General Report

on the Activities of the

European Hospital and Healthcare Federation

2012

hope
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General Report on the Activities of the European Hospital and Healthcare Federation — 2012

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Introduction

The crisis and its impact on health were at the core of the debates and priority setting for the year 2012. In January, HOPE published an updated review of the country-by-country crisis impact. This was later discussed during the June and October meetings of the Board of Governors. In the context of the financial and economic crisis, and to improve equity between members, Governors decided in June to adopt a new criterion in the fee mechanism, GDP per capita.

2012 was an active year with regard to the major healthcare related issues on the EU agenda: transposition of the Cross-Border Directive, revision of the Public Procurement Directive, revision of the Professional Qualifications Directive, revision of the Directive 2002/96/CE on Waste Electrical and Electronic Equipment (WEEE), proposal for Medical Devices Regulation, Data Protection as well as several pharmaceutical issues, such as the revision of the Clinical Trials Directive, Pharmacovigilance, the Directive of Pricing and Reimbursement of Medicines, among others.

Leaving aside the legislative agenda, 2012 was the European Year for Active Ageing and Solidarity between Generations. HOPE has greatly contributed to this issue with a variety of actions: joining the multi-stakeholder platform "European Innovation Partnership on Active and Healthy Ageing (EIPAHA)" and the AgeingWell project, a European network focused on improving the quality of life of elderly people by promoting the market uptake of ICT solutions for Ageing Well. This was also HOSPAGE "Ageing health workforce - ageing patients: multiple challenges for hospitals in Europe", the topic and final conference of the Exchange Programme 2012 on, hosted by the German Hospital Federation in Berlin with the participation of high level healthcare institutions and policy makers.

2012 was also a very productive year for projects. Two were successfully completed : EURHOBOP, producing a cardiology benchmarking tool, and Managed Outcomes, a project that aims to describe, analyse and compare the way Member States provide services and how they are prepared to address the present and future health service needs. Other projects started: the telemedicine thematic network MOMENTUM, the eHealth thematic network AgeingWell, the Joint Action on Patient Safety and Quality of Care (PaSQ), the cross-border care project HoNCAB, and the project Health Comm "Improving Crisis Communication Skills in Health".

Other projects were completed and accepted for co-funding: the Joint Action Health Workforce Planning and Forecasting, and EUROTRACS ("EUROpean Treatment & Reduction of Acute Coronary Syndromes Cost Analysis"). HOPE continued its work in DUQuE, as well as in the European Partnership of Action Against Cancer (EPAAC) where HOPE is specifically involved in the identification and promotion of good practices in cancer related healthcare. In October, the European Commission published a booklet presenting a selection of 33 successful projects co-financed by the EU Health Programmes with HOPE being a partner in several of them.

Apart from its annual HOPE Agora that took place in Berlin, HOPE participated in 2012 in the organisation of the conference Innovation in Healthcare without Borders and of the European Antibiotic Awareness day and contributed to many others as a speaker.

HOPE increased its visibility in 2012 with "HOPE Update". This electronic bulletin on the main activities of the organisation was launched targeting the European Institutions and health organisations settled in Brussels. HOPE also looked for innovative solutions to promote its Exchange Programme and developed three videos: one explicative video of 15 minutes, two other short videos of five minutes each, one targeting participants and the other one targeting hosts.

HOPE also published several reports: its annual publication "Hospital Healthcare Europe", "Personalised Medicine in European Hospitals", a report on Medical Equipment Donation, and the report of the HOPE Agora 2012 and HOSPAGE conference.

Chapter 1

LIFE AND GOVERNANCE

2012 was an enlarging year with HOPE welcoming a new member

Governance

HOPE gathers 35 national organisations of hospital and healthcare services — public and private — from 29 countries. In 2012, HOPE welcomed a new member: the Federation of French Comprehensive Cancer Centres. UNICANCER brings together 20 centres, one from each region. These Cancer Centres are private, not-for-profit entities but operate very closely with the Government by which they are approved. They bear a public duty for care and research with 200 clinical trials on going.

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 *Board of Governors* (BoG) consists of the President and the Governors, one for each EU Member State. It is the forum for all major policy decisions. The BoG met twice in 2012: on 11 June in Berlin (Germany) as part of the HOPE Agora 2012. The second meeting took place on 22 October in Warsaw (Poland).

Board of Governors Berlin

From left to right: Dr. György HARMAT (Hungary), Mr. Marc SCHREINER (Germany), Mr. Simon VRHUNEC (Slovenia), Mr. Francisco Antonio MATOSO (Portugal), Mrs. Eva M. WEINREICH-JENSEN (Denmark), Dr. John M. CACHIA (HOPE Past-President – Malta), Dr. Ulrike SCHERMANN-RICHTER (Austria), Dr. Jaroslaw FEDOROWSKI (Poland), Mr. Georg BAUM (HOPE President – Germany), Ing. Joe CARUANA (Malta), Mrs. Dr. Sara C. PUPATO FERRARI (HOPE Vice-President – Spain), Mrs. Miek PEETERS (Belgium), Dr. Vesna DJURIC (Serbia), Mr. Pascal GAREL (HOPE Chief Executive), Mrs. Pascale FLAMANT (France), Dr. Urmas SULE (Estonia), Mr. Yves-Jean DUPUIS (France), Mr. Marc HASTERT (Luxembourg), Mrs. Elisabetta ZANON (United Kingdom), Mr. Robbert SMET (Netherlands). Present but missing on the photograph: Dr. Aino-Liisa OUKKA (Finland), Mr. Erik SVANFELDT (Sweden)

In Berlin, HOPE President Georg Baum welcomed new colleagues to HOPE: Mrs. Pascale Flamant, the Chief Executive of the Federation of French Comprehensive Cancer Centres, Mr. Joseph Caruana from Malta, Mr. Robbert Smet from the Dutch Hospitals Association, and Dr. Vesna Djuric, representing the Chamber of Healthcare Institutions of Serbia.

The *President's Committee* (PsC) consists of the President, Mr. Georg Baum, the Vice-President, Mrs.Dr. Sara C. Pupato Ferrari, and three Governors. In June 2012, the mandate of the three sitting members, Dr. György Harmat (Governor for Hungary), Mrs. Eva M. Weinreich-Jensen (Governor for Denmark), and Dr. Urmas Sule (Governor for Estonia), were renewed for a 1-year term.

By decision of the President, two additional Governors became co-opted members for a 1-year term: Ing. Joseph Caruana (Malta) and Dr. Jaroslaw J. Fedorowski (Poland).

The PsC oversees the implementation and execution of the decisions taken by the Board of Governors, co-ordinates the work of the Liaison Officers and the working parties, acts for HOPE, and authorises legal representation. The PsC met in Brussels (Belgium) on 27 April and on 19 September to discuss the agenda of the Boards of Governors and the meetings of the Liaison Officers, and to decide on the priority activities of the organisation.

The network of *Liaison Officers* was created to improve activities and to professionalise them. In 2012, HOPE Liaison Officers met three times: on 15 March in Brussels (Belgium), on 11 June in Berlin (Germany) and on 22 November in Paris (France). At these meetings, Liaison Officers discussed the state of affairs of the projects, the 2012 topics and the transposition of Directives. This was also an opportunity for HOPE to find common positions regarding the Directives under negotiation.

As it does on a regular basis, the network of *National Coordinators* of the HOPE Exchange Programme met twice to work on the HOPE Exchange Programme: on 11 June in Berlin and on 23 November in Paris.

The *Central Office* is based in Brussels. It is organised and directed by the Chief Executive, Pascal Garel, assisted by Mrs. Colberte De Wulf. EU Policies Officer Silvia Bottaro replaced Emilie Vergauwe in October whereas Health Economist Isabella Notarangelo started working at HOPE in December, replacing Gloria Lombardi who left HOPE in August. In 2012, Beatriz Elola, Communication Officer, fulfilled a one year contract. From March to August HOPE welcomed Audrey Hernandez as a trainee.

GOVERNANCE AT THE END OF 2012

President	Mr. Georg BAUM
Chief Executive	Mr. Pascal GAREL

GOVERNORS

Austria	Mr. Nikolaus KOLLER
Belgium	Mr. Willy HEUSCHEN
Bulgaria	Mrs.Dr. Dora KOSTADINOVA
Cyprus	Mrs.Dr. Androulla AGROTOU
Czech Republic	Dr. Roman ZDÁREK
Denmark	Mrs. Eva M. WEINREICH-JENSEN
Estonia	Dr. Urmas SULE
Finland	Mrs.Dr. Aino-Liisa OUKKA
France	Mr. Gérard VINCENT
Germany	Mr. Marc SCHREINER
Greece	Dr. Yannis SKALKIDIS
Hungary	Prof.Dr. György HARMAT
Ireland	Dr. Fergal LYNCH
Latvia	Dr. Jevgenijs KALEJS
Lithuania	Dr. Dalis VAIGINAS
Luxembourg	Mr. Marc HASTERT
Malta	Ing. Joseph CARUANA
Netherlands	Mr. Robbert SMET
Poland	Dr. Jaroslaw J. FEDOROWSKI
Portugal	Mrs.Prof. Ana ESCOVAL
Romania	Dr. Eduard ARMEANU
Slovakia	Prof. Marián BENCAT
Slovenia	Mr. Simon VRHUNEC
Spain	Mrs.Dr. Sara C. PUPATO FERRARI, Vice-President
Sweden	Mr. Erik SVANFELDT
United Kingdom	Mr. Mike FARRAR

HEADS OF DELEGATIONS

Observer member	
Switzerland	Dr. Bernhard WEGMÜLLER
Consultant member	
Serbia	Prof. Georgios KONSTANTINIDIS

Chapter 2

INFLUENCE

A major part of HOPE's work is to help shape EU law to take account of the realities of healthcare.

To achieve this, HOPE has to follow the development of both hard and soft law.

Hard law is legally binding to various degrees whereas soft law isn't.

However, soft law instruments do carry some authority. With the long decision process that is specific to the EU it is difficult to know whether soft law will become hard.

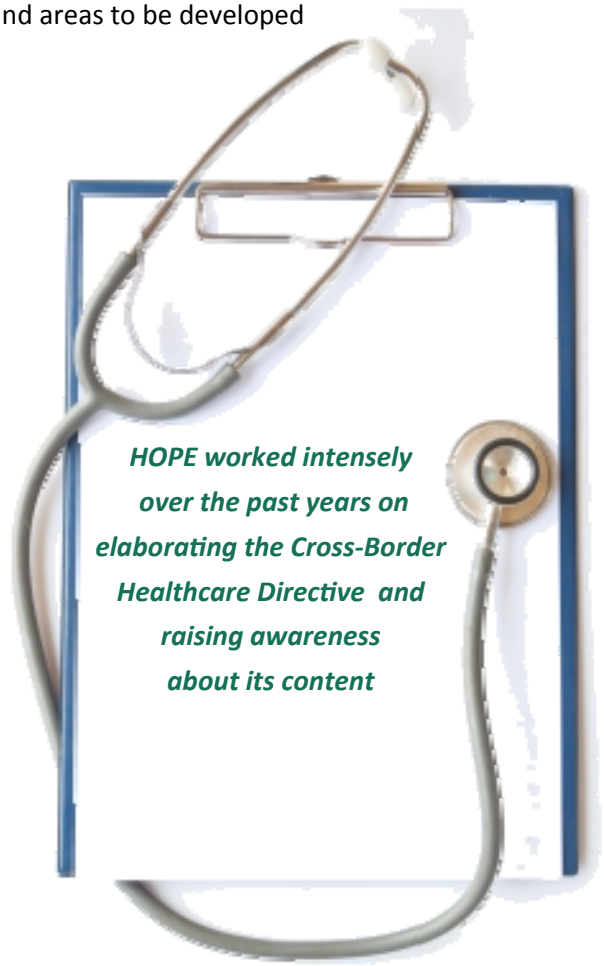
Hard Law

DIRECTIVES AND DECISIONS ADOPTED

CROSS-BORDER HEALTHCARE DIRECTIVE

The Directive 2011/24/EU on Patients' Rights in Cross-Border Healthcare adopted in March 2011 is one of the most controversial pieces of European healthcare legislation in recent years. Many questions remain unanswered on its possible impact. 2012 was then the second year for the preparation of the Directive's transposition, a period due to run until October 2013.

HOPE worked intensely over the past years on elaborating the Directive and raising awareness about its content. Unlike for most Directives, this one was followed closely by HOPE well after its adoption. This was a core topic during each meeting of Liaison Officers and Governors. It was taken as the subject of an October seminar held in Warsaw (Poland) following the Board of Governors' meeting. Underpinning HOPE's work were the exchanges about the Directive's transposition in Member States along with the cooperation activities defined under it, and areas to be developed by the Commission.



European Reference Networks

Article 12 of the Directive 2011/24/EU on the application of patients' rights in cross-border healthcare gives incentives to Member States to reinforce the continued development of European Reference Networks.

To prepare its decision on this issue the Commission organised several initiatives.

HOPE was first invited to the workshop on European Reference Networks held on 30 and 31 January 2012 in Brussels organised by Directorate General Health (DG SANCO)**.** The aim of the workshop was to exchange points of view, experiences and thoughts among experts and persons with very different backgrounds and expectations on the issue of Centres of Reference. The outcome of the brainstorming was used as input and support for preparing the Commission's decision on criteria and conditions for the establishment of European Reference Centres (ERC).

These centres should facilitate improvements in access to diagnosis and delivery of high-quality, accessible and cost-effective healthcare in the case of patients who have a medical condition requiring a particular concentration of expertise or resources. It is important to point out that the Directive is not aiming to "create" new centres, but to identify already established centres of expertise and encourage voluntary participation of healthcare providers in the future European reference networks.

HOPE and its members also worked on a publication, edited by the European Observatory on Health Systems and Policies "*Building European reference networks in healthcare. Exploring concepts and national practices in the European Union*". The book was edited by HOPE Chief Executive Pascal Garel and a team of the Observatory staff, including Willy Palm, Irene A. Glinos, Reinhard Busse, Bernd Rechel and Josep Figueras.

This book examines the ways in which reference networks have developed in European countries, for what kind of medical conditions or operations, the networks' rationale, the regulatory and administrative processes involved, and the financial arrangements needed. This study outlines the key policy implications and challenges of developing the concept of reference networks at national and European levels, and will assist policy-makers, health professionals, administrators and others involved in implementing the Directive.

Finally, on 23 November 2012, the European Commission launched a stakeholder consultation on the implementation of European Reference Networks to seek opinions and contributions of interested parties, based on evaluated experiences, regional or national models, technical and professional standards, criteria or recommendations which could provide inputs and facilitate the definition of technical and quality criteria (scope, general and disease specific elements).

Health technology Assessment

Article 15 of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare plans a permanent network on HTA in the EU by the end of 2013. To achieve this, the European Commission (DG SANCO) financed an economic and governance analysis on setting up a permanent secretariat for European cooperation on Health Technology Assessment (HTA). The survey compared three different scenarios of increasing intensity of cooperation and alternative options for hosting such a permanent secretariat.

Improving Health Technology Assessment (HTA) in Europe has been one of the highest demanded issues from research last year. There were a lot of complaints concerning the high variability of HTA with 96 different drug evaluation organisations, each with different levels of HTA and different outcomes from the different reimbursement agencies in Europe.

Back in 2006 already, the European Union and Member States established the EUnetHTA project to create a sustainable European HTA network. The EUnetHTA collaboration joined forces in 2009 with other partners from the EU Member States and the European Commission to implement the results of the EUnetHTA project and the Pharmaceutical Forum through a Joint Action on HTA 2010-2012 (EUnetHTA JA). HOPE, which was the leader of the Guideline for the Use of Health Technology Assessment in Cross-border Settings (a deliverable of Work Package 5 of the EUREGIO Project published at the end of 2011), became involved in the joint action as a stakeholder.

On April 2012, an interview was set up with HOPE to discuss the following aspects:

- current functioning of the EUnetHTA Collaboration/Joint Action 1;
- costs and benefits of each scenario of cooperation with a specific focus on the societal gains, gains for the HTA network and other;
- costs and benefits of each hosting alternative and specifically synergies that can either be reached or lost through the choice of hosting.

On 10 July 2012, the Eucomed Health Technology Assessment working group organised a multi-stakeholder workshop on stakeholder involvement in HTA. The workshop followed the Directorate-General for Health and Consumers' decision to launch a public stakeholder consultation on "Modalities of stakeholder consultation in the voluntary Health Technology Assessment (HTA) network to be established under Directive 2011/24/EU". Various stakeholder groups representing academia, providers, payers, medical professionals, national associations and European MedTech associations attended the event, where HOPE presented HTA and stakeholder involvement from a providers' perspective in a cross-border context with particular focus on the research which led to the "Guideline on HTA in Cross-Border Regions".

Simulation

At the beginning of June 2012, the European Social Observatory (OSE) released its report on the simulation of the EU Cross-Border Care Directive completed in late November with the contribution of Belgium, France, Germany, The Netherlands, Luxembourg and Spain in which HOPE members were involved . The report highlighted different approaches from stakeholder groups. In areas where purchasers and public authorities made clear that for care provision to be reimbursed it should comply with the conditions as defined by the patients' Member State, the providers were equally insistent that they would not adapt procedures or processes under the conditions of the cross-border patient's domestic health insurer or payer. However, the most striking set of conclusions from the simulation relates to the potential burden for patients travelling under the Directive. Patients will be responsible for many of the details involved in accessing planned treatment across borders: finding information on potential treatments, proving to insurers that the treatment has been carried out and submitting the correct documents were clearly seen to lie with patients. One of the key themes was the need for independent information on reimbursement, treatment, quality and safety, and the national contact points.

The simulation suggests that some of the provisions strongly argued for as the Directive made its way through the legislative process may be less important in practice. It also suggests that the Directive may have an unexpected impact on a number of areas, particularly on domestic health policy.

According to the report, there was a consensus in some areas, which suggests that the Directive will bring substantial legal certainty. This includes areas where tensions in implementation had been predicted such as on the articulation between the Directive and Regulation 883/04, but where, in practice, pragmatic solutions have been found.

With regards to other issues, although there was a large consensus within stakeholder groups in some areas, they had divergent approaches in other areas. For example, whereas purchasers and public authorities made clear that for care provision to be reimbursed it should comply with the conditions as defined by the patients' Member State, the providers were equally insistent that they would not adapt procedures or processes to the conditions of the foreign health insurer or payer of the cross-border patient.

The report also revealed that some of the areas subjected to heavy political wrangling were not seen to have much relevance on a practical level. This includes the provisions allowing Member States under certain conditions to prevent high inflows of patients.

However, the report suggests that in other areas the implementation of the Directive may have an important and largely unpredicted impact on domestic health policy, driving towards greater clarity on defining the benefit package for citizens and on providing information for patients.

The most striking set of conclusions from the simulation relates to the potential burden for patients travelling under the Directive.

One of the key themes to come through the stimulation was the need for independent information for the Directive to function well. This information refers to reimbursement, treatment, quality and safety and the national contact points. Currently, it is often unavailable, even domestically.

The stimulation also showed that the implementation of the Directive has important implications for managing health systems, even though the volumes of cross-border care under the Directive are expected to be relatively small in most countries and regions. In particular, the simulation looked at how the Directive and Regulation will work together, and explored questions about access to care, patient inflows and rare diseases.

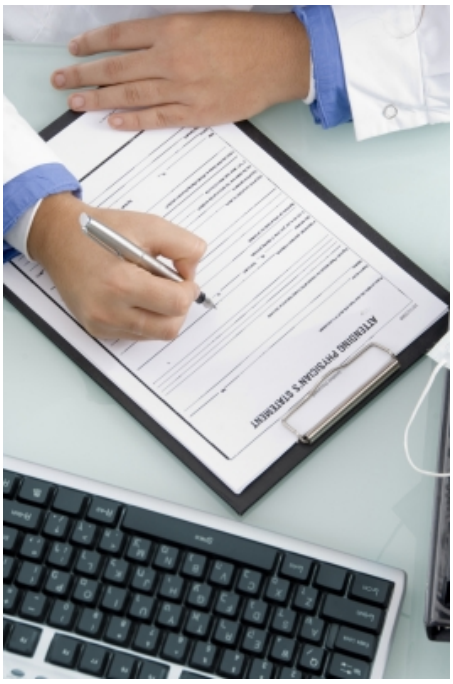
Finally, the report mentioned issues such as prior authorisation, medical records, language and quality and safety, which were also raised by the stimulation.

Recognition of prescriptions

Article 11 of the Directive 2011/24/EU on the application of patients' rights in cross-border healthcare addresses the recognition of prescriptions issued in another Member State.

On this basis the Commission has adopted the following:

- measures enabling a health professional to verify the authenticity of the prescription and whether the prescription was issued in another Member State by a member of a regulated health profession who is legally entitled to do so through developing a non-exhaustive list of elements to be included in the prescriptions and which must be clearly identifiable in all prescription formats, including elements to facilitate, if needed, contact between the prescribing party and the dispensing party in order to contribute to a complete understanding of the treatment, in due respect of data protection;
- measures to facilitate the correct identification of medicinal products or medical devices prescribed in one Member State and dispensed in another, including measures to address patient safety concerns in relation to their substitution in cross-border healthcare where the legislation of the dispensing Member State permits such substitution. The Commission shall consider, inter alia, using the International Non-proprietary Name and the dosage of medicinal products;
- measures to facilitate the comprehensibility of the information to patients concerning the prescription and the instructions included on the use of the product, including an indication of active substance and dosage.



A consultation entitled "Measures for Improving the recognition of prescriptions issued in another Member State" was organised from 28 October 2011 to 8 January 2012 exploring ways to improve the recognition of cross-border prescriptions. The results of the consultation were used for the impact assessment on measures to improve the recognition of prescriptions issued in another Member State. This impact assessment was published later in 2012. The European Commission presented its analysis of the answers to the consultation on 28 March 2012 .

On 20 December 2012, the European Commission adopted the implementing Directive to facilitate the recognition of medical prescriptions issued in another Member State. It represents an essential step forward in achieving the main goal of the recently adopted Directive on patients' rights in cross-border healthcare.

The new rules introduce a common set of descriptive elements to be included in a medical prescription to help identify prescribers, patients and prescribed products. Today, the number of cross-border prescriptions is estimated to be low (between 0,02% and 0,04% of all prescriptions in the EU). According to the Commission, thanks to the new provisions, an estimated extra 200.000 prescriptions will be dispensed every year, benefiting patients and health authorities by avoiding delays, interruptions in treatment, and extra costs.

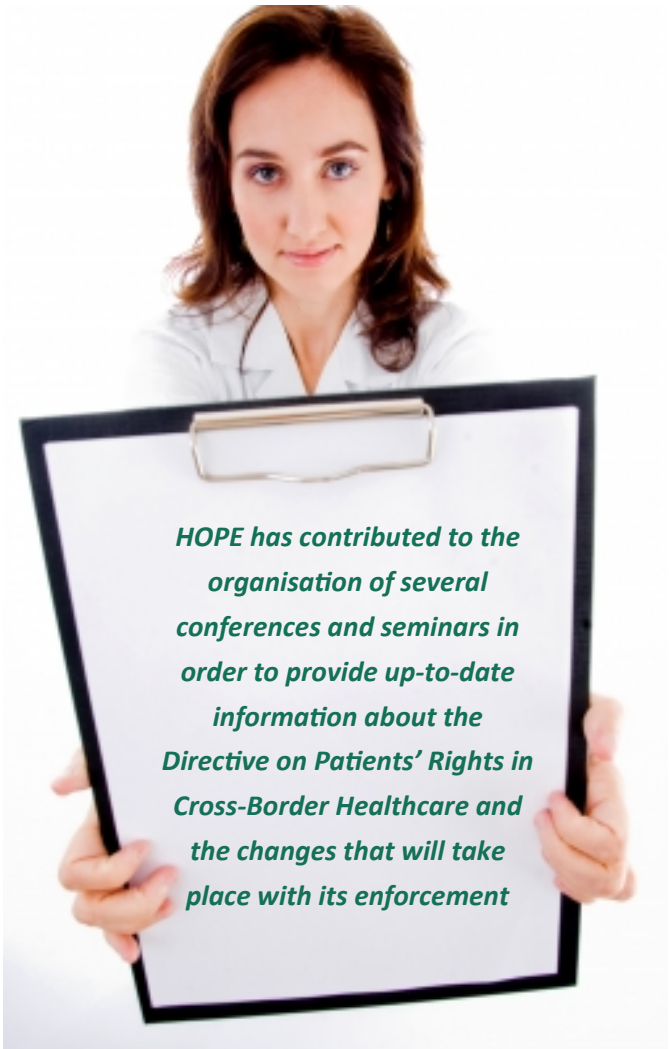
The provisions of the implementing Directive are to be transposed into national law by 25 October 2013.

Conference

HOPE has contributed to several conferences and seminars, in particular the one hosted by the University Medical Centre of Ljubljana (Slovenia) on 25 and 26 October 2012 to give feedback on the changes and challenges this Directive will bring to hospitals and healthcare systems in Europe.

The University Medical Centre of Ljubljana organised a conference on cross-border healthcare in Europe considering that the enforcement of the new European Directive will be an important landmark for the European healthcare system.

The conference provided the most relevant and up-to-date information about the Directive 2011/24/EU on Patients' Rights in cross-border healthcare; enabling healthcare institution managers, health funds management, patients, health systems regulators, healthcare providers and experts to thoroughly prepare their institutions and staff. It provided participants with all relevant information and facts regarding the changes that the new European Directive will bring about, guiding them and providing various perspectives on the upcoming Directive by competent international lecturers and experts in various fields of the healthcare system.



ENERGY EFFICIENCY DIRECTIVE

An important piece of legislation was also the Directive on energy efficiency. The Directive aims at enabling the EU to achieve its indicative objective of 20% energy savings by the end of the decade and possibly save the EU some 50 billion Euro per year through binding measures on energy savings, such as the renovation of public buildings, energy-saving programmes for public services, and energy audits for large companies.

The Directive compels Member States to develop three year plans (2014, 2017 and 2020) for energy efficiency, in order to reach the 20% target. In 2014, the Commission will take stock of progress made and may propose other measures, including binding national objectives, should the EU come off track.

Under these plans, Member States would have to establish long term roadmaps for the renovation of buildings.

Member States would have to renovate 3% of the total floor area of "heated and/or cooled buildings owned and occupied by their central government" (administrative departments whose responsibilities cover the entire territory of a Member State). This will apply to buildings with a "total useful floor area" of more than 500 m^2, and as from July 2015, of more than 250 m^2. However, Member States will also be able to use alternative means to achieve equivalent energy savings.

In the short term, the 3% rate of annual renovation of public buildings is strictly limited to the buildings of central national authorities. Public authorities should also set an example with regard to public procurement by buying greener goods and services, with the article of the text on this being reviewed in 2015.

On 11 September 2012, the European Parliament meeting in Strasbourg adopted the Energy Efficiency Directive by 632 votes in favour, 25 against and 19 abstentions.

On 4 October 2012, the Employment, Social Policy, Health and Consumer Affairs Council (EPSCO) endorsed the Energy Efficiency Directive, after adoption by the European Parliament on 11 September.

It establishes a common framework of measures for the promotion of energy efficiency within the European Union in order to achieve its 2020 20% headline target on energy efficiency and to pave the way for further energy efficiency improvements beyond that date.

Member States will have to comply with the provisions of this Directive within 18 months from its coming into effect (tentatively Spring 2014).

WEEE DIRECTIVE

On 19 January 2012, the European Parliament endorsed the electrical and electronic waste collection and recycling targets set by the proposed revision of the Waste Electrical and Electronic Equipment Directive (WEEE), putting an end to heated negotiations with the Council of Ministers.

EU legislation restricting the use of hazardous substances in electrical and electronic equipment and promoting the collection and recycling of such equipment has been in force since February 2003. However, in spite of the existence of such rules providing the creation of collection schemes where consumers return their used e-waste free of charge, only one third of all electronic and electrical waste in the European Union was reported as separately collected and appropriately treated.

HOPE has successfully convinced the European Parliament that some measures proposed would have made legitimate repair and refurbishment activities practically impossible

This issue is what led the European Commission to propose the setting up of mandatory rules on the recycling of electronic and electrical equipment, with the objective of increasing the amount of appropriately treated e-waste and reducing the volume going to disposal.

The new target endorsed by the Parliament, an ambitious 85% of WEEE generated, aims to ensure that around 10 million tons, or roughly 20 kg per capita, would be separately collected in 2020. Member States will be required to collect 45% of electrical and electronic equipment put on their markets by 2016, and then achieve 65% by 2019, or may opt alternatively for a target of 85% of waste generated. Some Member States will be able to derogate from these targets where justified by lack of necessary infrastructure or low levels of EEE consumption.

The new WEE Directive also provides tools for Member States to fight illegal export of waste more effectively and calls for greater harmonisation of national registration and reporting requirements for producers of electrical and electronic equipment.

HOPE has successfully convinced the European Parliament that some measures proposed would make legitimate repair and refurbishment activities practically impossible. They had the potential of limiting availability of refurbished systems and increasing costs, as repair of equipment whose warranty period has expired would no longer be possible. It would also limit the medical equipment donation. However, HOPE welcomed more control and harmonisation of exporting procedures, also to improve the way this donation is delivered. In this respect, HOPE published in 2012 a report on Medical Equipment Donation which evidenced the lack of rules in this activity.

The Directive 2012/19/EU was adopted in July 2012 with a transposition period ending on 14 February 2014.

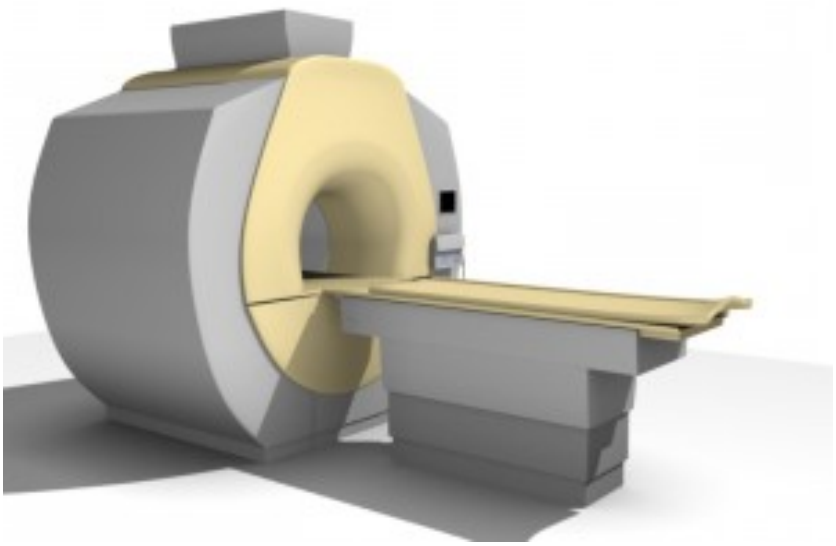
ELECTROMAGNETIC FIELDS DIRECTIVE

The Directive 2004/40/EC was adopted in 2004 alongside other measures aiming at protecting workers from the detrimental health effects of noise, vibration and optical radiation linked to the exposure to electromagnetic fields. However, soon after its adoption, the healthcare community, including HOPE, expressed concerns that the new Directive's overly strict exposure limits would hamper potential medical applications of MRI. As a result, it was decided that the deadline for the transposition of the Directive would be postponed, in order to take into consideration both safety and security dimensions, and the potential of the medical applications of MRI.

On 16 January 2012, the European social partners agreed with the European Commission that the transposition of the Directive on exposure of workers to magnetic fields should be delayed by two years.

On 14 June 2011, the European Commission adopted a proposal for the revision of Physical Agents 2004/EC Directive. The Directive's aim was to restrict occupational exposure of workers to electromagnetic fields because of the related health and safety risks. In its 2011 proposal, the Commission included a derogation from limit values for medical and research-related uses of Magnetic Resonance Imaging (MRI). The revision of the 2004/40/EC Directive results from expressed conerns that the Directive overly restrained the medical uses and applications of MRI.

In a letter addressed to the Commissioner for Employment, Social Affairs and Inclusion, Laszlo Andor, representatives of the trade unions (ETUC), small businesses and crafts (UEAPME), public companies (CEEP) and of BusinessEurope expressed their shared opinion on the delay of the Directive's transposition, which according to them, is "necessary from a practical point of view and to ensure legal certainty".



The social partners, who expressed concerns over the fixed deadline of 30 April 2012 for the transposition of the many amendments that have been made to Directive 2004/40/ECT, explained that "sufficient time is required by the Council and the European Parliament to find a satisfactory agreement".

HOPE attended the Alliance for MRI meeting of 25 January 2012, during which MEP Morin-Chartier (PPE-FR) confirmed the postponement by two years of the transposition of the electromagnetic fields Directive. She stressed however that this decision did not mean that this issue would not remain a priority on the Council's and Parliament's agendas. On 24 January 2012, the MEPs on the ENVI Committee had expressed their support for the revision of the 2004/40/EC through a vote at the European Parliament.

With regard to the exposure limits mentioned in the 2004 Directive, the Alliance for MRI believes that "these exposure limits are detrimental to patient care curtailing the use of MRI in therapeutic applications such as MRI-guided brain surgery or mapping of brain function".

On 4 October 2012, the EU's Employment and Social Policy Ministers agreed, after a lengthy negotiation process, on a general approach on a draft Directive for minimum health and safety requirements regarding the exposure of workers to the risks arising from electromagnetic fields.

During the Council meeting, the majority of the Member States expressed their support to the text prepared by the Cyprus Presidency. The text agreed reviews exposure limitations on the basis of new scientific evidence and provides for derogations, in particular for medical applications using magnetic resonance imaging (MRI), but to a certain extent also for other activities, whenever this can be duly justified.

Finally, a new Directive postponing the transposition of Electromagnetic Fields Directive 2004/40/EC by 18 months, i.e. to 31 October 2013, came into effect on 24 April 2012.

PHARMACOVIGILANCE – NEW RULES ADOPTED

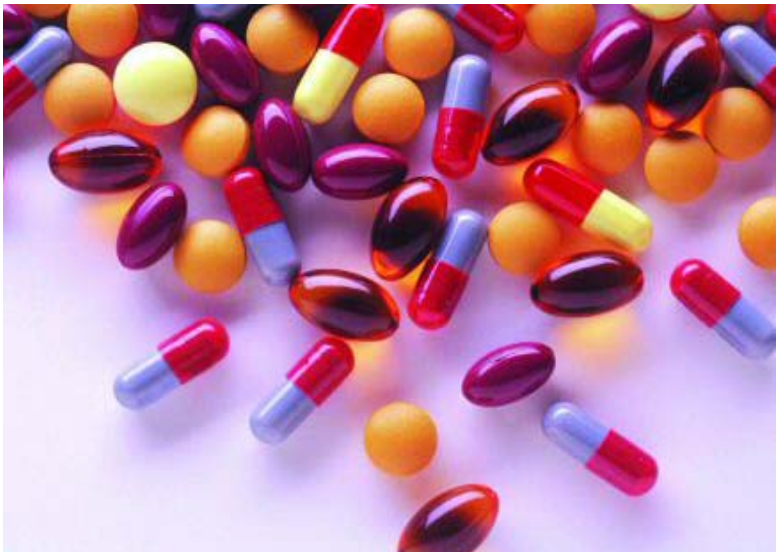
On 11 September 2012, the European Parliament and EU Ministers adopted a report by Linda McAvan (S&D, UK) in the field of pharmacovigilance, aiming at tightening up the European system for picking up and evaluating potential problems with medicinal products in any EU Member States.

The existing legislative framework for pharmacovigilance was revised in 2010 and came into effect in July 2012. However, following the Mediator Scandal in 2011, the European Commission subjected the framework to a stress test that revealed a number of weaknesses that needed to be addressed.

The new rules introduced an automatic emergency procedure, including an EU safety evaluation and possible EU-wide withdrawal if, for example, a Member State were to withdraw a medicinal product from the market. This procedure would also be triggered if a company decided not to renew a marketing authorisation for safety reasons.

In addition, the changes in legislation also forced companies to be more transparent: if a company withdraws a medicinal product from the market, it has to state explicitly whether it has done so for safety reasons. The aim is to determine whether the "commercial reasons" sometimes given by companies for withdrawing a product in fact mask safety concerns.

Finally, the European Medicines Agency will also have to set up a system to ensure that all new medicines and any medicines for which regulators have ongoing safety concerns are labelled with a black symbol, enabling patients and healthcare professionals to identify them.



Following the first reading agreement with the European Parliament in September, the Employment, Social Policy, Health and Consumer Affairs Council (EPSCO) adopted on 4 October 2012 the Regulation and the Directive aimed at strengthening the post-authorisation monitoring of medicines for human use ("pharmacovigilance").

The Council secured that the new provisions lead to the early discovery of potentially dangerous medicinal products and do not lead to adverse reactions going unnoticed due to "information overflow". For this purpose, the new legislation focuses in particular on obligations on marketing authorisation holders in relation to adverse reactions to medicinal products and further clarifies the procedures when competent authorities follow up such reporting.

Marketing authorisation holders withdrawing a medicine from the market will have to notify the competent authority and explain the reasons for their decision even if the withdrawal is voluntary. This also applies if the marketing authorisation holder withdraws a medicine from a third country market. This provision aims to prevent medicines withdrawn for safety reasons going unnoticed by or being hidden from competent authorities.

Finally, in order to better inform patients and medical professionals, additional groups of pharmaceutical products will be included on the publicly available list maintained by the European Medicines Agency (EMA) of medicinal products subject to additional monitoring (for instance for safety reasons).

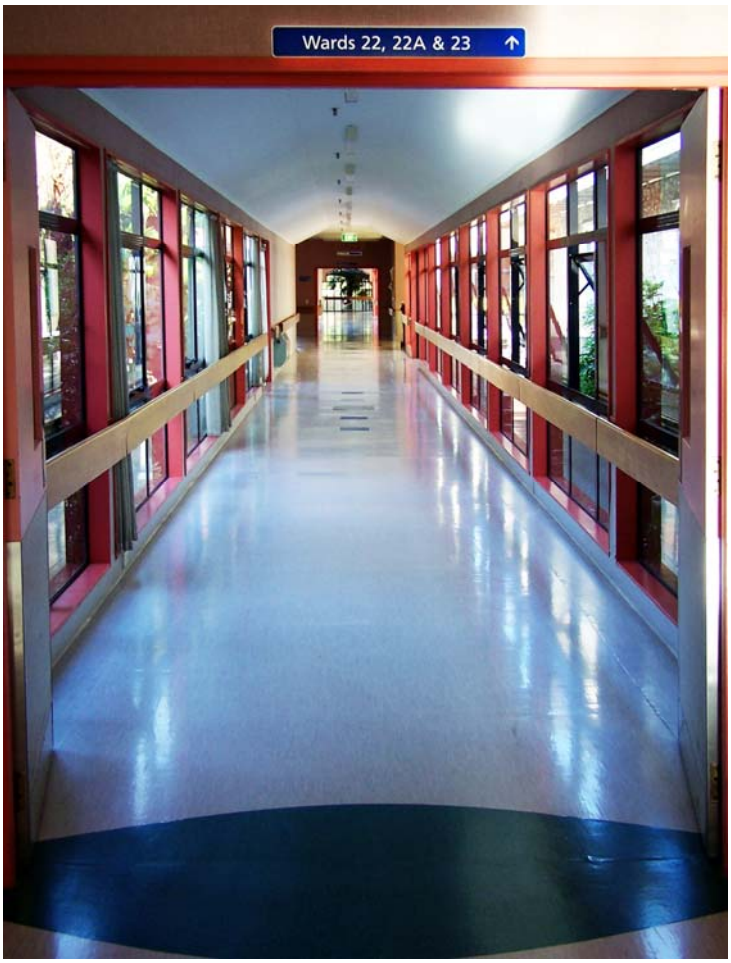
The new Regulation and the Directive of 25 October 2012 come into effect 20 days after their publication in the Official Journal of the EU. The provisions of the Directive will have to be applied twelve months after publication. The main provisions of the Regulation must be applied six months after its entry into force, the rest being applicable from the date of entry into force.

SERVICES OF GENERAL ECONOMIC INTEREST

Following a public consultation and a thorough revision process, the Commission adopted the first three texts of the new SGEI package on 20 December 2011 in order to define the conditions under which State aid in the form of public service compensation can be considered compatible with the EU rules. Hospitals remained exempt from notification.

On 25 April 2012, the Commission adopted, as the final pillar of the package, the *de minimis* Regulation for the field of services of general economic interest (SGEI). The *de minimis* Regulation establishes a threshold below which compensation is deemed no aid.

The Regulation exempts from EU state aid rules aid of up to € 500.000 per company over a three-year period that is granted as compensation for the provision of services of general economic interest (SGEI). Compensation of this magnitude is deemed unproblematic because it is too low to have any impact on trade and competition. This is the last pillar of a new package of state aid rules for SGEI, the bulk of which was adopted in December 2011.



CROSS-BORDER ORGAN TRACEABILITY

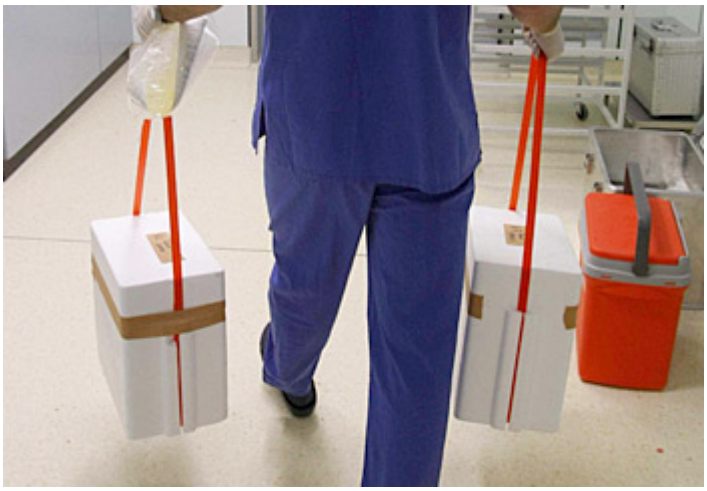
On 10 October 2012, the European Commission adopted implementing measures for Directive 2010/53EU on quality and safety standards for the transplantation of human organs.

It will aim to facilitate cross-border transmission of information about:

- organs and donors (e.g. types of organ – donor's age, gender, health history);
- the traceability of organs once exchanged, in compliance with confidentiality and data security measures;
- reporting of serious adverse events and reactions to specific organs.

The new piece of legislation makes it mandatory for national authorities to exchange and store information on cross-border organ exchanges and to provide a full-time service in cases of serious adverse reactions or events. This will allow medical teams to take appropriate and timely action and to ensure safety of patients.

In 2011, 30.000 organs were transplanted in the European Union, and many of them were transported across borders. It is therefore of utmost importance to ensure EU-wide traceability of organs, particularly to cover cases where recipients suffer from adverse reactions to donated organs.



REGULATION ON STANDARDISATION

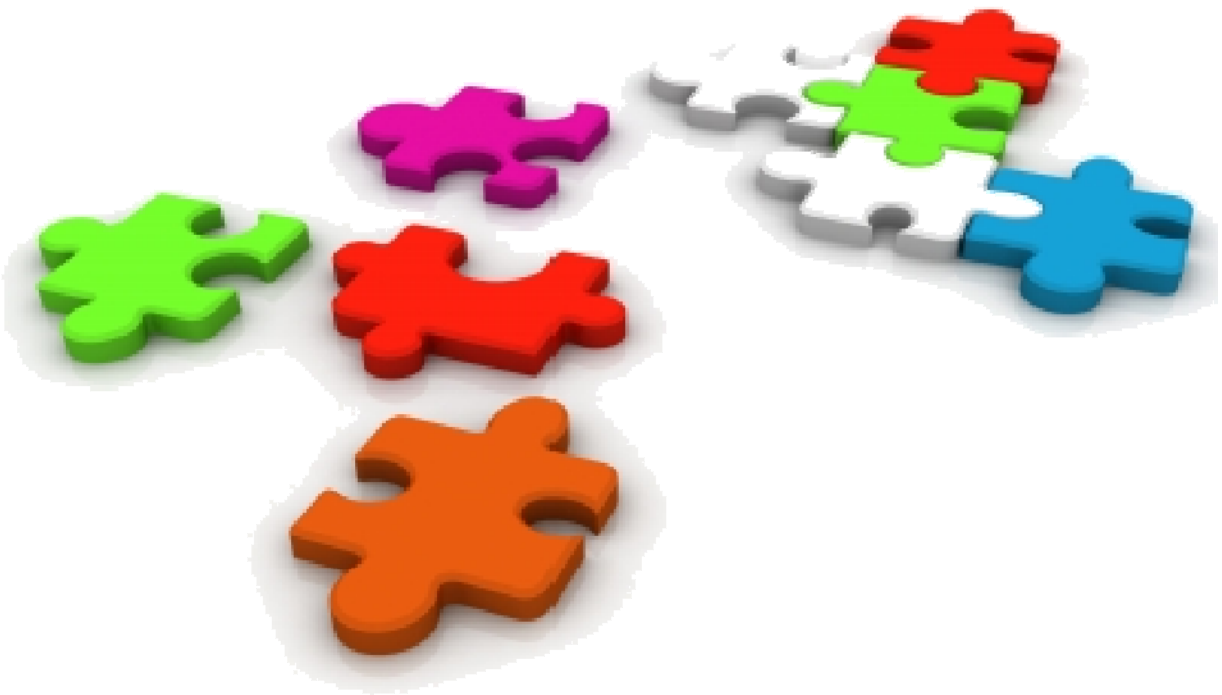
The work of European healthcare stakeholders such as HOPE has been successful in exempting healthcare services from the scope of the provisions envisioned by the legislative proposal

On Thursday 4 October 2012, the Council adopted a Regulation aimed at modernising and improving the European standardisation system. The Regulation adapts the current legal framework to simplify it and to cover new aspects in order to reflect the latest developments and future challenges in standardisation. It includes means for the development of voluntary standards for services and not only for products as it is the case nowadays.

In particular, the Regulation introduces several novelties such as a wider participation and involvement of SMEs, consumer and social organisations in standardisation activities and the possibility of a better use by public authorities of relevant technical specifications when procuring hardware, software and information technology services.

The work of European healthcare stakeholders such as HOPE has been fruitful in exempting healthcare services from the scope of the provisions envisioned by the legislative proposal.

The adopted Regulation has been applicable since January 2013.



PROPOSED DIRECTIVES AND REGULATIONS

PROFESSIONAL QUALIFICATIONS DIRECTIVE

As in the previous year, the modernisation of the Directive 2005/36/EC on the recognition of professional qualifications has been a very much discussed topic in the EU during 2012. The aim of Commission's proposal was to amend the system of mutual recognition of professional qualifications in the European Union aimed at facilitating the mobility of qualified professionals allowing them to exercise their profession in another Member State. But there were many issues remaining very much undefined. HOPE developed a position on several key topics.

HOPE developed a position on several key topics

Most elements were taken into account by the European Parliament

- **Alert mechanism** – Competent authorities should be obliged to inform each other whenever a decision is made to restrict a professional's practice, including when they are allowed to practice but with restrictions.
- **Language testing –** The proposal's wording is very confusing. HOPE considers that even if Member States allow competent authorities to check the language competence of a practitioner, the employer should also be able to perform normal recruitment checks. It is not necessary to specify in the Directive how this should be done.
- **Professional card –** How will this work in practice? There is a clear need to pilot the professional card before its introduction.
- **Assuring continuing competence** – Considering that people who obtained a qualification many years ago but who have not kept their practice up to date are still entitled to benefit from automatic recognition of their qualification and can practise in another Member State, HOPE considers that the Directive should add a requirement under Article 50 that a Member State may require the same evidence of recent practice that it requires of its own nationals.
- **Partial access** – It should be possible to reject partial access not only "by an overwhelming reason of general interest, such as public health" but also with a general exemption for "regulated professions having health and safety implications".
- **Basic education for nurses** – HOPE considers unnecessary the Commission's proposal of raising the minimum requirement to specify that people must have 12 years of general education rather than 10 before commencing training as nurses.
- **Remunerated traineeships** – Remunerated traineeship is not part of the scope of the Directive, which solely deals with fully qualified professionals .

On 10 October 2012, the European Parliament Committee on Internal Market and Consumer Protection (IMCO) discussed the draft report on the recognition of professional qualifications and administrative cooperation through the Internal Market Information System (IMI).

The rapporteur Bernadette Vergnaud (S&D, France) highlighted the following main points:

- partial access, for public health and safety reasons, should not apply to all professions. Derogations could be made on a case by case basis by national authorities;
- language skills tests should be carried out under the supervision of a national competent authority. Verification should be proportionate and at a reasonable cost to professionals.

Other issues such as the 12 years entry level to training for nurses were also discussed.

On 6 November 2012, IMCO discussed the amendments tabled on the draft report on the recognition of professional qualifications and administrative cooperation through IMI.

More than 653 amendments have been proposed, but Mrs. Vergnaud was confident that compromises could be found. Nevertheless, she stressed that more time was needed for discussion. Voting in Committee was then postponed to 2013. Most elements of HOPE's position were taken into account.

MEDICAL DEVICES REGULATIONS

The revision of the medical device legislation was the second major issue on the legislative agenda. A core element of the transparency is the discussion in the medical devices expert group to which HOPE is now invited on a regular basis. An important meeting took place on 10 January 2012 at the height of the PIP breast implants affair. The Commission explained that the scientific expertise of SCENHIR would give advice on the basis of data provided by Member States. This led to discussions on the consequences on the revision of the medical devices Directive. Concerns were expressed by the industry over the risk that this would unnecessarily increase the pressure on medical devices.

The other parts of the meeting dealt firstly with several legislative issues such as the Draft Commission Regulation concerning particular requirements as laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin. However, most of the attention centred on the revision of the medical devices Directive, the implantable medical devices Directive and the in vitro diagnostic (IVD) Directive.

Then on 26 September 2012, the European Commission published two new Regulation proposals, one on medical devices and one on in vitro diagnostic devices aiming at ensuring safer, more effective and innovative medical devices. The key issues were the following:

- wider and clearer scope of EU legislation, to include, for example, implants for aesthetic purposes, and clarified for instance, as regards medical software;
- stronger supervision of independent assessment bodies by national authorities;
- more powers and obligations for assessment bodies;
- clearer rights and responsibilities for manufacturers, importers and distributors;
- extended database on medical devices;
- better traceability of devices throughout the supply chain (a Unique Device Identification system will be introduced to enhance post-market safety of medical devices);
- stricter requirements for clinical evidence;
- adaptation of the rules applicable to technological and scientific progress, for example safety and performance requirements applicable to new health technologies, such as software or nanomaterials used in healthcare;
- better coordination between national surveillance authorities;
- Greater compliance with international guidelines to facilitate international trade.

For HOPE, the Commission has created contradiction at least on one aspect over which HOPE has been constantly vigilant for the last ten years: the reprocessing of so-called “single use” medical devices. HOPE mostly discussed this aspect.

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. Reuse of medical devices results in the reduction of procurement costs, better use of cleaning and sterilisation equipment and in the reduction of inventory, reduction of waste, overall reduction in the consumption of raw materials and primary energy. To be reused some medical devices need reprocessing. Some others, however, cannot be reprocessed without endangering patients.

This would then be simple had some manufacturers not used their right to name as “single use” some medical devices that evidence shows can be safely reprocessed.

The proposed Regulation is unfortunately going a step further in reducing the scope of reprocessing and adds to the confusion. It then seems to create unnecessary burden to healthcare services without increasing patient safety and the quality of healthcare.

If safety is the core concern, then it would be logical to provide detailed guidelines at the European level for such so-called single-use devices for which reuse is possible and feasible.

Today, the declaration as “single-use devices” is not a constituent element of the intended purpose. The intended use of a medical device refers to its function and/or primary effect (the diagnosis, prevention, monitoring, treatment or diminution of diseases/injuries) but not to the frequency of its use. The manufacturer of the device claims responsibility only for its first application. If such a device is reused, the responsibility therefore passes from the manufacturer to the distributor and/or user.

In this context, HOPE reiterates the conviction that manufacturers’ responsibility for their products must be strengthened. Manufacturers must provide more detailed information as to why a medical device cannot be reused or why reuse would threaten patient safety.

WORKING-TIME DIRECTIVE

In December 2011, the EU social partners began negotiations with the aim of updating the EU Working Time Directive (2003/88/EC).

The social partners had originally intended to reach an agreement on appropriate reform of the Directive by September 2012, but the European Commission gave them until 31 December 2012 to do so.

According to article 154 of the Treaty on the Functioning of the EU (TFEU), the European Commission is required to consult with the EU social partners before it can propose any changes to EU social legislation.

Negotiations for the updating the EU Working Time Directive (2003/88/EC), which were supposed to reach an agreement by September 2012, were postponed until 31 December 2012 by the request of the European Social Partners.

DATA PROTECTION REGULATION

On 25 January 2012, the European Commission released its proposal to reform the EU's 1995 data protection rules with many challenges concerning health data. The proposal aims to strengthen online privacy rights, reinforce consumer confidence in online services and boost Europe's digital economy. It also results from the realisation that Member States have implemented the 1995 rules on data protection in diverging ways, leading to a costly administrative burden and fragmented enforcement. One of the reform's key objectives is therefore to reduce unnecessary paperwork and administrative costs and provide a single law, applicable across the EU.

HOPE adopted a position on the Data Protection Regulation mainly covering aspects such as the right to access, the right to be forgotten, data portability, processing activities, impact assessment and research

Among other activities, the reform will establish a single EU-wide set of rules on data protection and reduce red tape. It will also provide easier access for people to their own data and greater possibility to transfer personal data from one provider to another.

"The right to be forgotten": people will be able to delete their data if there are no legitimate grounds for retaining it. EU rules will have to apply if personal data is handled abroad by companies that are active in the EU markets and offer their services to EU citizens. A new Directive, applying general data protection principles and rules for police and judicial cooperation in criminal matters will also be created.

On 26 October 2012, the Council (Justice and Home Affairs) took note of the state of play on the proposal for a Regulation on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation). The choice of legal instrument was raised during the debate. Some delegations expressed their preference for a Directive instead of a Regulation since it allowed for more flexibility where needed. However, some other delegations preferred the choice of a Regulation, as proposed by the Commission. Ministers have already discussed this proposal at the informal Ministerial meeting in July 2012 on the basis of three questions: the administrative burden, the need for special treatment for the public sector and the number of delegated acts.

The proposal is the subject of in-depth discussions by experts in the Working Party on Data Protection, which began under the Danish Presidency and continues under the Irish Presidency.

HOPE worked on a position finally adopted early 2013. HOPE welcomes the Commission's effort to further harmonise data protection requirements in the European Union. HOPE also welcomes the provisions to support healthcare and health research.

However, some areas must be improved to facilitate improvements in care delivery, continuous medical innovation, and to support medical research for the benefit of society. A considerable number of provisions will restrict the availability of health data, delay innovation, create legal uncertainty and increase compliance costs if they remain unchanged.

Access

It will be challenging for healthcare organisations to meet the timeline stipulated in article 12 to respond to access requests. Not only healthcare organisations receive a large number of requests but a significant proportion of health records are not yet available electronically.

Healthcare organisations are working to input all data retrospectively but this is a huge undertaking as it requires entering data for the entire duration of the individual health record of every single data subject within their system as well as from across other systems. The healthcare environment has a multi-contributory records environment.

There is also a need to ensure that any data passed on to the data subject does not inadvertently betray the privacy of third parties who may be mentioned within the record. For this reason, the record may have to be adapted before it is shared with the data subject. More time is required to do this.

Finally, it is unrealistic in a health context to specify how long data may be stored for beyond “as long as may be deemed necessary in order to guarantee the appropriate delivery of healthcare to the data subject”.

Right to be forgotten

Article 17 introduces the right to be forgotten but data subjects have no interest in the permanent erasure of data pertaining to health, particularly where such data is relevant to the effective and appropriate delivery of healthcare.

Deleting data from electronic health records may run counter to patient safety: healthcare providers will not have access to life-saving information on the patient when establishing a diagnosis: allergies, ongoing treatments, specific conditions (e.g. diabetes), blood type, medical history, etc.

Statistical analyses might be “depowered”, particularly in the case of orphan diseases or conditions with difficult inclusion and exclusion criteria, such as paediatrics.

Healthcare providers might object to the deletion of data for liability issues: in case of an investigation, clinicians may need to refer to the patient record to justify their decisions and treatment delivered.

Article 17.3 (b) suggests that the right to be forgotten does not apply in the healthcare context where there is a "public interest". The concept of "public interest" is not clear in the healthcare context. For clarity, HOPE suggests that the right to be forgotten should not apply where the retention of personal data is necessary for health purposes in accordance with Article 81.

Data Portability

With article 18, data subjects would have the right to obtain from the controller a copy of data undergoing processing. The Regulation should introduce the need for a way of verifying the authenticity of health information provided by the data subject, when such information is to be used to receive healthcare or for some kind of formal assessment of the individual.

Processing activities

Health care providers already retain detailed documentation of their processing activities. Article 28 is not clear on whether every individual processing operation should contain the information detailed in Article 28.2, or whether this is a more general stipulation. For example, a healthcare organisation may, as a general rule, state the information listed under Article 28.2. However, it will not maintain individual records for every individual patient or episode of care.

This general information will be made publicly available and the list (points a – h) may be revised annually.

Clarification is needed when referring to "all processing operations" under Article 28.1. Article 28.4 exempts an enterprise or organisation employing fewer than 250 persons that is processing personal data only as an activity ancillary to its main activities. The number of employees an organisation has or the fact that the data processing is not the organisation's main activity does not, in a healthcare context, render that data any less sensitive. There should not be a two-tier system of data privacy based on the number of employees an organisation contains.

It is not clear precisely what "an activity ancillary to its main activities" may mean in the healthcare context. Considering that the main activity of healthcare organisations is to provide care, will the processing of data be considered core to that or ancillary? This is an important point given that many healthcare providers are considered independent or belong to organisations employing fewer than 250 employees.

Impact assessment

Requirements for data protection impact assessment introduce unnecessary bureaucratic complexity. Article 33 requires that the processing of data concerning health is subject to the data protection impact assessment. The criteria for impact assessments are not yet clear as the Commission may clarify them by delegated act under Article 33 (6). While clarity is crucial to understanding under precisely what circumstances assessments are required, it is equally important that the processes used by varying types of entity (healthcare provider organisations, medical research organisations, eHealth service providers, etc.) are not constrained by prescriptive specifications under delegated acts. Given that processing activities are often different, impact assessments should not be "one-size-fits-all," rather they should be relative to the scope of processing, volume and type of data, and organisational aspects of those entities performing the assessments. Moreover, the data protection impact assessments will cause serious financial and administrative difficulties to small and medium sized medical practices.

In addition, while Article 34 provides for a prohibition to start the data processing before approval by the supervisory authority, it does not specify timelines for the processing of requests by national authorities. Legal certainty as to when a decision can be expected on the adequacy of impact assessment is crucial for stakeholders.

HOPE recommends that a data protection assessment should be permitted to cover similar processing activities and those activities which present similar privacy risks. Healthcare organisations should be able to construct

their own assessment, based on their specific type of organisation, legal requirements, contractual obligations, and, where appropriate, internal policies. Impact assessments should not constitute an unbearable administrative and financial burden to small and medium sized medical practices. Prior consultation should not be needed when processing is based on consent or contract. Where approval is required, a clear time line for the approval should be clarified prior to effective dates.

Research

Anonymised, and pseudonymised or key–coded data are used by the health sector to conduct medical research, monitor the efficiency of treatments, monitor disease trends, support public health policies, etc. HOPE recommends the Regulation is amended so that it is clear how the scope of the Regulation relates to the different types of data used by the healthcare sector and to ensure that the processing of these different types of data are regulated proportionately. One route to achieve this clarity and proportionality is to clearly exclude from the scope of the Regulation, data that does not relate directly to a data subject in the context of health or research.

REGULATION ON CLINICAL TRIALS

On 17 July 2012, the European Commission adopted a proposal aiming at boosting clinical research in Europe by simplifying the rules for conducting clinical trials. The measures will also better differentiate the obligations according to the risk-profile of the trial, and improve transparency including on trials carried out in third countries.

The proposed Regulation, if adopted, would:

- establish an authorisation procedure for clinical trials, which would allow for a fast and thorough assessment of the application by all Member States concerned and which would ensure one single assessment outcome;
- set up simplified reporting procedures that would spare researchers from submitting largely identical information on the clinical trial separately to various bodies and Member States;
- ensure more transparency on whether recruitment for participating in a clinical trial is still ongoing, and on the results of the clinical trial;
- give the Commission the possibility to conduct controls in Member States and other countries to make sure the rules are being properly supervised and enforced.

The European Science Foundation (ESF) and the European Medical Research Councils (EMRC) expressed their strong support for the revision of the Clinical Trials Directive, which had incorporated all of their recommendations. The legislative proposal is now being discussed in the European Parliament and the Council and it is expected to come fully into effect in 2016.

Once adopted, the proposed Regulation will replace the Clinical Trials Directive of 2001, which had placed strong emphasis on high-level patient safety, but whose divergent transposition and application led to an unfavourable regulatory framework for clinical research and contributed to the 25% decrease in clinical trials conducted between 2007 and 2011.

HOPE considers that the proposed Regulation represents a significant improvement to the current Directive and is a clear attempt to streamline the existing rules to reduce the administrative burden and speed up authorisations for new clinical trials.

INFORMATION TO PATIENTS DIRECTIVE

On 10 February 2012, the European Commission presented its third legislative proposals for the Information to Patients component of the pharmaceutical package. The existing legislative framework for pharmacovigilance was revised in 2010 and came into effect in July 2012. However, following the Mediator Scandal in 2011, the European Commission subjected the framework to a stress test that revealed a number of weaknesses that needed to be addressed. The amendments split into two parts relating to "Information to Patients" and "Pharmacovigilance" respectively.

With regard to Information to Patients, the proposals maintain Europe's ban on direct-to-consumer advertising and further restrict internet marketing by pharmaceutical companies. The proposal continues to place emphasis on the patient, based on the principle that the he/she should request information before receiving it. They also determine the type of information to be provided and limit the channels through which such information may be communicated.

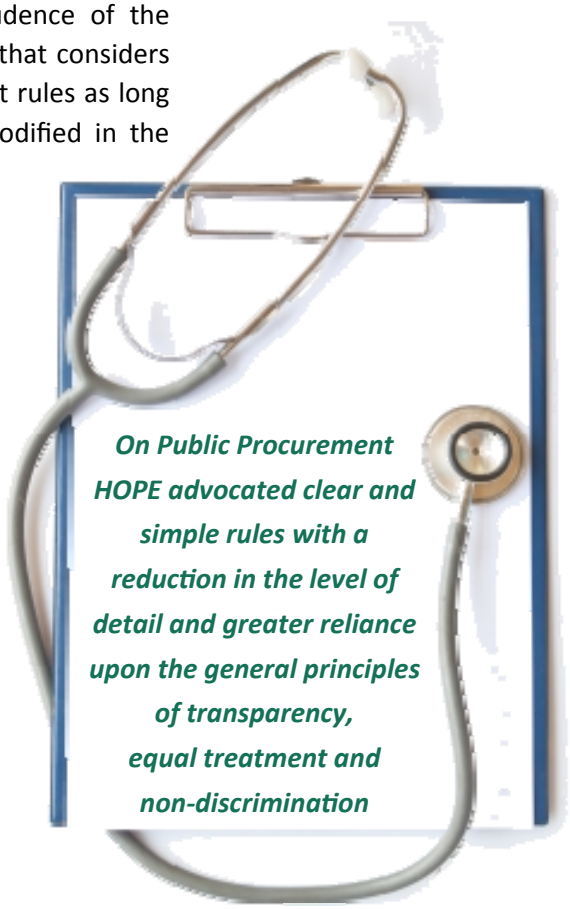
In addition, the legislative package suggests making registered websites for objective and non-promotional information mandatory and establishing specific rules on the monitoring of those websites in order to incorporate the cross-border nature of internet-provided information and allow cooperation between Member States.

PUBLIC PROCUREMENT DIRECTIVE

On 25 January 2012, MEPs on the Internal Market Committee started discussing the legislative package amending Directives on the awarding of public procurement contracts, proposed in 2011 by the Commission. Some of the ideas that circulated were the need for rules to be simplified and to provide better SME access with regard to public procurement contracts and to offer the possibility of choosing the most advantageous offer in economic terms rather than the cheapest offer.

MEPs took account of HOPE's position which stated that, in order to develop the full potential of public procurement, the criterion of the lowest price should be removed, and that in principle there should be only one option for awarding contracts: the most economically advantageous tender – including the entire life-cycle costs of the relevant goods, services or works – should be chosen. Increased awareness of the environmental and climate impact of products and activities means that the possibility for public authorities to favour local suppliers should be considered. And that any extension of the EU procurement rules into the "what to buy" area would lead to more complicated rules with many exemptions, which would be difficult to administer in practice.

HOPE's concerns were on the Directive's legal clarity, efficiency, simplification and flexibility. HOPE asked for clarification of the scope of the Directives and of the definitions used, in particular the definition of a "body governed by public law" in line with the jurisprudence of the European Court of Justice. HOPE recalled the ECJ case law that considers public-public cooperation not subject to public procurement rules as long as clear criteria are met. Those clarifications should be codified in the procurement directives.



On 20 February 2012, Ole Sohn, the Danish Minister for the Economy, presented the first position of the Council on the proposal of the Commission on public procurement. Member States agreed on the abolition of differential treatment for so-called non-priority services, whilst keeping a lighter regime for services related to health as well as education and culture. He confirmed the European Union's Competitiveness Council's approval of the new competition procedure with negotiation that the European Commission put forward in its "public procurement" Directive review. Competition procedures with negotiations would allow the adjudicating authorities to launch negotiation with selected contractors before introducing an initial written offer, in order to refine certain modalities, for example on legal and financial issues. HOPE believes negotiated procedures with prior announcement should be allowed as a standard procedure.

In its proposal, the European Commission also expressed its wish to discard the distinction between priority services in Category A and so-called non-priority services in Category B, which are currently subject to less strict rules. Only services related to health as well as culture and education will benefit from the lighter regime, and services that have a threshold below € 500.000 will not be covered by the Directive.

HOPE advocated clear and simple rules with a reduction in the level of detail and greater reliance upon the general principles of transparency, equal treatment and non-discrimination. In HOPE's opinion, the Commission should include more flexible provisions for framework agreements in the Directives.

PUBLIC HEALTH PROGRAMME 2014/2020

HOPE was invited on 17 February 2012 to comment on the draft opinion of the Committee of the Regions about the Proposal for a Regulation of the European Parliament and of the Council on "Establishing a Health for Growth Programme, the third multi-annual programme of EU action in the field of health for the period 2014-2020". The title "Health for Growth" is supposed to emphasise the tight link between health and economic development in the Member States.

The rapporteur on the opinion, Tilman Tögel (PES Germany), Member of the Saxony-Anhalt Landtag, had already drafted elements and wanted feedback from stakeholders. He considered that in the EU, local and regional authorities bear almost exclusive responsibility – whether direct or indirect – for public health. According to him, they are responsible for securing adequate provision of preventative care, treatment and public health-related services. The rapporteur then regretted that the draft Regulation makes no mention of regions and municipalities.

Very few stakeholders showed up but this was an opportunity for HOPE to present in detail not only its position but also the messages developed within the European Health Policy Forum. The proposal of the Commission does not grasp the reality of the health system's diversity. It does not tackle inequalities and seems more interested in moving towards greater influence on healthcare than in pursuing its public health goals.

Soft Law and Other Initiatives

AGEING

European Year for Active Ageing and Solidarity between Generations

On 18 January 2012, the European Year for Active Ageing and Solidarity between Generations was officially launched in Copenhagen, with a two day conference "Stay Active - what does it take?". The European Year's prior objective was to raise awareness about active ageing and promote independent living of older people. Along 2012, there were many initiatives dedicated to this issue (conferences, meetings, projects, partnerships, publications).

HOPE was actively involved in different projects, attending and organising conferences, joining working groups and partnerships on the issue as well as working on it in the Exchange Programme for health professionals whose topic on 2012 was Ageing workforce- Ageing patients.

European Year for **Active Ageing** and **Solidarity between Generations 2012**

European Innovation Partnership on Active and Healthy Ageing

HOPE joined the European Innovation Partnership on Active and Healthy Ageing, which was launched on 29 February 2012 and gathered over 50 regions, ICT companies and health providers.

The Partnership's main scope was to increase the average healthy lifespan in the EU by two years by 2020 pursuing 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 in new markets.

The priority actions fall under three pillars reflecting the "life stages" of the older individual in relation to care processes:

- prevention, screening and early diagnosis;
- care and cure;
- active ageing and independent living.

All stakeholders who wished to be involved in carrying out the specific actions of the Plan submitted their contributions. By the end of June 2012, the Partnership had received a total of 261 projects and 54 regions and municipalities put themselves forward as "reference sites", with the aim of exchanging good practices and sharing knowledge and experience on past successes in this field. The commitments were submitted by a wide array of stakeholders, with particularly high participation of universities and research groups (37%), public authorities (17%) and health providers (8%).

On 6 November 2012, the first Conference of Partners of the European Innovation Partnership on Healthy Ageing was held at the European Commission. The leaders of different Action Plans presented the activities and their expected results. HOPE is involved in the Action Plan A3 on Prevention of Functional Decline and Fragility.

In April 2012, the EC launched the website "Marketplace for innovation ideas" as part of the European Innovation Partnership on Active and Healthy Ageing for stakeholders to work together and develop their innovative ideas.

On 5 and 6 September 2012, a high-level conference on “Healthy Ageing” was organised by the Ministry of Health as part of the Cyprus Presidency. It strongly highlighted the fact that healthy ageing could be achieved by the implementation of preventive, early diagnosis and health promotion programmes throughout the lifecycle. There was an extensive discussion on the new trends in the area of healthcare provision, through multidisciplinary approaches which encompass patient and community involvement and which focus on preventive measures, early diagnosis including screening programmes, treatment and eventually active ageing and independent living. The Conference’s conclusions will set the basis for respective Council Conclusions that Member States will be called upon to adopt.

eHEALTH

The contribution of HOPE to the European agenda on this issue is mostly through the eHealth Stakeholder Group.

The eHealth Stakeholder Group established by the European Commission met for the first time on 29 March 2012. The group comprises 29 European umbrella organisations, including HOPE, representing different groups such as health professionals and managers, patients and consumers, industry, standardisation bodies.

The aim of the group is to ensure an informed dialogue with the European Commission and to add value to policy design and implementation. Areas for cooperation during the current year were agreed, namely patients' access to electronic health records, telemedicine deployment, interoperability, the EC Staff Working Paper and the eHealth Action Plan.

The group met again on 7 May 2012 in Copenhagen. For this second meeting, members were provided updates on the Commission's work in four key areas of cooperation: staff Working Paper on Telemedicine, patient access to health records, telemedicine deployment, and interoperability. In Copenhagen, a workshop was organised by DG INFSO and US Department of Health and Human Services & ePractice.eu. Most notable amongst this work is the jointly developed EC-HHS roadmap for the development of internationally recognised interoperability standards and interoperability implementation specifications for electronic health information systems.

On 7 December 2012, the European Commission unveiled an action plan to address barriers to the full use of digital solutions in Europe's healthcare systems.

It aims to improve healthcare for the benefit of patients, give patients more control of their care and reduce costs.

The action plan seeks to promote these improvements by:

- clarifying areas of legal uncertainty;
- improving interoperability between systems;
- increasing awareness and skills among patients and healthcare professionals;
- putting patients at the centre with initiatives related to personal health management and supporting research into personalised medicines;
- ensuring free legal advice for start-up eHealth businesses.

By 2014, the Commission will also publish a mHealth (Mobile Health) Green Paper addressing quality and transparency issues.

PATIENT SAFETY

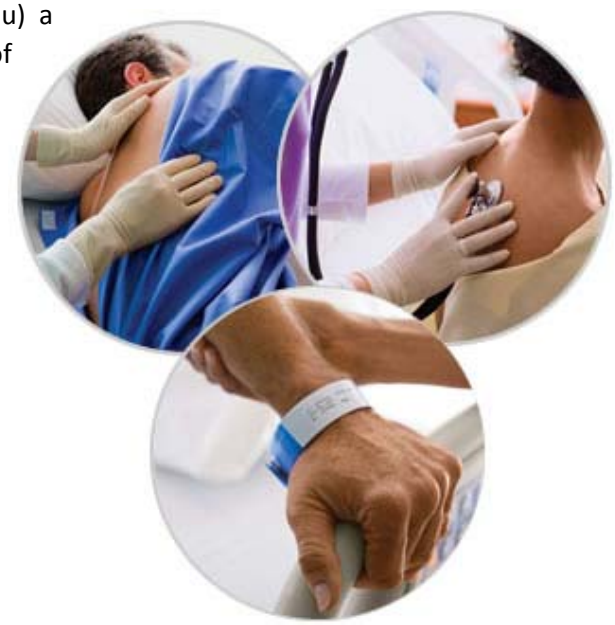
Since 2006, the Patient Safety and Quality of Care Working Group has bringing together representatives from all 27 EU countries, EFTA countries, international organisations, EU bodies and key EU stakeholders, including HOPE. The Group assists in developing the EU patient safety and quality agenda.

The last meeting of the Working Group took place on 20 November 2012 in Brussels. The main objective was to present and discuss the follow up of the Commission Report to the Council on the implementation of the Council Recommendation 2009/C 151/01, which was published on 15 November 2012.

The report notes that Member States have implemented various measures such as embedding patient safety in public health policies and identifying competent authorities on patient's safety. However, the Commission considers that more efforts are needed on training and education of health professionals and on provisions for patient empowerment.

It was underlined that the time between the adoption of the Recommendation and the reporting was insufficient. The Commission proposed an extension of the implementation period by 2 years, so a new progress report will be published in June 2014. Furthermore, it was stressed how more evidence about costs of unsafe care is needed to help political prioritisation.

During the meeting, Mr. Jean Bacou from the *Haute Autorité de Santé* (FR) provided an update on the work of the Joint Action on Patient Safety and Quality of Care (PaSQ), in which HOPE is a major partner. The main objective of the Joint Action is to support the implementation of the Council Recommendation on Patient Safety. To date, first achievements include the publication of the website (www.pasq.eu) a glossary and framework, as well as a first selection of safe clinical practices for implementation. A data collection process also started in November 2012: the next steps will be the preparation of exchange mechanisms (e.g. site visits, online courses, twinning programmes) and implementation of safe clinical practices in Member States.



CHRONIC DISEASES

On 5 November 2012, the European Commission's Directorate-General and the Executive Agency for Health and Consumers met Member States in Luxembourg to discuss and develop a concept for the Joint Action on Chronic Diseases, a topic on which HOPE has been working, in particular with the exchange programme. The proposal will then be finalised and submitted for evaluation by mid-March 2013.

Three possible specific objectives were identified:

- to map across Europe new innovative actions in the field of social media, behavioural science and new technologies as well as the more traditional actions on the risk factors;
- to examine the barriers to the uptake of prevention, targeted screening of risk groups, and treatment of major chronic diseases. Diabetes will be used as a case study;
- to look in detail at how to address multi-morbidity and other complex issues in the framework of chronic diseases.

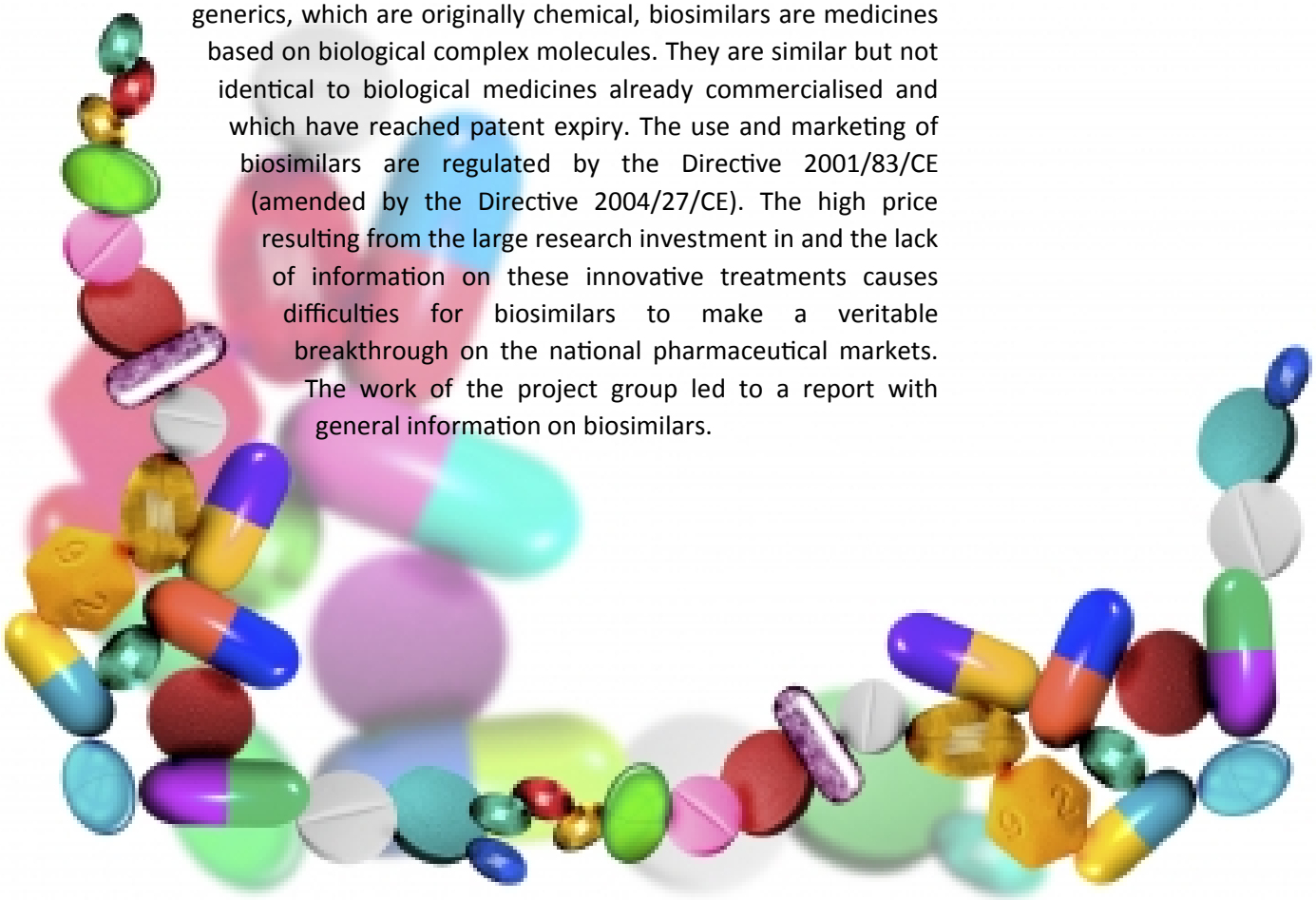
PLATFORM ON ACCESS TO MEDICINE

On 24 September 2010, as part of the Process on Corporate Responsibility in the field of Pharmaceuticals, the Commission organised in Brussels the first Steering group meeting of the Platform on access to medicines in Europe. This continued in 2011 and was closed in 2012.

Together with all Member States, HOPE was invited among key stakeholders to that meeting chaired by the Directorate General for Enterprise and Industry. Despite the official move of pharmaceutical issues to the Directorate General Health, some activities as this particular one did remain under DG Enterprise.

The work was organised around projects that started in 2011 and were concluded in 2012. The Commission proposed five topics: mechanism for coordinated access to orphan medicinal products, capacity building on contractual agreements for innovative medicines, facilitating the supply in small countries, promoting a good governance for non-prescription drugs, and market access for biosimilars.

HOPE participated in the Working Group on "Market access and uptake of Biosimilars" and "Small markets" which met several times in 2011. The aim of the biosimilar group is to promote uptake of biological medicinal products, especially biosimilars and enhance their accessibility. Unlike generics, which are originally chemical, biosimilars are medicines based on biological complex molecules. They are similar but not identical to biological medicines already commercialised and which have reached patent expiry. The use and marketing of biosimilars are regulated by the Directive 2001/83/CE (amended by the Directive 2004/27/CE). The high price resulting from the large research investment in and the lack of information on these innovative treatments causes difficulties for biosimilars to make a veritable breakthrough on the national pharmaceutical markets. The work of the project group led to a report with general information on biosimilars.



Concerning small markets, the Project group on facilitating supply in these markets met on 22 May 2012 in Ljubljana, Slovenia. This was the third face-to-face meeting of the project group on facilitating supply in small markets launched by the Commission within the framework of the Platform on access to medicines in Europe concerning the process of corporate responsibility in the field of pharmaceuticals. Further to previous meetings and teleconferences, the group had agreed to launch a mapping exercise and two questionnaires, one for competent authorities and one for economic operators, the results of which would be analysed with the scientific support of EMINET. The group continued to discuss the experiences of Member States and stakeholders in the area.

The literature review performed by EMINET spotted three examples of international experiences: Eastern Caribbean States Pharmaceutical Procurement Service Pan American, Pan-American Health Organisation Revolving Fund for vaccine procurement and, Gulf Cooperating Council. The examples seem difficult to match in a diverse European setting.

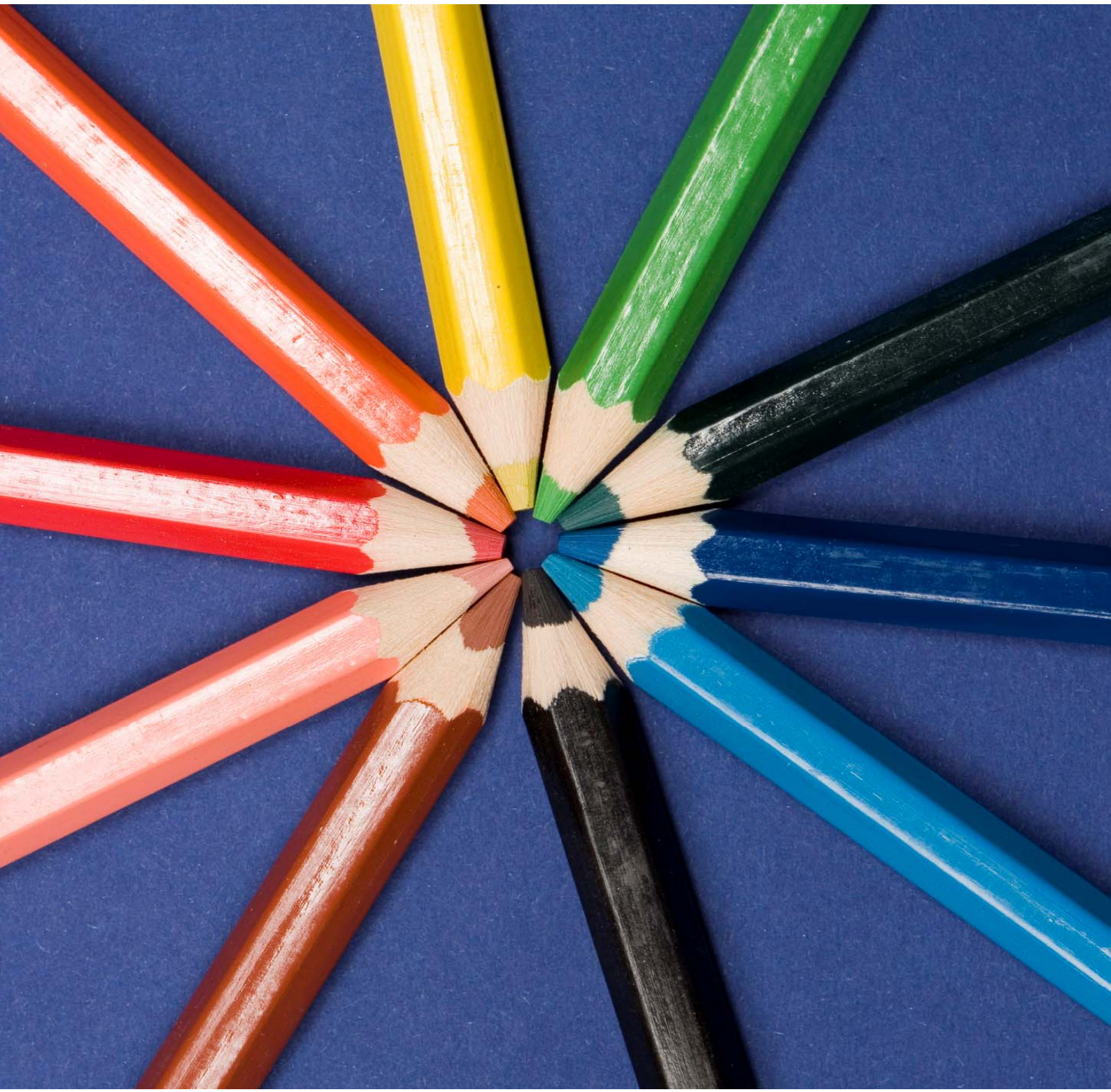
EMINET then presented the preliminary results of the mapping exercise based on the input received by the group members. Unfortunately, these preliminary results showed diverse deficiencies reported between countries, which made the analysis of results rather problematic. Different ideas were discussed on the way to validate the results or plan new questions. This was a challenging issue as it was estimated that it was not the best idea to reach any conclusions based on information provided for a limited list of products.

The process on corporate responsibility in the field of pharmaceuticals facilitated discussions on ethics and transparency of the sector but also on non-regulatory conditions for better access to medicines after their marketing authorisation. The process comprised three independent platforms, composed of several project groups.

Concerning the Platform on Ethics and Transparency, the text "List of Guiding Principles Promoting Good Governance in the Pharmaceutical Sector" will be distributed in 2013.

Chapter 3

KNOWLEDGE AND EXCHANGE



Developing knowledge and facilitating exchanges are the essence of HOPE.

Joining consortia, and participating in projects and joint actions are now a regular practice.

In 2012, HOPE also celebrated the 31st edition of its Exchange Programme.

HOPE was also active in organising or co-organising several conferences.

HOPE AS A PARTNER— COMPLETED PROJECTS

PUBLIC HEALTH – CARDIO-VASCULAR BENCHMARKING – EURHOBOP

The EURHOBOP Project held its final conference on 18 and 19 June 2012 in Barcelona. EURHOBOP provides European hospitals with a validated set of statistical functions - including determinants of in-hospital case fatality outcome indicators - to benchmark themselves about the quality of the management of myocardial infarction or unstable angina patients and in the use of the treatments aimed at removing coronary artery occlusion. Its general aim was to produce a tool to compare hospitals in Europe in strict confidentiality. HOPE's role was to engage hospitals as well as disseminate the results.

The project, based on the preliminary results obtained in the EUPHORIC (www.euphoric-project.eu) cardiovascular pilot study, was led by the Institut Municipal d'Assistència Sanitària - Institut Municipal d'Investigació Mèdica (IMAS-IMIM), Spain with the following partners, apart from HOPE: Hellenic Cardiologic Society; ASL Roma E - Dipartimento di Epidemiologia (DEASL), Italy; Faculdade de Medicina da Universidade do Porto (FMUP), Portugal; Helmholtz Zentrum München - Deutsches Forschungszentrum für Gesundheit und Umwelt (HMGU), Germany; Terveyden ja hyvinvoinnin laitos (THL), Finland; Association pour l'étude et la prévention des maladies dégénératives du système cardio-vasculaire - "Projet MONICA" (AEPMCV), France; Istituto Superiore di Sanità (ISS), Italy.

Coronary heart disease kills more than 2.000.000 people in Europe every year and, if acute cases (> 700.000 in age range 35-64 years) are not adequately managed, it may result in a high case fatality (currently > 35%). Hospitals were requested to provide data of 200 consecutive patients with discharge diagnosis of myocardial infarction (MI) or unstable angina (UA) retrospectively recruited. Two types of collaborating hospitals participated: hospitals that participate with extensive data (selected in the countries of 7 partners), and any hospital that wished to participate with its own data directly on the website.

The results consist of a set of validated hospital mathematical functions suitable for benchmarking European Hospitals by cardiovascular disease management performance and for European citizens to determine their risk of in-hospital death when submitted to these procedures. The results show that the outcomes in these procedures and general MI and UA management do not differ by sex. There are no outcome inequalities between men and women in the use of these procedures and in disease management in European hospitals.

The final versions of the benchmarking functions are validated and posted on the project web site (www.eurhobop.eu) with appropriate disclaimer and user contract specifications and a large sample of European hospitals invited to register and use them to benchmark themselves.

RESEARCH – MANAGED OUTCOMES

In December 2012, the project managed Outcomes of which HOPE was a partner, held its final seminar in Brussels. The project describes, analyses and compares the way Member States provide services and how they are prepared to address the present and future health service needs.

Case studies and patient surveys have been completed referring to the process of delivering health services in four areas: osteoarthritis, stroke, dementia and diabetes. The countries involved in this research were Finland, Germany, Greece, the Netherlands, Spain and the UK. A comparative analysis of results has also been completed, while scenario development (including the connection between processes and outcomes) has been drafted.

From February to April 2012, local scenario workshops for each case study were held in each country with the aim of gathering information and validation about “in-country” analyses, future scenarios and making sense of local data and circumstances.

The project, led by AALTO UNIVERSITY of Finland started on January 2010. HOPE activity involved supporting data collection and the diffusion of scenario models.

HOPE AS A PARTNER — ON GOING PROJECTS

RESEARCH – DUQUE – QUALITY STRATEGIES

On 17 December 2012, the DUQuE "Deepening our understanding of quality improvement in Europe" project held its final conference in Berlin. The project officially closes in April 2013.

Using data from 188 hospitals from seven European countries (Czech Republic, France, Germany, Poland, Portugal, Spain and Turkey), this four year multi-method project assessed the relationship of various quality improvement governance approaches with quality indicators of hospital care (specifically clinical effectiveness, patient safety and patient reported outcomes). HOPE was the leader of Work Package 6 "Analysis of policy implication and impact".

At the final conference, the main findings of the DUQuE project were presented and discussed. Evidence-based guidance documents, practical toolkits and appraisal schemes for hospital managers, purchasing agencies and governments interested in the development and assessment of hospital quality improvement systems were also presented.

The DUQuE research project, financed by the EU 7th Research Framework Programme, has successfully achieved in this way its main goal of studying the effectiveness of quality improvement systems in European hospitals.

eHEALTH THEMATIC NETWORK – AGEINGWELL

HOPE took part on 12 January 2012 as a partner in the kick-off meeting of AgeingWell, a Thematic Network co-funded by the European Commission.

The aim of this network is to build and run a European network focused on improving the quality of life of elderly people by promoting the market uptake of ICT solutions for ageing well. To achieve its aim, five main objectives for AgeingWell were set as follows:

- develop guidelines for deployment and sharing of best practices between key competence centres;
- build an ICT for Ageing Knowledge Centre with the aim of sharing the results with the Ageing Well Community;
- develop an ICT for Ageing Society Strategic Agenda, with the aim of providing a study on options for future structure and implementation of EU innovation funding;
- promote the European innovation reinforcement between innovative ICT industries & Ageing (in particular SMEs) and Venture Capital firms, Business Angels and other;
- raise awareness within the European community of ICT & Ageing stakeholders.

The AgeingWell network comprises experienced organisations in ICT for ageing well, covering the industry, user organisations, public authorities, investors, housing and insurance companies, and ICT solutions providers that will share and participate in an interactive online platform, sharing a vision of "Market uptake of ICT for Ageing Well". The 16 founding members' expertise relates to all aspects of ICT and people's lives: ICT for health, health/medicine, community care, transport, the built environment, education, employment, pensions, social welfare, civic participation, new technologies, sporting and cultural activities, and elders as consumers.

eHEALTH THEMATIC NETWORK – MOMENTUM

On 15 and 16 February 2012, a new Thematic Network on telemedicine, MOMENTUM, was launched in Brussels. Funded under the European Union's Information and Communication Technologies Policy Support Programme and coordinated by the European Health Telematics Association (EHTEL), MOMENTUM aims to support the deployment of telemedicine in daily practices. Its objective is to create a platform across which the key players can share their experience and knowledge in deploying telemedicine practices into routine care, in order to build a body of good practices:

- it will assist countries and telemedicine practitioners in their telemedicine implementation, and validate the work of past initiatives;
- it will document the roadblocks that obstruct telemedicine implementation in daily practice - the lack of robust methods to support telemedicine implementation process being perceived as one of them;
- it will propose a set of policy recommendations; these will help to create the enabling environments needed to accelerate overall telemedicine deployment in Europe.

HOPE, which is a collaborative partner of the project, is participating in Work Package 3 - Knowledge gathering & consolidation, Work Package 4 - SIG on telemedicine strategy and management, and Work Package 5 - SIG on organisational implementation and change management.

MOMENTUM's activities will be built on special interest groups (SIGs) and their workshops. There will be four specific work domains: telemedicine strategy and management, organisational implementation and change management, legal and regulatory issues, and technical infrastructure and market relations. The Momentum thematic network will run from February 2012 to July 2014.

The MOMENTUM project had its first workshop in Luleå, Sweden on 20 and 21 June 2012, which gathered local, regional and national politicians, representatives from the business industry, public sector officials and healthcare providers. HOPE was present at this first workshop, during which along a brief overview of the project, case studies from Norway, Italy and Spain were presented.

momentum
ADVANCING TELEMEDICINE ADOPTION IN EUROPE

EUROPAID – MEDICAL EQUIPEMENT DONATIONS

In 2012, HOPE carried out a study "Practices of the European Member States donors of medical equipment" with the aim of identifing the key donors of medical equipment among the European Union countries (before 2004) and analyse the way donation is delivered. This project is of special relevance regarding the revision of the Directive WEEE of 2002/96/CE on Waste Electrical and Electronic Equipment. The report, co-financed by EUROPAID, was compiled in collaboration with the NGO Humatem.

The study points out the lack of consensus in the definition of "material equipment", "donation" or "donors" and no attention is made to patient safety. The study also highlights the lack of organisation in the donation process. There is no legislation on the subject while WHO's guidelines appear to be insufficient, most of all regarding practical issues. According to the report, this is the reason why there is a high variety of actors and practices.

One of the recommendations made in the report is to share efforts and encourage the different actors interested in transferring their medical equipment to donate together. In this way, each of them could specialise in one part of the process (collecting the equipment, testing it, the delivery, the training of the beneficiaries, maintenance) and share costs. The study also welcomes the modernisation of the Directive WEEE du 2002/96/CE in order to settle common quality standards to improve the way donation is carried out.

Europaid

JOINT ACTION ON PATIENT SAFETY

The Joint Action on Patient Safety and Quality of Care (PaSQ) was officially launched on 24 and 25 May 2012 in Roskilde, Denmark. The general objective is to support the implementation of the Council recommendations on patient safety by co-operation among Member States and stakeholders. The leader is the French Haute Autorité de Santé (HAS) that was also the leader of EUNetPaS.

HOPE is involved in three work packages: patient safety - safe clinical practices, led by Denmark; patient safety - good practices implementation, led by Germany with HOPE as co-leader; exchange of good organisational practices on patient safety and Quality Network, led by Spain.

The Joint Action also plans to facilitate the exchange of information and establish common principles at EU level through the integration of knowledge, experiences and expertise gathered from Member States and EU stakeholders.

In addition, it will work on facilitating the development of Patient Safety programmes in Member States, provide support to those countries less advanced in the field, and promote the involvement of stakeholders through national platforms organised around one PaSQ National Contact Point in every EU Member State.

The origin lies in the 2009 Council Recommendation (implementation) on Patient Safety. The Council Working Party on Public Health at Senior Level proposed to organise a joint action on quality of care and patient safety, based on the Reflection paper on healthcare quality, including the topic patient involvement. It is also based on the achievements of EUNetPaS, a 30 months project that started in 2008 to establish an umbrella network of all 27 EU Member States and EU stakeholders to encourage and enhance collaboration in the field of Patient Safety. HOPE played an important role in EUNetPaS, whose work package 4 on medication safety was supervised by the Federation.

JOINT ACTION EUROPEAN PARTNERSHIP FOR ACTION AGAINST CANCER

The European Partnership for Action Against Cancer (EPAAC) was launched in 2009, after the European Commission published its Communication on Action Against Cancer: European Partnership. The specificity of the partnership is that it combines the efforts of different stakeholders into a joint response to prevent and control cancer. In its initial phase, until early 2014, the work of the partnership will be taken forward through a Joint Action (co-financed by the EU Health Programme). The EPAAC Joint Action encompasses 36 associated partners from across Europe and over 90 collaborating partners.

The EPAAC Joint Action runs from February 2011 to February 2014 with the aim of drawing together relevant organisations to share expertise and identify challenges in order to reduce the number of new cancer cases in the EU by 15% by 2020. The joint action foresees international co-operation in four main areas: prevention, research, healthcare and information.

HOPE is specifically involved in the identification and promotion of good practices in cancer related healthcare. In the future development of the project HOPE will be required to present experiences and collect good practices concerning different areas of cancer care such as new organisational perspectives, application of organisational guidelines, psychosocial support and communication, especially referring to children affected by cancer, and all innovative tools and methodologies used to improve outcomes in cancer care.

In June 2011, HOPE Chief Executive participated in the first EPAAC Open Forum '"Research and Healthcare" with the presentation "Challenges posed by the management of cancer patients in hospitals".

On 19 and 20 June 2012, the European Partnership for Action Against Cancer successfully organised its second Open Forum in Rome, Italy. The event was hosted by the Italian Ministry of Health and casted a spotlight on Health Promotion & Prevention and Cancer Data & Information (Work Packages 5 & 9). A diverse group of stakeholders from across Europe met in Rome to discuss cancer prevention and the promotion of better health, and to exchange views and best practices. Leading experts in the field of cancer information and cancer registries discussed the Proposal for a European Cancer Information System.

2012 also marks the 25th anniversary of EU policy on cancer. In 1985, the European Council emphasised in Milan the importance of launching a European programme of action against cancer, which resulted in the development of the first of the three successive “Europe Against Cancer” action programmes, which ran until 2003. After 2003, efforts to combat cancer continued in the framework of horizontal health programmes. Overall, the fight against cancer, and in particular cancer prevention, has been at the forefront of European Union action for the past 25 years. Former EU Health Commissioner John Dalli emphasised that “from the first Cancer Programme in 1987, to our present Partnership against Cancer, the Commission has fostered action on prevention, research, control and care which has made a difference for Europeans living with cancer. Information is key for shaping and implementing effective cancer prevention and control strategies. The Commission is committed to fostering a sustainable, comprehensive European Cancer Information System”.

Alojz Peterle, Member of the European Parliament (MEP) and President of the Group MEPs Against Cancer (MAC) added that "cancer is still progressing and we are still facing significant inequities in efficiently combating it. Partnerships at national level based on National Cancer Plans and partnerships on EU level aimed at exchange of knowledge, best practises (especially with regards to screening programmes) and research cooperation are vital to win this challenge. Further political support at all levels of action is needed as well. Stronger efforts have to be devoted to the primary prevention, in particular in health education".

The Italian Minister of Health, Renato Balduzzi, emphasised that Italy was honoured to host the 2012 Open Forum of the European Partnership Action Against Cancer (EPAAC). He considers this responsibility as a recognition of the commitment and strong contribution Italy has given to the fight against cancer, both at national and international level, and in particular for European cooperation.

Tomaž Gantar, the Minister of Health of the Republic of Slovenia, recognised the high value of the partnership against cancer and highlighted that “an approach based on joint action and partnership implies added value, as experts from across the EU collaborate and shape actions to combat cancer, exchange best practices, define obstacles and more easily achieve goals”.

HONCAB PROJECT

The project to support the creation of a pilot network of hospitals related to payment of care for cross-border patients (HoNCAB) was officially launched on 24 and 25 October 2012 in Luxembourg.

The HoNCAB project strives to take advantage from the interval between the adoption of the Directive 2011/24/EU on the application of patients' rights in cross-border healthcare and its final application in the Member States. The Directive represents a major step forward in providing clarity about the rights of patients who seek healthcare in another Member State. However, it has also opened up uncertainties about the practical implications that the Directive will have on the organisation of healthcare systems, especially when it comes to payment and reimbursement of services.

Therefore, the general objective of the project is to obtain a better understanding of the financial and organisational requirements that may arise as a result of a patient receiving health care outside the Member State of affiliation.

To this end, the project will make available some preliminary but "real" data on the impact of patient mobility and will fine-tune the methods of classification of the tariffs and related techniques for comparison. Furthermore, the HoNCAB project aims to provide a framework for the launch of a pilot hospital network, designed to grow over time. Such a network will allow the participating hospitals to have a practical experience of the opportunities and critical issues of cross-border care and to share problems and solutions with other Member States.

The HoNCAB project is co-financed by the European Commission, Executive Agency for Health and Consumers, under the Second Programme of Community Action in the Field of Health (2008-2013).

HOPE is the Leader of Work Package 2, dedicated to the dissemination of the project.

HEALTH C – IMPROVING CRISIS COMMUNICATION SKILLS IN HEALTH EMERGENCY MANAGEMENT

The kick-off meeting of "Health Comm – Improving Crisis Communication Skills in Health Emergency Management" took place in Porto, Portugal on 4 and 5 December 2012. The aim of the two-year EU co-funded project, led by the Portuguese Innova+project, is to support health authorities staff in developing competences required for managing communication in emergency situations caused by a health crisis in a scenario of trans-national emergencies. Training particularly focuses on the communication strategy with the general public and the media on how to respond and to positively contribute in emergency cases.

HOPE is the leader of WP 2 "Identification of target groups' training needs and competences". ASL Brescia, Azienda Sanitaria Locale della provincial di Brescia (Italy), LMU, Ludwig-Maximilians-Universität München (Germany), AaSHCC, Aarhus Social and Health Care College (Denmark), and ARTICA, ARTICA TELEMEDICINA (Spain) are partners in the project.

HEALTH
Improving Crisis Communication Skills
in Health Emergency Management

HOPE AS AN ADVISOR

NURSING – RN4CAST

HOPE was one of the stakeholders participating in the project RN4CAST that released on 20 March 2012 a study "Patient safety, satisfaction, and quality of hospital care: cross sectional surveys of nurses and patients in 12 countries in Europe and the United States", published in the British Medical Journal.

The study aimed to determine whether hospitals with a good organisation of care (such as improved nurse staffing and work environments) could affect patient care and nurse workforce stability in European countries. It found that nurses who reported better working conditions in hospitals and less likelihood of leaving also had patients who were more satisfied with their hospital stay and rated their hospitals more highly.

The research developed a cross sectional study of 1 105 general acute hospitals; 488 in 12 European countries (Belgium, England, Finland, Germany, Greece, Ireland, Netherlands, Norway, Poland, Spain, Sweden, and Switzerland), and 617 in the US. It included 61 168 professional bedside care nurses and more than 130.000 patients from participating hospitals. The study was developed by a consortium of investigators from 13 countries led by the University of Pennsylvania School of Nursing in the US and the Catholic University of Leuven (Belgium) in Europe with a 3 million Euro grant from the European Commission with additional funding from the National Institute of Nursing Research of the National Institutes of Health in the US.

The project results show that perceptions of nurses and patients about hospitals are related. There does exist a high consistent relationship between working environment and indicators of job satisfaction (burnout, intention to leave) and nurse staffing has a significant impact on patient outcomes (mortality) in 9 European countries.

EVALUATING CARE ACROSS BORDERS – ECAB PROJECT

HOPE was invited to be an observer within the ''Users' Advisory Board'' of the EU-funded research project ECAB, evaluating care across borders, which held a meeting in Berlin on 24 and 25 May 2012. This project brings together major academic researchers from several European universities {e.g. London School of Hygiene & Tropical Medicine, Semmelweis University (Budapest), Universidad Barcelona, London School of Economics} to look into various issues relating to cross-border care in Europe: such as healthcare professionals, prescriptions, hospital collaboration, health and many more.

This fourth meeting of project's partners essentially aimed at giving an overview of the progress of the ECAB project and discuss management, milestones and deliverables, to review substantive progress on individual work packages, and to prepare policy recommendations.

Concerning hospital collaboration in border regions, seven case studies were examined: Finland-Norway, Germany-Denmark, the Netherlands-Germany, Belgium-France, Spain-France, Austria-Germany and Romania-Bulgaria. Interviews were conducted by each team responsible for a case study. Harmonised definition of hospital collaboration was established in order to allow comparison.

The first findings identified many commonalities between all case studies but variety exists concerning:

- the format of collaboration, ranging from recruiting, contracting, leasing, cross-border branch, multi-site, merger, building new hospital (to be opened) with two forms: either purchase abroad or joint capacities;
- composition of agreements: range from to involvement of authorities;
- length and stage of collaboration.

Pending questions mainly involved the need for collaboration. This was said to originate mainly from the need for new infrastructure but also because the healthcare sector was an important economic driver in the regions studied. Areas still to be explored encompassed the coherence of incentives and opportunity considerations.

Evaluating care across borders

ECAB

European Union Cross Border Care Collaboration

WHO EUROPEAN POLICY FOR HEALTH "HEALTH2020" – PUBLIC CONSULTATION

HOPE has been invited by WHO Regional Directorate for Europe to take part in the written consultation on the European policy for health "Health 2020".

"Health 2020" is the new European health policy, aiming to accelerate progress towards achieving the European Region's health potential by 2020. Its purpose is to strengthen health systems, revitalise public health infrastructures and institutions, engage the public and a range of health players, and develop coherent and evidence-based policies and governance solutions capable of tackling health threats and sustaining improvements over time.

Three documents are now available for a written consultation:

- the short "Health 2020" policy document which contains the key evidence, arguments and areas for policy action in the "Health 2020" policy framework which addresses the public health challenges and opportunities for promoting health and well-being in the European Region;
- the longer "Health 2020" policy framework and strategy document, which provides the contextual analysis and the main strategies and interventions that work to implement the "Health 2020" policy;
- the European Action Plan for Strengthening Public health Capacities and Services, which is central to implement the "Health 2020" strategy.

WHO Europe has identified a limited set of questions especially concerning the first two documents; however, a comprehensive response and general comments on any aspect of these documents are welcome. HOPE worked with its members to reach a collective statement submitted at the end of March 2012.

PROJECTS IN CONSTRUCTION

JOINT ACTION HEALTH WORKFORCE PLANNING AND FORECASTING

On 5 July 2012, the Commission released its decision on the awarding of grants for proposals for 2012 under the second Health Programme (2008-2013). 19 operating grants, 16 projects, 7 conferences and 5 Joint Actions will be co-funded for a total of €27.183.663. The topics cover diverse subjects from "increasing healthy life years" and "promoting healthy ageing" via "protecting citizens from health threats" to "addressing health determinants" and take action on key factors such as nutrition and physical activity.

Among the projects that were granted funding was the joint action on workforce planning.

HOPE was invited to join the plenary meeting to prepare the Joint Action Health Workforce Planning and Forecasting on 11 January 2012 in Brussels, a proposal submitted in March. The general objective of the joint action on health workforce planning is to put into practice a platform for collaboration of Member States in Europe to better prepare the future of the health workforce. This platform will support Member States and the European Union to take effective and sustainable measures in view of the expected shortage of health workforce on European and national level.

Health Workforce Planning and Forecasting (HWFPF) is considered to be the major tool for evidence based policy action to tackle the challenge of expected health workforce shortage in the future. A European organisational structure to oversee the health workforce planning could therefore be an important requirement for success. This is the reason why the European Council invited the European Commission to set up this platform. It will keep the momentum induced by the Green Paper on the European Workforce for Health (Commission, 2008).

It took place in the context of the adoption on 18 April 2012 by the European Commission of a Communication "Towards a job rich recovery", laying out a set of measures to boost employment and economic growth in Europe. It included a specific health workforce action plan.

The general proposal, which focuses on the demand-aspect of job creation, emphasises the need for a stronger employment and social dimension to EU governance. It lays down ways for Member States to involve employers' and workers' representatives more in setting EU priorities. In its communication, the European Commission identifies three sectors as key fields with high employment potential for the future: healthcare, green economy and Information and Communication Technologies.

Recognising healthcare as one of the areas having the biggest job potential, which accounts for approximately 8% of all jobs in the EU and with an increasing demand for healthcare due to the ageing of the population, the Working Document describes the contribution of the EU's health workforce to meet the 2020 employment target of 75% for women and men aged 20-64. However, the Commission considers that the demanding working conditions and relatively low salaries of a majority of health professionals can represent an obstacle to the recruitment of the healthcare workforce.

In its Communication, the European Commission expresses the need for EU health systems to identify innovative solutions through the means of new technologies, products and organisational changes. The Action Plan's goal is to help Member States tackle these challenges and put in place actions that will encourage European cooperation, the sharing of good practices and the improvement of health workforce planning and forecasting.

In June 2012, a feasibility study was released by the European Commission about EU level collaboration on forecasting health workforce needs, workforce planning and health workforce trends. It was undertaken by Matrix Insight Ltd, in collaboration with the Centre for Workforce Intelligence (CfWI). The research draws upon 34 country profiles, 12 case studies and a focus discussion with an expert panel. One of the conclusions was the recommendation to put in place a European Observatory on Health Workforce Planning for coordination and support.

PUBLIC HEALTH – EUROTRACS

Among the projects that were granted funding for 2012 under the second Health Programme (2008-2013) was the EUROTRACS project, entitled "EUROpean Treatment & Reduction of Acute Coronary Syndromes Cost Analysis", of which HOPE is a partner. The aim of this project which flows from EURHOBOP is to analyse the efficiency in terms of cost per Quality-Adjusted Life Year gained in two fields: three population interventions (and their combinations) designed to prevent coronary artery disease incidence by lowering classical cardiovascular risk factor population prevalence, and optimal use of procedures in patients with acute coronary syndrome) with special emphasis on the elderly (>64 years) to minimise the inequalities in this patient subgroup that has higher mortality risk than patients <65 years.

Exchange Programme

31 YEARS OF HOPE EXCHANGE PROGRAMME

In 2012, the HOPE Exchange Programme celebrated its 31st edition. Although the crisis has had its effects on the number of participants and institutions, around 130 professionals benefited from this 4-week training period in 102 institutions in most Member States of the European Union and in Switzerland.

This year, the topic "Ageing health workforce - ageing patients. Multiple challenges for hospitals in Europe" was in line with the European Year of Active Ageing but added the perspective of the ageing of the workforce to the debates. Starting on 14 May 2012, the HOPE Exchange Programme closed with the HOPE Agora, the final events held in Berlin from 11 to 13 June 2012.

As in previous years, a prize was awarded to the three best country presentations. Winners were chosen by the HOPE National Coordinators. Latvia won the first prize, Denmark the second and the third one was awarded to the health professionals who stayed in Belgium.

Participants and host institutions showed their satisfaction with and enthusiasm for this unique experience of learning and sharing best practices throughout Europe.

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THREE VIDEOS TO BOOST THE HOPE EXCHANGE PROGRAMME

To boost the programme, HOPE shot three videos on the experience of participants and hosts. One explantory video of 15 minutes was made as well as two short videos of 5 minutes each, one targeting participants and the other targeting hosts. The shooting took place in Spain, The Netherlands, Belgium and Berlin. The videos were uploaded on YouTube.

These videos will be used as communication tools for National Coordinators to promote the programme, also serving as a graphic document for the participating institutions to show what the Programme is about. The press release announcing the videos included examples of good practices.

CONFERENCES ORGANISED BY HOPE

HOSPAGE

AGEING HEALTH WORKFORCE - AGEING PATIENTS

Hosted by the German Hospital Federation, HOSPAGE "Ageing health workforce - ageing patients. Multiple challenges for hospitals in Europe", was the high level conference organised in Berlin on 12 June 2012 as part of the HOPE Agora and the HOPE Exchange Programme 2012. The topic has gained a particular relevance in the last years: the European Commission released in April 2012 an Action Plan in order to tackle the challenges linked to this trend around the European Innovative Partnership on Active and Healthy Ageing; the WHO European Observatory on health systems and policies also published a number of studies on the topic. The event therefore gathered several hundred of participants at an optimal time.

Georg Baum, President of HOPE and Chief Executive of the German Hospital Federation, welcomed Daniel Bahr, the German Minister of Health, followed by a video message of John Dalli, European Commissioner for Health. Recognising the importance of the event and relevance of the topic, speakers highlighted the need of learning from each other, foster innovation, improve prevention and workforce planning.

Conference keynotes were delivered by Rita Süssmuth, former President of the German Parliament, and by Josep Figueras, director of the WHO European Observatory on health systems and policies.

In the panel discussion that followed, Georg Baum, Maria Iglesia Gomez from the European Commission, Evert Jan van Lente representing the European Social Insurance Platform (ESIP) and Anders Olauson, President of the European Patients' Forum (EPF), exchanged views on these future trends, how to face changes, and views on the European Partnership on Active and Healthy Ageing that the latter had promoted.

Parallel session 1 — Ageing health workforce

The first parallel session of the conference on the topic of "Ageing health workforce" was opened by Prof. Juhani Ilmarinen with an overview of the change of work ability across life years.

Eva Weinreich-Jensen (Danish Regions) gave the perspective of Regional Authorities. Prof. Walter Sermeus (coordinator of EU-funded project RN4cast) illustrated some findings of the project RN4cast aimed at forecasting the future needs of nursing staff in Europe and the United States. Lastly, Caroline Hager (European Commission) illustrated the Action Plan for the EU health workforce.

Parallel session 2 — Ageing patients

The second panel discussion on the topic of "Ageing patients" was opened by Dr. John Cachia, Past-President of HOPE, illustrating the Maltese agenda on active ageing. Dr. Božidar Voljč (AGE Platform Europe) from the Anton Trstenjak Institute of Gerontology and Intergenerational Relations, Slovenia emphasised the role of different elements influencing patients' behaviour, needs and expectations in different areas such as the use of primary care, hospital stay, consultations, drug consumption and palliative care.

Finally, Prof. Elisabeth Steinhagen-Thiessen from the Charité University hospital of Berlin discussed factors affecting ageing and their interdisciplinary relationships, and the patterns of multidimensional diagnostics and integrated care adopted in Germany.

A further presentation about the reconciliation of work and older persons' care was given by Anine Linder, project manager of "Network Success Factor Family", Germany. A wrap up session reporting on the results of the two parallel sessions concluded the conference.

CONFERENCES CO-ORGANISED BY HOPE

INNOVATION IN HEALTHCARE WITHOUT BORDERS

For the third successive year, HOPE co-organised with the European Commission and other stakeholders a conference on innovation that took place in Brussels on 16 and 17 April 2012. The aim was to bring together the key stakeholders involved in the innovation process of the healthcare sector, in the perspective of Europe 2020 and the Innovation Union Plan. The specific objectives were to identify major challenges and build consensus to address them, and then develop initiatives and opportunities for Healthcare Innovation.

Building on the events of May 2010 and March 2011, the 2012 Conference sessions developed two tracks: "Removing borders in the health supply chain", assessing priorities achieved to date and areas where additional efforts are needed, and "Inequality and solidarity", exploring new challenges within EU and beyond. The programme of plenary and parallel sessions allowed a large space for debate and networking which was complemented by a small "fair" where associations and support structures provided information to participants.

EUROPEAN ANTIBIOTIC AWARENESS DAY

HOPE contributed to the launch event of the fifth European Antibiotic Awareness Day on 16 November 2012, an annual European public health initiative coordinated by the European Centre for Disease Prevention and Control (ECDC). HOPE is part of this initiative, which aims to raise awareness about the problem of antimicrobial resistance, and provide a platform and support for national campaigns on the careful use of antibiotics.

On this occasion, the ECDC released new EU-wide data on antibiotic resistance and consumption. Data shows that antibiotic resistance remains a major European and global public health problem, originated for a large part from the misuse of antibiotics.

Over the last four years, there has been a Europe-wide increase of antibiotic resistance and of multi-drug resistance in bacteria such as *Klebsiella pneumoniae* and *Escherichia coli*. The increasing trend of combined resistance means that, for patients who are infected with these multidrug-resistant bacteria, only few fast-line therapeutic options remain available. This is translated in increasing healthcare costs, extra length of stay in the hospital, treatment failures, and sometimes death.

The European Antibiotic Awareness Day dates back to November 2001 when the EU Health Ministers adopted a Council Recommendation on the careful use of antimicrobial agents in human medicine, which stated that EU Member States should inform the general public of the importance of careful use of antimicrobial agents by, in particular, raising awareness of the problem of antimicrobial resistance and encouraging realistic public expectations for the prescription of antimicrobial agents.

As a result, national awareness campaigns to educate the public and primary care prescribers about appropriate outpatient antibiotic use have in some countries successfully resulted in a decrease in antibiotic prescriptions. The success of these campaigns stimulated a European initiative coordinated by the European Centre for Disease Prevention and Control (ECDC), and named “European Antibiotic Awareness Day” (EAAD), to take place each year around the 18 November.

Ten days earlier, the European Parliament’s Committee on Environment, Health and Food Safety (ENVI) adopted with the contribution from HOPE a draft report on “Microbial challenge - rising threats from antimicrobial resistance”.

The report wanted to tackle the problem of antimicrobial resistance by underlining the need for a more cautious use of drugs, improvements in animal welfare and development of new business models to stimulate innovation.

It focused on six main areas:

- careful use of antimicrobials in human and veterinary medicine;
- prevention;
- development of new antimicrobials or alternatives for treatment;
- monitoring and reporting;
- communication, education and training;
- international cooperation.

CONFERENCES WITH HOPE AS SPEAKER

INTEREST GROUP ON MENTAL HEALTH, WELL BEING AND BRAIN DISORDER

On 24 January 2012, HOPE joined the meeting of the European Parliament Interest Group on Mental Health, Well being and Brain Disorder.

Chaired by MEPs Antonyia Parvanova (ALDE) and Nessa Childers (S&D), the meeting focused on the issue of depression in Europe and was launched by a short video of former Norway Prime Minister Kjell Magne Bondevik, who answered a few questions about his personal experience of depression. The former Prime Minister strongly highlighted the major role played by the stigma that affects citizens who suffer from depression or other mental illnesses and that often prevents them from seeking help and treatment.

Professor Charles Pull from the University of Luxembourg, also mentioned stigma as one of the main challenges that were identified by the European Survey that was conducted from July 2009 to February 2011 on the state of health care services in the field of depression. The survey also identified the disparity of health services for mental illnesses in Europe and the failure to diagnose depression as a major challenge to tackle at European level. According to Prof. Pull, half of Europeans who suffer from depression are not properly diagnosed.

The meeting also focused on the issue of the cost of depression and mental brain disorders. As stated by Prof. Cyril Höschl from the European Brain Council, over 33 million people are affected by mood disorders in Europe, and the cost related to these disorders (including depression) is higher than the financial burden of cardiovascular diseases and cancer put together, amounting to 113 billion Euro per year.

The event was the opportunity for the European Commission and the Expert Platform on Mental Health to give updates on their activities in regards to this topic. The Commission mentioned the recent activities related to the European Pact for Mental Health and Well Being, with a special focus on the Joint Action on mental health and well-being, which will start at the end of 2012 or at the beginning of 2013.

Throughout the meeting, the various speakers including HOPE made several recommendations for tackling the burden of depression and brain disorders in Europe. The necessity of improving the diagnosing of depression was brought forward by many speakers, as well as the importance of including the people who suffer from depression and mental disorders as well as their relatives in the initiatives aimed at addressing these issues.

Finally, emphasis was put on the need to raise awareness and to identify and exchange best practises.

EUROPEAN HEALTH SUMMIT, NUFFIELD TRUST

On 24 January 2012, HOPE was invited to contribute to the European Health Summit 2012 of the Nuffield Trust, a forum of a select audience of around 40 experts from across Europe, to examine recent innovations, future opportunities and challenges facing European health systems, and to debate how best to respond to these.

The aim was to provide the latest information and evidence on innovations on payment reform in Western Europe, to draw out cross-country learning, to identify the next steps required to reform payments in healthcare, to progress the agenda beyond the event to reach policy-makers, health professionals, and academics.

The meeting was held in Brussels by the Nuffield Trust, an independent foundation based in London focused on health policy analysis, and was supported by KPMG. A briefing paper for delegates “Reforming payment for health care in Europe to achieve better value” prepared the meeting. This briefing paper concerned the structure of payment for healthcare, principally to doctors and hospitals by payer bodies (not individual patients).

EUROPEAN REGIONAL HEALTH AUTHORITIES (EURHEGA)

HOPE was invited to speak in Brussels at the Committee of the Regions during the launch of the European Regional and Local Health Authorities EUREGHA as a new legal entity. HOPE was invited to contribute on health Quality and Equity together with Fritz von Nordheim Nielsen, Policy Coordinator Unit Active Ageing, Pensions, Health and Social Services, Directorate General Employment.

Originally gathering a large group of regions, EUREGHA is now limited to very few founding organisations: Catalunya (Spain), East of England (United Kingdom), Flanders (Belgium), NÖGUS (Austria), North West Health (United Kingdom), Podlaskie Voivodship (Poland), Skane (Sweden), Vastra Gotaland (Sweden), Veneto (Italy), ECTC between Austria and Italy, Emilia Romagna (Italy), German speaking community (Belgium), Vysocina (Czech Republic) and Wallonia (Belgium).

The aim is that sharing information and being better heard needs resources. The regions are then invited to contribute with a fee. Activities are to build a website, an eHealth database, meetings with EU presidencies and drafting answers to consultation.

Three working groups have already been constituted: mental health, cancer, cross-border healthcare. A new one will be created on eHealth.

AMERICAN CHAMBER OF COMMERCE – INVESTMENT IN HEALTHCARE

The American Chamber of Commerce to the European Union (AmCham EU) invited HOPE to present its views during its February Plenary Meeting dedicated to investment in healthcare. The meeting took place in Brussels on 28 February 2012.

The monthly plenary meetings bring together AmCham EU members and key decision makers. AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues for the resolution of transatlantic issues that impact business. It plays a role in creating better understanding of EU and US positions on business matters. According to AmCham aggregate US investment in Europe totalled €1.2 Trillion in 2008 and currently supports 4.8 million direct jobs in Europe.

The on 28 February 2012 by AmCham released paper "Explaining AmCham EU's Position on Investment in Healthcare" aims to demonstrate why health matters highlight promising areas for investment and seek out more sustainable solutions to maintain and increase Europe's competitiveness. It identifies five areas for investment such as prevention: e-health, medical innovation, integrated care, and investment in citizens and patients.

AmCham EU recommends in particular:

- safeguarding innovation in the long run by implementing policies that overcome static thinking and unleash dynamic efficiency;
- providing smart regulations that are limited to their purpose;
- supporting innovative partnerships between the public and private sectors;
- taking a consumer approach to empower citizens to be innovators in their own health.

Robert Madelin, Director General for Directorate General Information Society, delivered a keynote speech clearly in line with the AmCham.

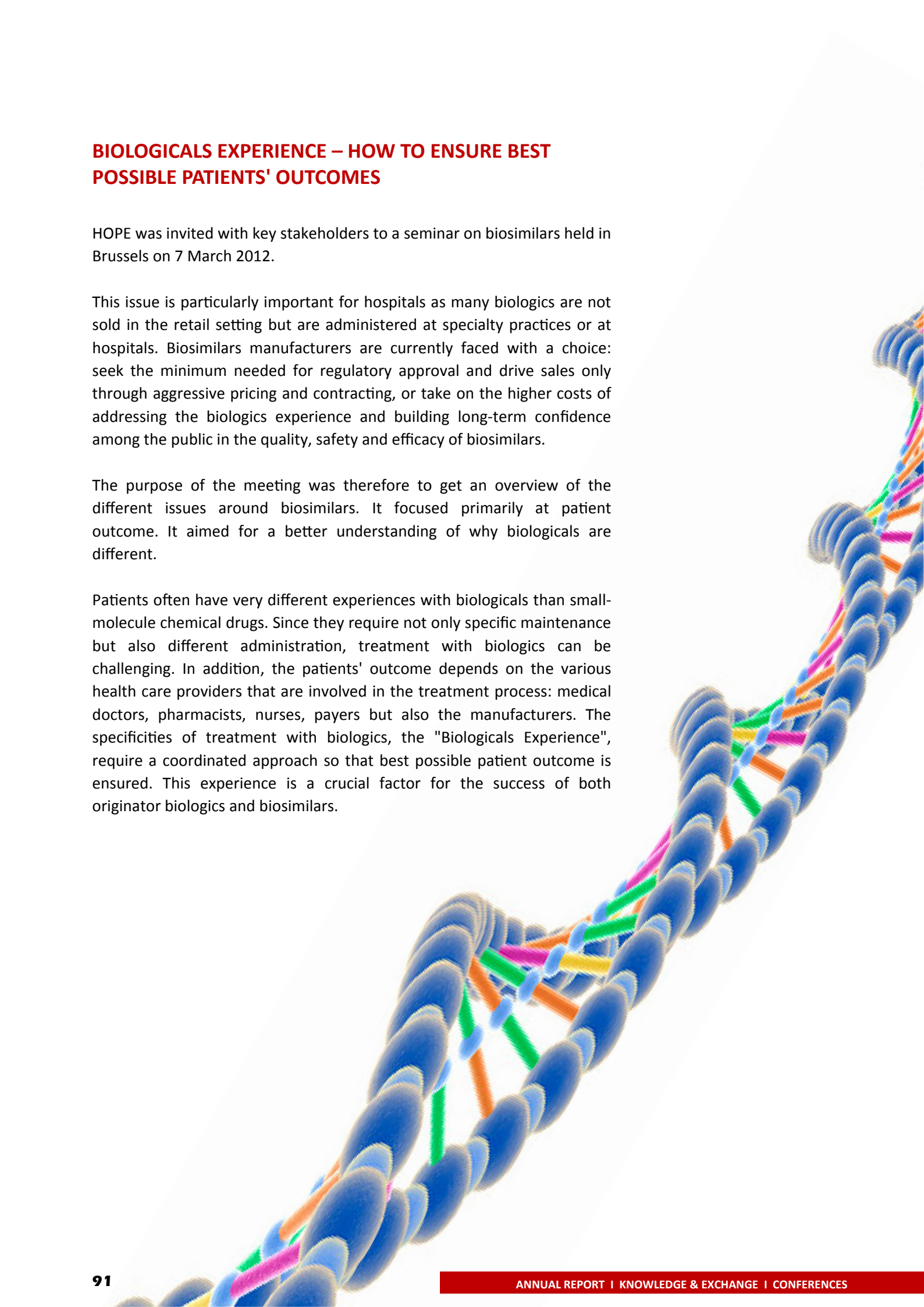
BIOLOGICALS EXPERIENCE – HOW TO ENSURE BEST POSSIBLE PATIENTS' OUTCOMES

HOPE was invited with key stakeholders to a seminar on biosimilars held in Brussels on 7 March 2012.

This issue is particularly important for hospitals as many biologics are not sold in the retail setting but are administered at specialty practices or at hospitals. Biosimilars manufacturers are currently faced with a choice: seek the minimum needed for regulatory approval and drive sales only through aggressive pricing and contracting, or take on the higher costs of addressing the biologics experience and building long-term confidence among the public in the quality, safety and efficacy of biosimilars.

The purpose of the meeting was therefore to get an overview of the different issues around biosimilars. It focused primarily at patient outcome. It aimed for a better understanding of why biologicals are different.

Patients often have very different experiences with biologicals than small-molecule chemical drugs. Since they require not only specific maintenance but also different administration, treatment with biologics can be challenging. In addition, the patients' outcome depends on the various health care providers that are involved in the treatment process: medical doctors, pharmacists, nurses, payers but also the manufacturers. The specificities of treatment with biologics, the "Biologicals Experience", require a coordinated approach so that best possible patient outcome is ensured. This experience is a crucial factor for the success of both originator biologics and biosimilars.



EUROPEAN ALLIANCE ON PERSONALISED MEDICINE – CALL TO ACTION

On 27 March 2012, the European Alliance for Personalised Medicine (EAPM) launched its call to Action in the European Parliament. Personalised medicine is defined by the Alliance as products and services that leverage the science of genomics and proteomics (directly or indirectly) and capitalise on the trends towards wellness and consumerism to enable tailored approaches to prevention and care.

The EAPM, which is a multi-stakeholder platform, pointed out five main objectives of the call:

- ensuring a regulatory mechanism which allows early patient access to novel and efficacious personalised medicine;
- increase research and development for personalised medicine;
- improve the education and training of health care professionals;
- acknowledging new approaches to reimbursement and HTA assessment, which are required for patient access to personalised medicine and its value to be recognised;
- increase awareness and understanding of personalised medicine.

Paola Testori Coggi, Director General of DG SANCO, declared that the Commission will revise the regulatory system "to have it flexible enough" as now it is "too complex" and "a burden" for clinical trials.

Patricia Reilly for DG Research pointed out the progress achieved with cancer treatment so far. The Commission has already allocated 900 million Euro in research related to personalised medicine in the FP7.

Marian Harkin, member from the European Parliament, explained that in Horizon 2020, the next Framework for Research and Innovation will provide research with 80 billion Euro and that "personalised medicine will remain among the priorities". She pointed out the importance of finding the right equilibrium between patient's protection and a more simple Regulation for clinical trials.

HOPE, together with PriceWaterhouseCoopers, was invited to present its recently published "Personalised Medicine in European Hospitals." This report identifies key elements in the development of personalised medicine in European hospitals. This collaboration will help determine the current state and the desired future state of personalised medicine practices within European hospitals, and will thoughtfully facilitate the creation of a culture of customised healthcare.

QUALITY – EUROPEAN VOICE HEALTH CHECK BRIEFING

On 4 June 2012, at the Press Club Brussels Europe, European Voice held a lunchtime briefing about how developments in evaluation techniques and tools can lead to better decision-making in healthcare. Pascal Garel, Chief Executive of HOPE, and Jean Hermesse, Secretary-General of Belgium's Mutualités Chrétiennes (also chair of Association Internationale de la Mutualité's health systems reform working group) commented on the presentation of one of the world's leading experts in this field, Professor Niek Klazinga.

Klazinga is the head of the healthcare quality indicators project at the OECD. He has been coordinating the OECD's work on healthcare quality indicators since 2007. This medical doctor holds a professorship at the University of Amsterdam and is chairman of the advisory committee on transparency in healthcare at the Dutch Ministry of Health.

RESTRUCTURING HEALTH SYSTEMS – HOW TO PROMOTE HEALTH IN TIMES OF AUSTERITY?

On 6 June 2012, the European Public Health Alliance organised its Annual Conference, hosted by the European Economic and Social Committee: "Restructuring Health Systems: How to promote health in times of austerity?"

HOPE was invited to speak and a briefing paper “The economic crisis & EPHA fact & figures on the impact of the financial crisis on health” included several elements produced by HOPE in its report “The Crisis, Hospitals and Healthcare”.

What is the cost of the crisis on populations and their health? Are the austerity measures viable or do they put health systems into a long-term crisis? How can the EU and national authorities create a new way of thinking to tackle the consequences of the crisis and yet secure sustainable healthcare systems?

Commissioner for Health John Dalli, Zsuzsanna Jakab, Director for the WHO Europe, Sanjeev Gupta, International Monetary Fund, and Pervenche Beres, chair of the Employment and Social Committee in the European Parliament, took part in the debate and discussed with civil society organisations the impact of the crisis and the way forward.

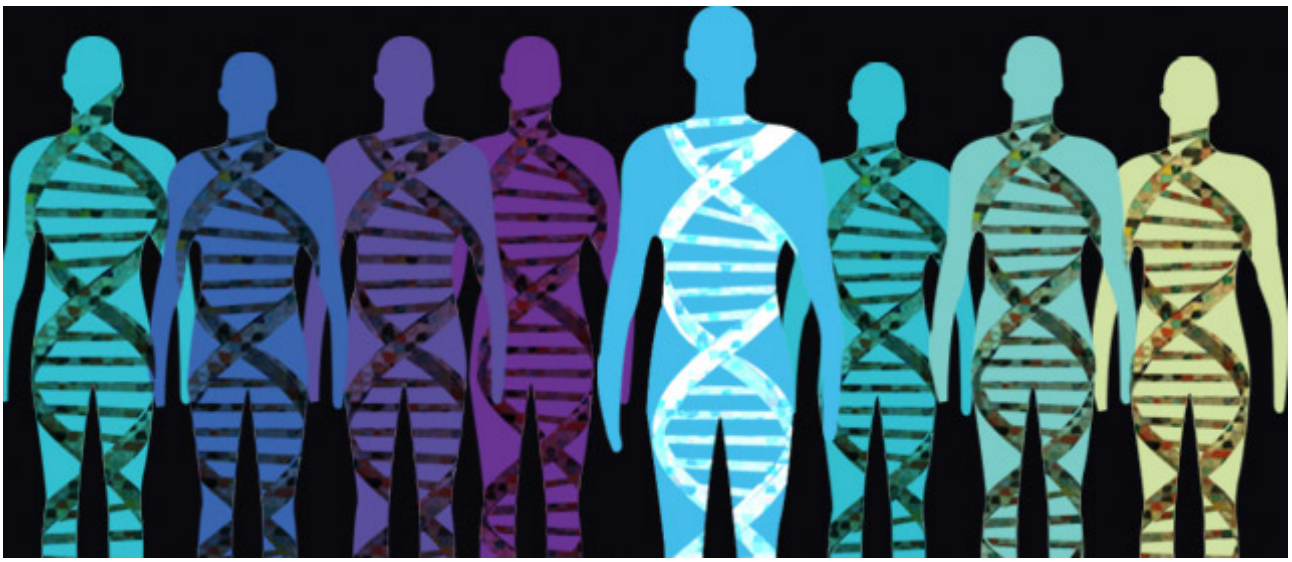
THE FUTURE OF PERSONALISED CANCER MEDICINE IN EUROPE – ECCO ONCOPOLICY FORUM

On 11 October 2012, the European Cancer Organisation (ECCO) organised in Brussels its 4th edition of the Oncopolicy Forum dedicated this year to the future of personalised medicine in Europe. The high number of researchers among the speakers made of this event a very technical and particularly interesting one.

Cornelis J.H. van de Velde, ECCO President, chairing the first part of the conference, said personalised medicine (PM) will change the cancer landscape in Europe from detection to diagnosis, treatment and care, and will bring the optimal treatment based on the individual particularities of patients' specific needs. However, "it is important to define the state of art" to find out the consequences the implementation of PM will bring in economic, organisational and professional terms, he said.

Máire Geoghegan-Quinn, European Commissioner for Research, Innovation and Science, said in a video address that our treatments are not selective enough. The European Commission will "reward evidence" and support "what really works" through Horizon 2020, the new funding instrument for research of the EC, which has allocated 8,5 billion Euro for health and demographic change, she said.

Maria José Vidal-Ragout, Head of Unit of Medical Research, DG Research and Innovation of the European Commission, gave some examples of EC funded projects (Mammi and Cancerdip) and of the private-public partnerships (Eurocourse, Eurocam Platform and Trascan). She said the challenges of PM are finding the predictive and prognosis biomarkers, deal with co-morbidity and the side effects of drugs. She, again, spoke about Horizon 2020.



INTERNATIONAL CONFERENCE ON CROSS-BORDER HEALTHCARE

On 25 and 26 October 2012, HOPE was invited to share view at the International Conference on Cross-border Healthcare, held in Bled, Slovenia.

The conference was organised by HOPE Governor for Slovenia Simon Vhrunec, under the patronage of the President of the Republic of Slovenia, Dr. Danilo Türk. The main goal was to provide the most relevant and up-to-date information on the Directive 2011/24/EU on the application of patient's rights to cross-border healthcare to an audience of healthcare institution managers, health funds, patient groups, regulators, health care providers and national experts from Slovenia and other countries in the region.

The cross-border healthcare Directive will be applicable from 25 October 2013. This means Member States have less than one year to introduce the necessary legislative and organisational changes. To date, many Member States are still far from completing the transposition of the EU legislation.

For HOPE this was an opportunity to reiterate that patients crossing borders is not something new and that we can learn from past and present experiences. It is clear that cross-border care is more complex in an already complex environment. Continuity of care is certainly the most important element to take into consideration. The major overall change of the cross-border Directive is the push for more transparency on availability, prices and quality indicators.

EU PATIENT ROUNDTABLE ON CLOSTRIDIUM DIFFICILE INFECTION

On 7 November 2012, HOPE hosted the EU Patient Round Table on Clostridium difficile infection (CDI) and other healthcare associated infections (HAIs).

CDI is a leading healthcare associated infection in Europe and it is mainly caused by the use of antibiotics, which can clear the normal "good" bacteria from the bowel and allow the overgrowth of CDI. CDI causes diarrhoea, which in some cases can be severe, and is associated with significant morbidity and mortality. Although CDI can occur in the community setting, it is most common in hospitals and nursing homes.

Despite its importance, there is limited awareness of CDI across Europe, particularly among people at risk (people over the age of 65 years, in those using broad spectrum antibiotics, and in patients who have a prolonged period of hospitalisation). Therefore, the main aim of the round table was to try to reverse this trend and ensure all patients potentially at risk of CDI are properly informed and educated about the infection, and empowered to communicate with their healthcare providers about CDI and HAIs.

In the first part of the round table, the burden of CDI within the policy context of European action on HAIs was presented. CDI experts also provided a comprehensive picture of the disease.

In the second session, all participants discussed best ways to inform patients about HAIs and the risks of CDI. Information to patients, patient empowerment and health literacy were considered key resources to ensure patients become effective partners on issues related to the safety and quality of their care.

4TH INTERNATIONAL CONGRESS OF HOSPITALS – "AGEING AND HEALTH: CHALLENGES IN TIMES OF CHANGE"

HOPE was invited to give a speech on the 4th International Congress of Hospitals organised by its member APDH (Portuguese Association for the Development of Hospitals) on 7, 8 and 9 November 2012 in Lisbon on the theme "Ageing and Health: Challenges in times of Change". The aim of the event was to analyse the effects of the strong rationalisation of services and the strict control of the expenditure in the health sector organisations, particularly the hospitals, due to the economic and financial crisis.

This situation was studied taking into account demographic changes, the difficulties in accessing the healthcare, the weakening of the social security systems and the inevitable need for more sustainable policies.

EUROPEAN PUBLIC HEALTH ASSOCIATION

HOPE was accepted to deliver a presentation during the 5th joint conference combining the 20th annual EUPHA meeting and 34th annual ASPHER meeting, organised by the European Public Health Association (EUPHA), the Association of Schools of Public Health in the European Region (ASPHER) and the Malta Association of Public Health Medicine (MAPHM).

The European Public Health Conference aims to contribute to the improvement of public health in Europe by offering a means for exchanging information and a platform for debate to researchers, policy makers, and practitioners in the field of public health and health services research as well as public health training and education in Europe.

Organised in partnership with the University of Maastricht (Netherlands), a session was devoted to the crisis. HOPE's presentation covered the results of its various reports on the impact of the crises on hospitals and healthcare services.

RISK MANAGEMENT FOR PATIENT SAFETY – WORKSHOP

On 21 November 2012, HOPE co-chaired one of the sessions of the European workshop on "Risk Management for Patient Safety" organised by Det Norske Veritas (DNV). The objective of the workshop was to bring together national, European and international experts on patient safety and risk management to discuss the current challenges and needs in this field.

The workshop was addressed among others, by representatives from the European Commission, WHO and DNV, who highlighted the respective work carried out in the area of patient safety. 10% of patients hospitalised in the EU suffer from an adverse event, demonstrating how there is still considerable room for improvement. More competences on proactive risk assessment methods are needed, but there is also the necessity to raise awareness on the costs of unsafe care, especially in times of austerity.

Overviews of the Joint Action on Patient Safety and Quality of Care (PaSQ), as well as the projects QUASER and DUQuE - three projects in which HOPE is involved - were also provided.

The main messages from the event were that exchanging experiences among Member States on patient safety is crucial for further improvements in this area. More efforts regarding continuous education and training of health care professionals, information to patients and their empowerment are also the ways forward.

Finally, healthcare suffers from under management; to date, there has been limited use of proactive approaches to identify and manage risk within clinical healthcare practices. Exploring how knowledge on proactive risk management can be shared between healthcare and other safety critical industries might help to improve patient safety.

WHY HEALTH IS CRUCIAL TO EUROPEAN RECOVERY

HOPE Chief Executive was invited to speak at the Friends of Europe high-level European Policy Summit "Why health is crucial to European recovery" that took place on Tuesday 27 November 2012 at Bibliothèque Solvay, Brussels.

With the subtitle "Health care systems under pressure: eradicating inefficiencies and freeing up resources", the conference looked at the long -term consequences of the crisis. Rising unemployment and reduced tax revenues mean most EU governments will struggle to provide their citizens with reliable and affordable healthcare. In Greece, an estimated 30% of people have started to turn to street clinics for their medical needs, while in Spain, a measure introduced earlier this year requires older people to pay in part for drugs they previously received for free through the healthcare system. Across Europe longer waiting times, lower patient satisfaction and reduced healthcare provisions all underline the need for reform. But where can greater efficiencies be found? Which cost-cutting measures are beneficial, and which detrimental? Can eHealth help deliver better care for less money within citizen-centred health delivery systems? Is greater centralisation of healthcare the answer, and what should policymakers focus on to ensure healthcare drives rather than drains European economies?

Among the other speakers were Erik Briers, Executive Director of the European Cancer Patient Coalition (ECPC), Josep Figueras, Director European Observatory on Health Systems and Policies & Head, WHO European Centre on Health Policy, Alojz Peterle, MEP President of MEPs Against Cancer (MAC), Substitute of the European Parliament Committee on the Environment, Public Health and Food Safety, and Paola Testori Coggi, European Commission Director General for Health and Consumers.

WORKSHOP ON CARDIOVASCULAR REGISTRIES

HOPE was invited to the first workshop on cardiovascular registries and data standards, organised in Brussels on 12 December 2012 by the European Society of Cardiology.

The workshop looked at current cardiovascular data collection, existing data standards for cardiovascular diseases, how to make use of the collected data, defining a roadmap towards standardisation and centralisation of cardiovascular diseases data collection in Europe.

The European Society of Cardiology is involved in several registries, within the EurObservational Research Programme but also through projects such as EuroHeart 2, EUROCISS or CARDS.

The European Organisation for Research and Treatment of Cancer was also invited to show a parallel initiative at a pan European level but in the field of cancer clinical research. Other presentations included the European Health Examination Survey, the use of registries in Sweden, the relevance for cost effectiveness of a cardiovascular registries repository.

More generally, the European Society of Cardiology and the European Heart Network are pushing for a centralised, comprehensive European cardiovascular disease registry with a set of predetermined patient data on health status, consumed resources, demographics and socioeconomics.

Partly answering this, the Cross-border Patient Registries Initiative (PARENT), also presented that day, is a joint action aimed at supporting Member States in assessing registries and provide guidelines and IT components to design them. It raises the question of what needs to be centralised by the overall governance, security, trust and processes.

Chapter 4

PUBLICATIONS

In 2012, HOPE published two reports and the 2012 edition of "Hospital Health-care Europe", the official HOPE Reference Book

Publications

HOSPITAL HEALTHCARE EUROPE 2012

In April HOPE published the 2012 edition of "Hospital Healthcare Europe", the official HOPE Reference Book. It contains in-depth management reviews, informed articles and case studies. There is one section, HOPE Bulletin, devoted to HOPE articles and individual sections on facilities management, IT and communications, laboratories, radiology and imaging, theatre and surgery, clinical care, nursing and patient care, pharmacy and therapeutics.

HOPE Bulletin consisted of the following articles:

- Representing public and private hospitals,
- Cross-border care, a joint hospital conference, a report on the joint conference with the European Association of Senior Hospital Physicians and the European Association of Hospital Managers held in Dusseldorf on 18 November 2011;
- Health Technology Assessment in cross-border settings;
- EU mechanisms: making health policy at EU level;
- Hospital in Europe - Data and trends;
- The current crisis, hospitals and healthcare, a report made from the interviews of 12 HOPE members who explain the impact of the economic and financial crisis on their healthcare systems.

Hospital Healthcare Europe also offers expert comments and reports by European Health Ministers, the European Parliament, the European Commission, the Council of Ministers, the Court of Justice and WHO.

PERSONALISED MEDICINE IN EUROPEAN HOSPITALS

In February 2012 HOPE published a report called “Personalised Medicine in European Hospitals”, which examines the strategies European hospitals are undertaking to adapt to a individual patient-focused culture and identifies key elements in the development of personalised medicine in European hospitals.

Personalised medicine is still in its early stage of implementation in the European healthcare market but receives major support from EU institutions, researchers (most of all in cancer) and the pharmaceutical industry. It can be defined as products and services that thanks to today’s progresses in genomics and proteomics enable tailored approaches to prevention and care. Personalised medicine aims at providing timely, precise, personalised diagnosis and treatment of patients, with a particular emphasis on wellness and disease prevention.

The report outlines the move towards personalised medicine in six European hospitals located in Denmark, Finland, France, Hungary, Slovenia and Spain, and compares the pathway each is taking.

The main findings highlight that most European hospitals focus on initiatives related to diagnostics and therapeutics; genetic screening is widely used for treatment in cancer patients, stems cells programmes are ongoing but they are rarely applied to the clinical setting, while telemedicine services are largely but not fully deployed yet. Only a few European hospitals focus on nutrition and physical activities to encourage wellness and improve the treatment of patients; most do not tackle prevention as part of their approach. The development of relationships or affiliations with other sector organisations is a usual practice, since cooperation between the many stakeholders in the life science and medical sectors is essential in fostering innovation in the field of personalised medicine.

The report concludes by identifying the main barriers for the implementation of personalised medicine within the European hospital environment: lack of research funding, lack of strong scientific evidence in some fields, lack of knowledge among doctors, and lack of a clear reimbursement system for related services.

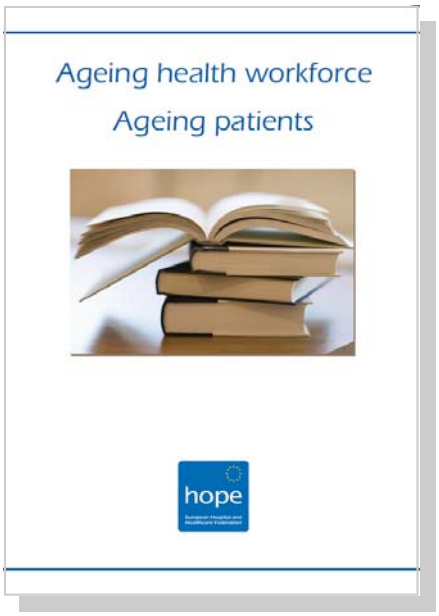
Finally, it outlines that today hospitals have a clear opportunity to adapt to the new healthcare paradigm and provide services that are targeted to the individual patient. However, it is important to recognise that different hospitals require different models; hence personalised medicine must be designed and implemented according to each hospital needs, organisation and operational pattern.

The hospitals that have participated in the study are the following: Herlev Hospital/Copenhagen University Hospital (Denmark), Kuopio University Hospital (Finland), University Hospital of Dijon (France), Medical and Health Science Center University of Debrecen (Hungary), University Medical Centre Ljubljana (UMCL) (Slovenia) and Hospital Clinic de Barcelona (Spain°.

AGEING HEALTH WORKFORCE - AGEING PATIENTS. MULTIPLE CHALLENGES FOR HOSPITALS IN EUROPE

HOPE published on 31 October 2012 its report "Ageing health workforce – Ageing patients. Multiple challenges for hospitals in Europe". The report illustrates the contents and findings of HOSPAGE, the June conference that took place at the end of the HOPE Exchange Programme.

The report goes through the debates and results of the conference and informs about the solutions and situations identified by the HOPE Exchange Participants. It complements and completes the Reflection paper "Population aging and the role of hospitals" specifically prepared for the event by Bernd Rechel from the WHO European Observatory on Health Systems and Policies.



General Report on the Activities of the European Hospital and Healthcare Federation 2012