025 and meeting Sustainable Development Goal which aims to reduce premature mortality from non-communicable diseases by one third by 2030. In addition, there is a need to better prioritise and increase the impact of actions supported by the EU in order to improve the population's health and the sustainability of health systems.

Rather than focusing only on one disease area or risk factor the Steering Group on Promotion and Prevention is a horizontal group to allow for a higher-level prioritisation of

policies to be implemented by the Member States. It will help in overcoming the silo mentality between disease areas and allow for setting up a lighter, more effective system of priority setting in the area of public health against the current and future EU priorities. It will allow for a more coordinated and joined up approach to tackling non- communicable diseases in a situation where we all face economic and resource constraints. The Steering Group is chaired by the Commission and it has met three times, latest on 26 October 2017.

The WHO targets a 25% relative reduction in the overall mortality from non-communicable diseases, as well as targets on health determinants (alcohol, nutrition and physical activity, tobacco, blood pressure) and on accessibility of care. The Mid-term evaluation of the 3rd Health Programme 2014-2020 highlighted the Programme's achievements in generating, using, exchanging best practices and recommended better defining Member States needs to integrate best practices into national policies to increase its impact. The Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases has held meetings in November 2016 and in April and October in 2017. All EU Member States and the EEA countries are represented in the Group which is chaired by the European Commission.

The Steering Group takes positions on priority actions to be implemented in all areas of health promotion and non-communicable disease prevention

The Steering Group will be a central mechanism for taking positions on priority actions to be implemented in all areas of health promotion, including nutrition and physical activity and reduction of alcohol-related harm; disease prevention including screening, and management of non-communicable diseases including all relevant health challenges including cancer, mental health, rare diseases, cardiovascular diseases, diabetes etc.

As the Commission plans to put the Steering Group on Promotion and Prevention on a formal footing, it considers that it should consequently need to simplify and streamline work to avoid a risk of duplication. It is against this background that the objective of the current expert group on patient safety will be embedded into the aims of the Steering Group and therefore, the expert group will be discontinued.

Nevertheless, the Commission envisages integrating relevant aspects of its work into other on-going activities according to the field in question, like into the Joint Action on Antimicrobial Resistance and Healthcare-Associated Infections. This action will aim to, inter alia, support strategy development at national, local, and health care setting level in the field of health-care associated infections, develop and enhance the implementation of evidence-based tools to enable sustainable improvements in practice by health care staff and teams in hospitals, as well as in long term care and community settings and promote awareness and commitment by governments and stakeholders.

The Joint Action on Chronic Diseases will also cover patient safety aspects, like quality in prevention and care in chronic diseases. Lastly, with the help of the Steering Group on Promotion and Prevention, we will also be able to review the large number of best practices created by past actions and make strategic decisions on selecting those best practices which Member States will want to implement nationally.

E-HEALTH

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

Established by the Commission in 2012 and renewed in 2016, this group 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.

HOPE joined the meeting of the eHealth Stakeholders group organised in Brussels on 27 April 2017. The European Commission presented the first elements of the Blueprint for digital innovation in health and care to help scale up digital transformation of health and care, reaching concrete targets by 2018.

The aim is to reach at least EUR 500 million investment with the identification of 5 scenarios with investment commitments. The medical device regulation was also covered, more precisely on software falling under the definition of a medical device. Apps are regulated as software.

The Directorate General CONNECT presented several elements: the digital single market review and digital health and care task force, the eHealth week in Malta in May and the Estonian presidency eHealth event from 16-18 October 2017. mHealth was discussed since the draft code of conduct has been submitted to member states for a first feedback expected in May. The mHealth working group results will be submitted to the eHealth network of member states.

DG SANTE raised several points: the eHealth Network meeting and the new joint action supporting the eHealth Network reporting with 2,7 million euros. The IT platform of the European reference networks was presented. It is a collaborative platform, tailored for the European reference networks but with no exchange of clinical patient data. This will be done with a clinical patient management system which focus is on diagnosis and treatment, but not yet on research.

Finally, the eHealth stakeholders working groups presented their first results on: citizens and digital health data; standards and interoperability; integrated care; side effects of eHealth; and reimbursement.

The meeting was also an opportunity for HOPE to present the work in process with the European Cybersecurity Organisation but also the joint conference organised in Dusseldorf on 16 November 2017.

HOPE also attended its fourth meeting on 24 October 2017 in Brussels. The meeting was an opportunity to get the first results from the Public Consultation, a short recap on the Estonian presidency eHealth conference and the General Data Protection Regulation workshop that was organised the day before. Then Directorate General SANTE presented several specific topics:

- The eHealth Network meetings: eHN will meet on 28 November 2017 talking about EU strategy and activities on digital health;
- The Multiannual Work Programme 2018-2021 to be adopted during the 12th eHealth network: patient empowerment, innovative use of health data, continuity of care, implementation challenges;
- The 3rd Joint Action on eHealth 2018-20121 called eHAction, gathering 30 countries with a kick-off meeting in June 2018;
- Then, Directorate General CONNECT presented a series of specific topics:
- For the Horizon 2020, the Draft publication of the Work Programme 2018 - 2020 that will be made publicly available soon;
- The proposed Cybersecurity package that is trying to build strong cybersecurity for the EU in which healthcare providers are in the scope of NIS directive as operators of essential services;
- The proposed legal framework for the free flow of non-personal data in the EU;
- Ongoing studies, in particular the telemedicine study to which HOPE is associated.
- The meeting was concluded by feedback from members: the French initiative of "Dossier Pharmaceutique" and the reports from the five working groups: Citizens and Data, Care continuum, Interoperability and standards, New and shifting balances, Reimbursement.

On 20 July 2017, the European Commission had launched the public consultation on digital transformation on health and care to which HOPE contributed.

During the eHealth Tallinn Conference, the preliminary results of the EU public consultation on the future of digital health and care were presented and a Digital Health Society Declaration was announced. The preliminary results of the public consultation on the Transformation of Health and Care in the Digital Single Market made it clear that EU citizens are asking for this:

- over 90% agree that citizens should be able to manage their own data;
- over 80% agree that sharing health data can help improve treatment, diagnosis & prevention of diseases;
- around 60% of respondents say that they do not have access to digital health services. Of these people 2 out of 3 would like to have it;
- Respondents want the EC to take action for EU wide standards for electronic health records and interoperability based on open formats.

In addition, **HOPE was invited to speak at the European Economic and Social Committee on 15 June 2017 for a public hearing** under the responsibility of Martin Siecker, President of the Section for the Single Market, Production and Consumption.

The meeting was chaired by the rapporteur, Mr Alain Coheur who presented he preliminary draft opinion on the Impact of the digital healthcare revolution on health insurance.

The first panel was looking at the impact of the digitalisation on health insurance with the views of a Belgian Mutual Health Insurance, a French one and a German one.

The second panel on the Impact of the digitalisation on medical professions and patient communities started with a challenging presentation Pr. Philippe Coucke, radiotherapist at the academic hospital of Liège, Belgium. His views on the determinism of technologies were particularly provocative.

HOPE Chief executive raised the key issues for the workforce: new workforce skills and competences to interpret, communicate and act on health data, working more in a team due to more data, capacity building with education and continuous professional development around those two issues as well as on the relation patient/family/carers and health and social care professionals. He took as examples two current EU projects in which HOPE is involved: ICT4LIFE and MedEye.

The views of the European Commission were both from Directorate General CONNEXT and Directorate General SANTE mentioning in particular a public consultation soon to be published.

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, composed of a public webpage and of 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.

The second annual meeting of the EU Health Policy Platform took place on 27 November 2017. John F. Ryan, Director of public health, country knowledge and crisis management, DG Health and Food Safety, European Commission, chaired the meeting. More than 70 interest groups participated.

Among the four Joint Statements, which had been prepared by Thematic Networks under the lead of a stakeholder organisation, two interesting ones were presented:

The European Public Health Alliance presented a Joint Statement on "Antimicrobial Resistance (AMR)" with proposals aiming to support the Commission's new "EU One Health Action Plan on AMR", to which HOPE contributed and then supported;

The Joint Statement on "Migration and Health" prepared under lead of the Platform for Undocumented Migrants together with the International Rehabilitation Council for Torture Victims focuses on proposals for a better targeted response to migration health needs and inequalities, and for tackling existing structural and educational gaps, with the contribution of HOPE.

The Commission (DG SANTE), together with the OECD and the European Observatory on Health Systems and Policies, presented the new deliverables from the "State of Health in the EU"-process, country health profiles for all Member States and a companion report.

Finally, the Commission (DGs EMPL) gave a presentation about the principles and rights summarised in the European Pillar of Social Rights and the Social Scoreboard, which measures progress. DG SANTE presented data and activities related to principle 16 of the Pillar ("Health care") on unmet medical needs.

AGEING EU HEALTH POLICY FORUM

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 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 is particularly engaged in the area of ageing and integrated care as leader of the EU-funded project ICT4Life Work Package on Dissemination and Exploitation of project results. More information on this topic is provided in this report in Chapter III (section "Ongoing Projects").

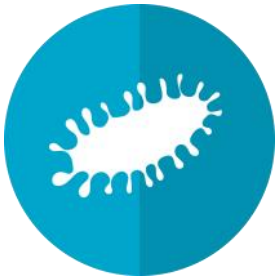
European Innovation Partnership on Active and Healthy Ageing

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 April 2017, HOPE replied to the Public consultation launched by the European Commission on a "One Health" Action Plan against antimicrobial resistance (AMR).

The European Commission launched the consultation on possible activities to be included in the Action Plan in January 2017, in view of its forthcoming adoption in mid-2017. These activities will support EU countries in the fight against AMR.

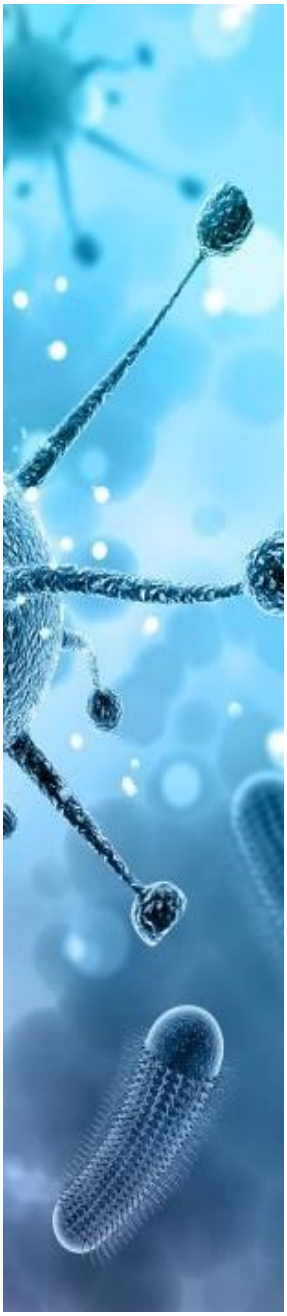


The new Action Plan will build on the evaluation of the existing one, expanding towards innovative approaches, whilst ensuring the continuation of EU actions that are still needed. It will focus on activities with a clear EU added value and, where possible, on measurable and concrete outcomes. These activities have been grouped in three main fields of action, defined as Pillars, namely:

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

In June 2017 the Commission adopted the new EU One Health Action Plan against AMR. It builds on the first Action Plan (2011-2016), its evaluation, to which HOPE took part, the feedback received on a European Commission on AMR and an open public consultation. 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 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 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 around 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 2017 campaign, the ECDC released a new toolkit addressed to professionals in hospitals and healthcare settings, including hospital managers and administrators. Over the past two years, HOPE collaborated with the ECDC in the creation of the key messages and communication materials included in the toolkit.

The objective of this toolkit is to support efforts to increase prudent use of antibiotics in hospitals and other healthcare settings through dissemination of evidence-based educational and information materials. Moreover, the materials aim at creating a sense of individual responsibility in tackling antibiotic resistance and at empowering professionals to take action.

During the 2017 European Antibiotic Awareness Day, HOPE supported the initiative by disseminating information and EAAD promotional material among 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 contributing to the debate on Twitter (with the official hashtag #KeepAntibioticsWorking). This year the event marked the 10th anniversary of this EU-level initiative aimed at raising awareness about the threat to public health of antimicrobial resistance (AMR) and the importance of using antibiotics prudently.

HOPE has joined 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 as well as international organizations (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.

The kick-off meeting was held in Paris on 13-14 September. Its overarching objective is to support EU Member States develop and implement effective one health policies to combat AMR and reduce healthcare-associated infections.

VACCINES

In order to find ways to help the EU and its Member States to increase vaccine coverage in Europe, the European Commission Directorate-General Health and Food Safety (DG SANTE) is planning 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 aims and objectives of the initiative. The public consultation is also running until 15 March 2018.

Added to that, a stakeholder consultation opened. It focusses on how EU can act with Member States to address some of the vaccination challenges we are facing today, how can the EU reach the people who are refusing to be vaccinated, how can the EU boost research on vaccines, how can the EU tackle shortages in vaccines, how can the EU communicate more effectively about vaccines, who are the key actors in vaccination and other suggestions to achieve the objectives of strengthening cooperation against vaccine diseases.

Supporting the initiative of HOPE Maltese member, HOPE started a survey on flu vaccination of healthcare professionals, a field that lacks comparative elements.

SAFETY OF PUBLIC PLACES

HOPE was invited to speak on 20 December 2017 in Brussels at the first meeting of the EU Operators Forum created by the European Commission to enhance public-private cooperation on the protection of places accessible to the public.

On 18 October 2017, the European Commission has adopted an Action Plan, which proposes new measures to support the protection of EU citizens against terrorist attacks in public spaces. The Commission is providing €18.5 million from the Internal Security Fund to support transnational projects improving the protection of public spaces. In 2018, a further €100 million from the Urban Innovative Actions will support cities investing in security solutions. Over the next year, the Commission will issue 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 will include technical "security by design" solutions to make public spaces more secure while preserving their open and public nature. The Commission will establish 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, an important action of the European Commission was to launch a new forum to facilitate enhanced public-private cooperation on the protection of places accessible to the public: the so-called EU Operators' Forum. In this forum, relevant stakeholders have the opportunity to gather available guidance, develop recommendations and discuss and share best practice.

On 20 December 2017, Sir Julian King, Commissioner for the Security Union opened the first meeting of the Forum. The Commission representatives (Directorate General HOME) then addressed lessons learnt from recent attacks on public spaces and the various actions taken to mitigate and counter the threat. Finally, in the exchange on good practices various sectors presented examples of good practices (such as hotels, entertainment, sports stadiums, transport and, aviation security).

Pascal Garel, HOPE Chief Executive, presented the specifics of the hospital sector and some examples collected, in particular the French strategy by which all hospitals had until June 2017 to adopt a security plan integrating the terrorist threat.

The next step will be to create several thematic groups. HOPE will take part in the hospitality one.

EUROPEAN SOLIDARITY CORPS

On 6 February 2017, the European Commission launched a Public consultation on the European Solidarity Corps. The consultation was open until 2 April 2017.

The European Solidarity Corps will create opportunities for young people to support communities and people in need. These opportunities will include volunteering and solidarity-related jobs, traineeships and apprenticeships, both in the young people's home countries and abroad. The Commission is now consulting stakeholders and the general public to define key priorities and shape the implementation of the European Solidarity Corps. The consultation results will inform the Commission's legislative proposal.

The healthcare sector is involved in this new initiative thanks to the presence of the category “health and wellbeing projects” among the available choices. The Commission mentioned that it will concern supporting projects which encourage general health and wellbeing, such as healthy lifestyles and active ageing.

HOPE replied to the Commission Public Consultation: the response wants to advocate for the Commission to take an ambitious and comprehensive approach on the implementation of the European Solidarity Corps.

On 9 February 2017, the Council adopted conclusions on investing in Europe's youth, focusing on the European Solidarity Corps. The conclusions provided a political response to the Commission's December Youth initiative, which proposed a package of measures aimed at improving young people's skills and opportunities, including a communication on the European Solidarity Corps.

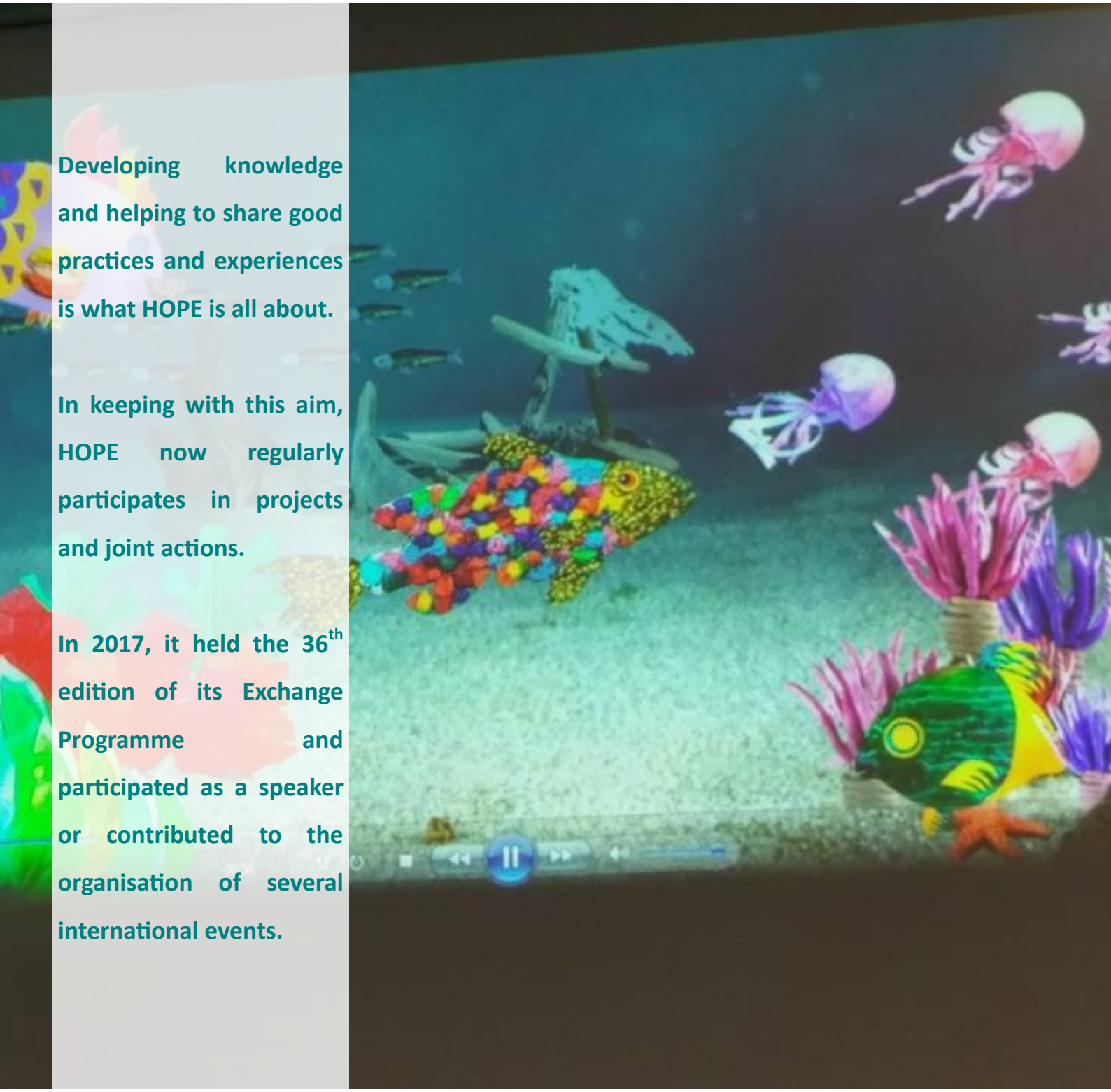
In the conclusion, Ministers urge the Commission to:

- present during the first semester of 2017 an appropriate legislative and evidence -based proposal, a clear framework, including how the European Solidarity Corps is to be funded, implemented, and evaluated;
- ensure that the European Solidarity Corps will not only be capable of reaching its objective in terms of young people’s active involvement and participation but also ensure quality placements and projects with a strong learning dimension which enable positive outcomes for young people’s future personal, social and professional development, whilst avoiding undesirable effects on the labour market.

HOPE attended on 12 April 2017, the European Solidarity Corps Stakeholder Forum brought together in Brussels national and European representatives of civil society organisations, authorities and other stakeholders to discuss the key issues related to the future development of the European Solidarity Corps in the frame of the consultation.

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 2017, it held the 36th 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

ADVANCE eHEALTH INTEROPERABILITY—eSTANDARDS

The eStandards project was financed under Horizon 2020, the EU Framework programme for research and innovation programme. The project started in May 2015 and ran for two years with the main objective of advancing eHealth interoperability and global alignment of standards for health information sharing. HOPE was a partner of the project, together with other health stakeholder organisations and leading standards organisations in Europe.

On 26 and 27 June 2017, the project held its final conference in Brussels. As member of the Consortium, HOPE was invited to speak at the event about best practices in the implementation of large scale eHealth deployment projects from the end-users' point of view.

During the conference, the participants were invited to think of a global eHealth ecosystem where everyone enjoys timely safe and informed health anytime and anywhere and where interoperability assets fuel creativity, entrepreneurship and innovation.

The project eStandards nurtures large-scale eHealth deployments with Trust and Flow to strengthen Europe's voice and enable co-creation in interoperability where trusted dialogs on health, costs, and plans meet great expectations.

The project started ran for two years with the main objective of advancing eHealth interoperability and global alignment of standards for health information sharing.

HOPE AS A PARTNER – ONGOING PROJECTS

ICT SERVICES FOR LIFE IMPROVEMENT FOR THE ELDERLY - ICT4LIFE

In 2017, HOPE was deeply involved in implementing ICT4Life project activities as leader of the Work Package on Dissemination and Exploitation of project results.

Financed by Horizon 2020, the EU Framework Programme for Research and Innovation, ICT4Life is a three-year project that kicked-off in Madrid on 19 January 2016 with the ambition to provide new services for integrated care employing user-friendly ICT tools. The ultimate aim is to improve quality of life and autonomy at home for patients with Parkinson's, Alzheimer's and other dementias, and to support their caregivers too.

To reach this goal, ICT4Life brings together nine partners representing academia, industry and end users' groups, all committed to improving patients' lives and advancing Europe's leadership role in personalised services for integrated care.

As leader of the project's dissemination activities, HOPE organised from 17 to 19 January 2017 an event addressing *"ICT4Life approach and contribution to the challenges of integrated care,"*. The event took place in Brussels, at HOPE central office, and gathered representatives from policy-making organisations, who actively participated in the discussion on ICT4Life technologies.

A Consortium Meeting took place at the same time. It represented for the partners of the project an opportunity to exchange information on the activities implemented and on the objectives reached so far, but also to define the next steps. HOPE, being the leader of ICT4Life dissemination and communication, is in charge of raising awareness about the project and ensuring its visibility at the EU level. During these days, HOPE organised an event to show the ICT4Life technologies developed during the first year of the project, focusing on the ICT4life approach and contribution to the challenges of integrated care. It gathered key policy making organisations representatives who provided valuable inputs for the improvement of the ICT4Life platform as regards end-users needs.

On 4 and 5 April 2017, HOPE took part in the ICT4Life consortium meeting in Thessaloniki (Greece). The meeting aimed to coordinate partners' work and review achievements and project results. During the two-day meeting, ICT4Life consortium has agreed on the schedule for iterative testing that will be performed in the upcoming months with patients, health professionals and caregivers. A first wave of tests of the technologies developed so far, including the application for smartphones and smart-TVs, was already implemented in France, Spain and Hungary by the end-users' organisations E-Seniors and Madrid Parkinson Association as well as by ICT4Life members from the University of Pécs.

Patients and caregivers' responses to the technologies tested were promising, especially from the point of view of patient's empowerment. The meeting also provided to ICT4Life technical partners an opportunity to discuss about integration of ICT4Life different technical modules. The ICT4Life final product will allow patients to improve their autonomy and quality of life through integration of

different technologies able to monitor their movements at home and health status and notify caregivers and health professionals about abnormal behaviours detected. Moreover, the mobile app will help patients to train their memory thanks to cognitive games easily adaptable to their own needs and skills.

ICT4Life partners organized and participated to the Smart Indoor Event and Activity Recognition Workshop (SIEARW 2017). The workshop has been organized in conjunction with the IEEE AVSS 2017 on 29 August 2017 in Lecce, Italy. The scope of the Workshop was to bring together researchers and developers working in the area of human activity analysis and event prediction in indoor environments, also leveraging on the results of the ICT4Life project.

Besides organising face-to-face events and the final conference, HOPE is also in charge of managing ICT4Life online communication activities on social media, updating the project website and drafting ICT4Life newsletters, and building collaboration with similar projects and initiatives.

HOPE was invited to speak at the 2017 AAATE Congress, a 4-day event about Assistive Technologies taking place from 12 to 15 September 2017 in Sheffield (UK). The 2017 Congress was addressing the global challenge of meeting the needs of the increasing number of people who could benefit from Assistive Technology. The Congress was adding to its usual breadth a focus on the translational research agenda.

On 21 November 2017, HOPE took part in this event in Glasgow to share ICT4Life experience as regard the implementation of SCIROCCO methodology, as a tool to assess the integrated care maturity of the geographical areas interested by the pilots forecasted by the project. The event brought together public policy-makers, healthcare professionals, representatives of social care, housing and voluntary sectors, academia and end users to discuss the experience of European regions and organisations in developing and delivering integrated health and social care. The event was an opportunity to explore the potential of the tool to facilitate the partnerships and knowledge transfer in order to accelerate the journey of European regions towards integrated care.

The ultimate aim of ICT4Life is to improve quality of life and autonomy at home for patients with Parkinson's, Alzheimer's and other dementias, and to support their caregivers too.

ICT4Life Consortium meeting held at CERTH Campus, Thessaloniki, April 2017

EURO-CAS

The EURO-CAS project was launched in Vienna on 26 January 2017, a few weeks after the kick off meeting. HOPE is involved in the project as a partner and will contribute to the dissemination and communication activities of the project.

The aim of the project is 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. Based on recommendations of the Antilope project and the state of the art in interoperability testing in eHealth, 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 aim of the project is to foster the testing of ICT solution interoperability against identified eHealth standards and profiles defined in the eHealth European Interoperability Framework (eEIF)

HOPE is member of the EURO-CAS multi-disciplinary consortium composed of organisations focused on implementing international standards as well as industry stakeholders and healthcare providers. The consortium will review the state of the art of 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.

EURO-CAS presented its initial work and results on 21 October 2017 in Athens (Greece), as part of the programme of the eHealth Forum held from 19 to 24 October 2017. At this event, almost one year into the project, speakers from the consortium presented the outline and elements of the eHealth Conformity Assessment Scheme for Europe (CASforEU), which will assist public authorities, industry and users in testing eHealth solutions against identified eHealth standards and profiles. During the event, HOPE chief executive delivered by video message some key information regarding the importance of a CASforEU for European Hospitals.

Also in conjunction with the eHealth Forum 2017, on 20 October the EURO-CAS consortium also met for its second validation workshop, where results of the work carried out by the members of the EURO-CAS core team have been presented to and discussed with the EURO-CAS deployment team, of which HOPE is a member.

MEDEYE

The MedEye Project has been officially launched on 28 February. HOPE is a partner of this project, funded from the European Union Horizon 2020, the EU Framework Programme for Research and Innovation. HOPE is involved in the project as leader of the Work Package on Dissemination and Exploitation of project results.

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

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

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

MedEye 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. One for long-term care through central pharmacy Pharmaforce.

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

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

MedEye Technology

HOPE AS AN ADVISOR

PRIMARY HEALTH CARE

In 2016, following the approval of the European Framework for Action on Integrated Health Services Delivery, the WHO Regional Director for Europe established the Primary Health Care Advisory Group to support the continued advancement of primary health care, inviting HOPE Chief executive as a member. Through its annual meetings, the Primary Health Care Advisory Group intends to bring together renowned experts on primary health care and other relevant topics, alongside representatives of special interest groups to share their technical knowledge, experiences and perspectives to inform a future vision for primary health care. Specifically, it seeks to examine how primary health care must continually evolve, working towards integrated health services and people-centred health systems in the WHO European Region.

On 20 and 21 June 2017, the WHO European Centre on Primary Health Care hosted the first meeting of the Primary Health Care Advisory Group in Almaty (Kazakhstan). The event convened appointed members of the Primary Health Care Advisory Group as well as temporary advisers and guests with the aim of reflecting on two critical considerations: what should primary health care look like in 2030? What do health systems need to do to get there? This reflection was guided by the WHO European Framework for Action on Integrated Health Services Delivery exploring changing demands for acute and chronic care needs in primary health care and then priority avenues as gateways for transforming services in practice: primary health care and hospitals, long-term care and public health services.

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.

JOINT PROGRAMMING INITIATIVE

Joint Programming is a new approach to foster collaboration and coordination in R&D in Europe. It is a member-states driven activity. The Joint Programming Initiative (JPI) “More Years, Better Lives – The Potential and Challenges of Demographic Change” seeks to enhance coordination and collaboration between European and national research programmes related to demographic change.

Areas affected by demographic change cover a wide range of research fields and policy topics ranging from health to social welfare, education and learning, work and productivity to housing, urban and rural development and mobility. The JPI “More Years, Better Lives” therefore follows a transnational, multi-disciplinary approach bringing together different 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 in the JPI “More Years, Better Lives”. The aim of Joint Programming is to making better use of Europe’s limited R&D funds through enhanced coordination and cooperation of research programmes in strategic areas. Joint Programming targets national public research and European programmes first and foremost. A group of member states taken up this approach and presented a proposal for a new Joint Programming Initiative (JPI) under the title “More Years, Better Lives – the Potentials and Challenges of Demographic Change” to the Joint Programming Group (GPC) of ERAC in the beginning of 2010.

The proposal discussed the scope and need for a more coherent European approach.

Exchange Programme

HOPE EXCHANGE PROGRAMME – 36TH EDITION

In 2017, the HOPE Exchange Programme reached its 36th edition. It welcomed 120 healthcare professionals from 18 European countries and focused on the theme "Organisational innovation in Hospitals and Healthcare".

The HOPE Agora 2017, the HOPE Exchange Programme closing event, took place at the Trinity College in Dublin, from 11 to 13 June 2017 and was hosted by the Health Management Institute of Ireland (HMI). The main theme was on innovations in organisation and management that the Exchange Programme participants have encountered during their stay in their host country.

During the two-day conference, the 2017 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, such as:

- Jim Breslin, General Secretary, Department of Health of Ireland.
- Dr. Aine Carroll, National Director of Clinical Strategy and Programmes, Health Service Executive;
- Richard Corbridge, Chief Information Officer, Health Service Executive and Chief Executive Officer, eHealth Ireland;
- Deirdre Glenn, Director, Lifesciences & Food Commercialisation and Lifesciences Sector Manager, Enterprise Ireland;

Karin Jay, Senior Director, Senior Director, International Business Development and Operations, Planetree;

Presentations of the findings focused on Organisational Innovation in Hospitals and Healthcare. Innovations were identified in the fields of patient care, clinical work, nursing, human resources, information systems, drug management, laboratory operations, finances, quality management, and patient involvement.

HOPE Agora 2017 World Café in Dublin.

HOPE Agora 2017 Conference in Dublin.

HOPE Agora 2017 Conference in Dublin.

Conferences

STUDY TOURS

LEAN MANAGEMENT IN HOSPITALS IN LYON

The Hospices Civils de Lyon and the French Hospital Federation organised on 2 and 3 February 2017 a HOPE study tour on Lean Management.

Created by Toyota in the 1970s, Lean Management is a method of organizing work that intends to improve production with fewer resources. To this end, Lean Management relies on the active participation of all stakeholders to optimize the overall performance of organizations and reduce waste. While many French companies have already adopted lean management, what about the first experiments conducted in the French public hospitals?

This HOPE study tour was an opportunity for European professionals to discover a successful experience of Lean development in public hospitals on site. In addition to meeting a number of management and field staff, this study tour made it possible to understand the contribution of Lean Management in hospitals and to cover the issues raised by its implementation in one of Europe largest university hospital group.

Hospices civils de Lyon, the second largest university hospital in France, integrate all disciplines, and bring together 14 multidisciplinary or specialized establishments. They employ more than 22,000 professionals with the most advanced equipment.

QUALITY AND SAFETY

PAQS ASBL organised a HOPE Study Tour on Quality and Safety on 4 and 5 May 2017 in Brussels. PAQS ASBL is a newly created organization bringing together most healthcare stakeholders in Brussels and Wallonia with the objective of improving quality and safety in healthcare.

During those two days, participants to the study tour learnt about how things are currently organized in Belgium, which policies have been implemented for which results, and how future policies may look like. Some participants also briefly presented the Quality and Safety policies existing in their countries and exchanged opinions and ideas on how things are evolving throughout Europe.

OULUHEALTH ECOSYSTEM AND OULU UNIVERSITY HOSPITAL TESTLAB

HOPE organised a study tour in Oulu (Finland) on 1 and 2 June 2017 to present the OuluHealth Ecosystem and Oulu University Hospital TestLab.

During the study tour, participants had the possibility to understand the way the Healthcare Ecosystem is designed in order to meet the needs and challenges of the future, how the testing laboratory is connected to serve the University Hospital activity, and how the Oulu University Hospital will be renovated by 2030.

The OuluHealth ecosystem comprises several stakeholders from academia, the public sector, and the private sector. The principal idea is to facilitate open collaboration and to accelerate innovation by bringing together various partners able to contribute to the needs of the health care sector. The ecosystem approach enables the combination of expertise from wireless information technologies and life science to introduce smart ICT solutions for delivering advanced, personalised, connected health service solutions.

CONFERENCES CO-ORGANISED BY HOPE

IMPROVING PATIENT ACCESS TO RARE DISEASE THERAPIES

To mark the occasion of Rare Disease Day 2016, HOPE co-organizes with Eurordis the 2nd Multi-Stakeholder Symposium on Improving Patient Access to Rare Disease Therapies in Brussels.

The event took place from 22 to 23 February 2017 with the collaboration of a range of multi-stakeholder partners. Eurordis brought together a unique combination of nearly 300 patient advocates, academics, policymakers, industry representatives, payers and HTA bodies and aimed to develop sustainable and durable solutions to improve patients access to rare disease therapies across Europe.

Ms. Karolina Hanslik from DG SANTE speaking at Eurordis event

HEALTH PROMOTING HOSPITALS 2017

The 25th anniversary of the International Health Promoting Hospitals (HPH) Conferences was held in Vienna, from 12 to 14 April 2017. HOPE is member of the HPH Conference Scientific Committee and was co-organiser of the event.

Health Promoting Hospitals 2017 Conference

4TH EUROPEAN HOSPITAL CONFERENCE

The 4th European Hospital Conference (EHC) took place on 16 November 2017 in Düsseldorf, as part of MEDICA 2017 and the 40th German Hospital Conference. The EHC addressed in the past different political, medical and economic topics from across all of Europe. The event was dedicated this year to the topic "Chances and Challenges of E-Health".

The European Hospital and Healthcare Federation (HOPE) was co-organising the event with the European Association of Hospital Managers (EAHM) and the Association of European Hospital Physicians (AEMH). Eva Weinreich-Jensen, President of HOPE presented the point of view of hospitals and chaired the afternoon session on the specific national E-Health Concepts.

4th European Hospital Conference

AMR AND WORKPLACE LEARNING

On 22 November 2017, the European Hospital and Healthcare Federation (HOPE) and the European Hospital and Healthcare Employers' Association (HOSPEEM) organised a workshop "AMR and workplace learning-The case for a multi-professional approach in hospitals" hosted by MEP Soledad Cabezón Ruiz (Spain, S&D) at the European Parliament in Brussels. This Joint Workshop was connected to the 2017 European Antibiotic Awareness Day (EAAD) and the launch of the new EAAD Toolkit for Hospital Staff.


AMR and Workplace Learning workshop

Pascal Garel, HOPE Chief Executive, emphasized the importance of inter-professional cooperation in combatting AMR while workshop moderator Jesper Rijpma, Senior advisor public affairs at Dutch Hospital Association (NVZ), defined the AMR phenomenon as a threat for society in the form of a "tsunami in slow motion".

The panellist were: the Head of the Disease Programmes on AMR and Health-Associated Infections (HAI) at ECDC, Dominique Monnet; Angela Bolufer de Gea from the AMR Task Force of the European Commission, the CEO of the Platform for Continuous Improvement of Quality of Care and Patient Safety (PAQS) in Belgium, Denis Herbaux; Marcel Mennen from the National Institute for Public Health and Environment Centre for Safety and Security in the Netherlands, Member of the European Parliament (MEP) Karin Kadenbach (S&D, Austria) and the Secretary General of the European Hospital & Healthcare Employers' Association (HOSPEEM), Tjitte Alkema.

AMR and Workplace Learning workshop

SOME CONFERENCES WITH HOPE AS A SPEAKER

IMPACT OF THE DIGITAL HEALTHCARE REVOLUTION – PUBLIC HEARING AT ECSC

HOPE was invited to speak at the European Economic and Social Committee on 15 June 2017 for a public hearing under the responsibility of Martin Siecker, President of the Section for the Single Market, Production and Consumption.

The meeting was chaired by the rapporteur, Mr Alain Coheur who presented he preliminary draft opinion on the Impact of the digital healthcare revolution on health insurance.

HOPE Chief executive raised the key issues for the workforce: new workforce skills and competences to interpret, communicate and act on health data, working more in a team due to more data, capacity building with education and continuous professional development around those two issues as well as on the relation patient/family/carers and health and social care professionals. He took as examples two current EU projects in which HOPE is involved: ICT4LIFE and MedEye.

The views of the European Commission were both from Directorate General CONNEXT and Directorate General SANTE mentioning in particular a public consultation soon to be published.

SAFER EUROPE WITHOUT FALSIFIED MEDICINES

On 8 and 9 October 2017, The Estonian State Agency of Medicines and the Association of Pharmaceutical Manufacturers in Estonia have invited HOPE to speak at the international Conference in Tallinn organised together with the Ministry of Social Affairs during the period Estonia is holding the presidency of the Council of the EU.

The main focus of the Conference was the implementation of safety features appearing on the packaging of medicinal products for human

use in the European Union that come into effect February 2019 (Commission Delegated Regulation (EU) 2016/161). The practical aspects of the preparations made by governments and stakeholders, also including the legal and IT aspects and challenges that need to be solved in Member States, were also addressed.

EUROPEAN REFERENCE NETWORK WORKSHOP

HOPE CEO was invited on 16 and 17 November 2017 in Rotterdam Erasmus Medical Centre to speak during a workshop co-organised with the European Commission devoted to the European Reference Networks.

This discussion helped to better understand the benefits and impact of the ERNs and its Members in the Hospitals host of the ERN Coordinators and Members, but also to identify best practices and possible actions of Hospital board members and CEOs to support the ERNs members.

Some of the outcomes of the discussion were to align goals and activities in a win-win patient centred strategy of ERNs, Member States and Hospital boards and to discuss future actions, links and next steps as well as the feasibility to create an ERN Hospital Boards Group.

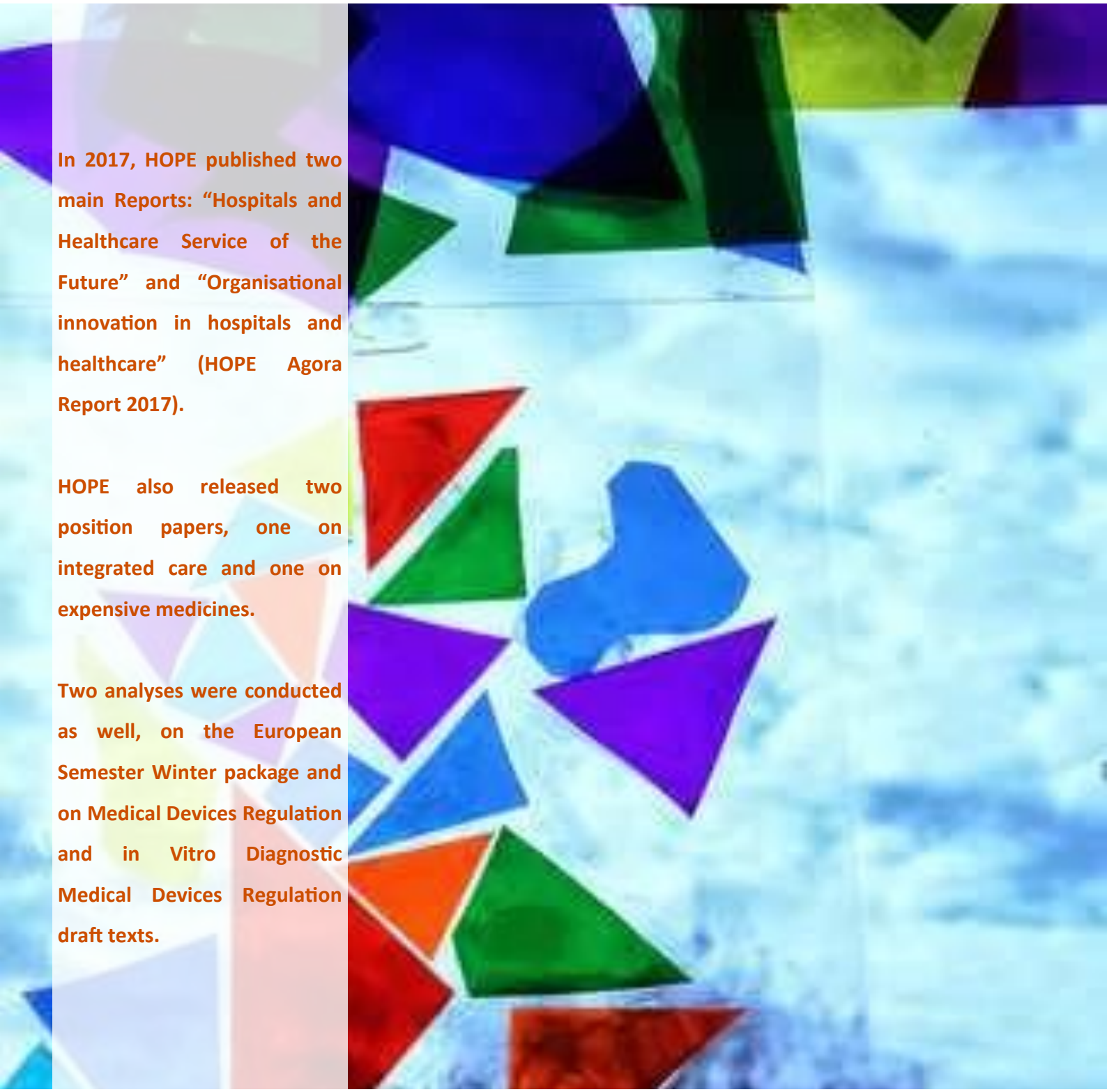
PERSONALISED MEDICINE CONFERENCE

HOPE President Eva Weinreich-Jensen spoke at the 1st Inaugural European Personalised Health Congress: Personalising Health taking place from 27 to 30 November 2017 in Belfast. A parallel session organised by HOPE was devoted to Converting Hospitals to a Personalised Health Agenda.

HOPE Chief Executive Pascal Garel chaired the session for the four speakers. Eva Weinreich-Jensen (President, HOPE & Senior Advisor, Danish Regions) presented unique possibilities for realizing the potential of personalised medicine in the Danish healthcare system.

Chapter 4

PUBLICATIONS



In 2017, HOPE published two main Reports: "Hospitals and Healthcare Service of the Future" and "Organisational innovation in hospitals and healthcare" (HOPE Agora Report 2017).

HOPE also released two position papers, one on integrated care and one on expensive medicines.

Two analyses were conducted as well, on the European Semester Winter package and on Medical Devices Regulation and in Vitro Diagnostic Medical Devices Regulation draft texts.

Publications

HOSPITALS AND HEALTHCARE SERVICES OF THE FUTURE

In May 2017, HOPE released a publication on "Hospitals and Healthcare Services of the Future". Taking into account different factors like scientific innovation, socio-economic factors, demography, financial sustainability, the report tries to foresee the possible evolution of hospitals and healthcare services.

Hospitals and healthcare services are not passive in the face of current and coming challenges, namely greater health needs, fewer resources and changing social values. The significance of the upheavals caused by transformations in medicine call for critical reflection as well as political, social and humanistic consideration that measure up to the challenges to be overcome. It is all the more necessary to mobilise civil society given the significant ethical impacts of the progress being made. Seen from this stance, and in spite of the growing number of bodies dedicated to these issues, these changes are applied with relatively little collective debate. The reinforced position and role of the patient in healthcare systems, the critical importance of streamlining healthcare systems and the need to promote medical research all require vigilance.

HOPE AGORA REPORT 2017: ORGANISATIONAL INNOVATION IN HOSPITALS AND HEALTHCARE

In October, HOPE released the HOPE Agora Report 2017: "Organisational Innovation in Hospitals and Healthcare".

The HOPE Agora 2017 took place at the Trinity College in Dublin from 11 to 13 June. It was hosted by the Health Management Institute of Ireland (HMI) and focused on the "Organisational Innovation in Hospitals and Healthcare", and more precisely on the implementation of new methods or processes in relation to the use of new technologies, health services provision, human resources management, and patients' empowerment.

The Agora concluded the 36th edition of the HOPE Exchange Programme. This edition welcomed more than 120 health professionals from 18 European countries. During the Agora, HOPE Exchange participants reported on their 4-week stay abroad. For their presentations, they were asked to identify examples within their host country's healthcare system inspiring for the challenges they face at home. Without judging the system of the country visited, participants described what they would like to see implemented in their own country, region, institution, or ward.

POSITION PAPERS

EXPENSIVE MEDICINES: HOSPITALS ARE CONCERNED

HOPE adopted in January 2017 a Position Paper "Expensive Medicines: Hospitals are concerned".

This two-page document aims to call for greater attention on the consequences that several "innovative" medicines can bring about in hospital activities. Expensive medicinal products pose new challenges influencing hospitals financing models and organisation, also potentially leading to treatment rationing, unethical and ineffective from a public health perspective.

The Position Paper provides an overview of the current situation at European level - welcoming the 17 June 2016 Council conclusions - and calls for further development of Member States driven voluntary cooperation between relevant authorities and payers. Finally, it gives recommendations on possible actions to take at hospital and healthcare services level to address this issue.

HOPE VISION ON INTEGRATED CARE

HOPE adopted its “HOPE vision on integrated care” in January 2017. The document was presented for the first time during the ICT4Life project event on the challenges of integrated care held at HOPE central office on 19 January 2017.

The document outlines the complexity of the concept of integrated care. Despite various goals are being given to integrated care services – from enhancing quality of care and quality of life to creating system efficiency for patients with long term problems – the paper also addresses the lack of evidences when it comes to better financial management in the health care sector thanks to integrated care.

Finally, the document describes different trends in the European Union regarding integration of care and provides recommendations for its effective implementation, which should not consist in a simple shift from inpatient to ambulatory and outpatient care, but requires investment in holistic care, including health promotion and ill health prevention strategies that support people’s health and well-being.

ANALYSES

2017 EUROPEAN SEMESTER WINTER PACKAGE – HOPE STRATEGIC NOTES

On 22 February 2017, the European Commission released the European Semester Winter Package. HOPE decided to gather in a strategic note the improvements reported by the Commission in the implementation of health-related reforms in the Member States.

According to the Commission Country Reports, during the 2016 European Semester, Member States showed greater engagement in the implementation of structural reforms as well as improved absorption of the European funds for the purpose.

However, Member States that received Country-Specific Recommendations in 2016 to reform their health and long-term care systems made only limited or some progress in this regard (Summary Table 2016 CSR implementation).

ANALYSIS OF THE MEDICAL DEVICES REGULATION AND IN VITRO DIAGNOSTIC MEDICAL DEVICES REGULATION DRAFT TEXTS

On 25 May 2016, the European Parliament and the European Council jointly announced the agreement reached about the Regulations for Medical Devices (MDR) and In Vitro Diagnostic Medical Devices (IVDR). Following the agreement, the draft texts of the MDR and the IVDR were published on 15 June 2016 and the consolidated texts on 27 June 2016.

In January 2017, prior to the formal publication of the Regulation final texts, HOPE has released an analysis of the draft texts. It gives an overview of the main changes introduced by the Regulations, and the foreseen effects on the different actors involved. While the Regulations are largely welcomed as they are expected to provide more safety for patients, HOPE underlines that pre-market scrutiny of medical devices keeps being based on decision made private companies and not public authorities. Also, while the Regulation is likely to benefit the healthcare professionals working conditions, it is likely to highly affect manufacturers.

General Report on the Activities of the European Hospital and Healthcare Federation 2017

hope
European Hospital and Healthcare Federation