



NEWSLETTER

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6-8 June 2016 – Rome (Italy)

HOPE AGORA₂₀₁₆

THE FUTURE OF HOSPITALS AND HEALTHCARE

**STAKEHOLDERS MEETING –
UPDATE ON MEDICAL DEVICES DOSSIER**

On 10 December 2015, the upcoming Dutch Presidency of the Council invited stakeholders to an informative meeting about the Regulations on medical devices and in vitro diagnostic medical devices currently under negotiation.

During the meeting, an update on the state of play and activities planned by the future Presidency was provided by Ricco Buitink, Health Attaché and Daniëlle van Mulukom, Project manager, the persons in charge of this dossier at the Permanent Representation of the Netherlands to the EU.

The Luxembourg Presidency worked very hard during its mandate and 5 trilogues and around 7 technical meetings took place. About a quarter to a third of the text has been covered at technical level. An update about the state of play was provided during the last EPSCO Council on 7 December (<http://bit.ly/1Qo2S5H>).

The Dutch Presidency plans to hold 5 trilogues and 10 to 15 technical meetings with a view to reach an agreement at the EPSCO meeting in June. Trilogues will start at the end of January 2016.

It followed an overview of the main political issues at stake:

- Genetic testing
- CMR substances
- Reprocessing
- Liability insurance
- Scrutiny mechanism/special Notified Bodies
- Validity of certificates (CH X)
- Classification rules (6, 19, 21 MD; 1,4,5 IVD)
- Clinical investigations, performance studies IVD

Finally, the upcoming Presidency declared its interest in hearing the views of stakeholders and invited to submit any available positions on this dossier.

HEALTH COUNCIL BRIEFING AND PRESIDENCY PRIORITIES – EPC POLICY BRIEFING

On 10 December 2015, HOPE attended the policy briefing organised by the think tank European Policy Centre (EPC) on the future Dutch Presidency priorities in the area of health.

The meeting started with an overview of the achievements of the Luxembourg Presidency by Laura Valli, Health Counsellor at the Permanent Representation of Luxembourg to the EU. Personalised medicine and dementia were the main health priorities of the Luxembourg Presidency and the work carried out resulted in the adoption of Council conclusions at the EPSCO Council of 7 December.

The Ebola outbreak was also high on the agenda of the Presidency. A conference was organised in Luxembourg on 12-14 October and main lessons learned during this occasion fed the Council conclusions adopted by Ministers on 7 December.

Finally, the Luxembourg Presidency also discussed other topics during its mandate such as the public health dimension of migration, the implementation of the cross-border healthcare Directive and the health dimension in the European semester. It also continued negotiations on the two regulations on medical devices and in vitro diagnostic medical devices organising 5 trilogues and around 7 technical meetings. Ms Valli declared the Presidency is of the opinion that none of the issues debated during negotiations can block the adoption of the text, but more discussions are needed to reach an agreement.

The meeting continued with a presentation of the priorities of the Dutch Presidency presented by Marianne Vaes, Health Counsellor at the Permanent Representation of Netherlands to the EU.

During its mandate, the Presidency will focus on three main priorities.

- Antimicrobial resistance (AMR): a conference is planned in February and will bring together Ministers of Health and Agriculture to discuss the issue of AMR and preliminary findings from the Commission evaluation of the AMR Action Plan. The Presidency will adopt Council conclusions on this issue.
- Access to pharmaceuticals: although pricing and reimbursement of medicines is a national competence, the Presidency is of the view that some issues are worthy to be discussed at EU level. Discussions will inform the adoption of Council conclusions.
- Trans fatty acids in foods, continuing discussions already started by the Luxembourg Presidency.

Although not a priority, another topic very high on the agenda will be dementia, with the organisation of a high level conference in Amsterdam in the first quarter of 2016.

More information on the Luxembourg Presidency: <http://www.eu2015lu.eu/en/index.html>

EU INSTITUTIONS AND POLICIES



Public health

PERSONALISED MEDICINE FOR PATIENTS – COUNCIL CONCLUSIONS

On 7 December 2015, the Employment, Social Policy, Health and Consumer Affairs Council (EPSCO) met to discuss and adopt conclusions on personalised medicine for patients.

In this document, the EPSCO Council invites Member States and the Commission to continue their work and to promote research on the topic.

In particular, conclusions invite Member States to support access, as appropriate, according to national provisions, to clinically effective and financially sustainable personalised medicine and exchange best practices. They also call on Member States and the Commission to continue joint work to support to support HTA on personalised medicine in accordance with the HTA strategy and promote interoperability of electronic health records.

Finally, the Commission is invited to promote the possibilities offered by European Reference Networks and research through Horizon 2020 and Innovative Medicine Initiative funding instruments.

More information:

<http://data.consilium.europa.eu/doc/document/ST-14393-2015-INIT/en/pdf>

SUPPORTING PEOPLE LIVING WITH DEMENTIA – COUNCIL CONCLUSIONS

On 7 December 2015, the Employment, Social Policy, Health and Consumer Affairs Council (EPSCO) adopted conclusions on “supporting people living with dementia: improving care, policies and practices”. This was the second major priority for the Luxembourg Presidency in the field of health, after personalised medicine.

Currently, 47.5 million people around the world are living with dementia, including 6.4 million in the EU. This figure is going to increase, due to the ageing of population.

Thus, the conclusions invite the Member States to provide appropriate treatment and care for people living with dementia, their families and care staff, with the objective of reducing the stigma associated with dementia, promoting the exchange of good practices on the prevention, diagnosis and treatment of dementia, investing in research, adapting the role and training of formal and informal carers and, finally, ensuring adequate support for patients and those close to them. The

Council conclusions take into account the discussion held among the Ministers for Health during the informal meeting in Luxembourg on 24 and 25 September 2015.

More information:

<http://data.consilium.europa.eu/doc/document/ST-14395-2015-INIT/en/pdf>

LESSONS LEARNED FROM THE EBOLA OUTBREAK – COUNCIL CONCLUSIONS

On 7 December 2015, the Employment, Social Policy, Health and Consumer Affairs Council (EPSCO) adopted conclusions on “Lessons learned for Public Health from the Ebola outbreak in West Africa”.

The conclusions stress the planning and preparation and the response by EU Member States to serious cross-border threats to health and cooperation to strengthen health security in the European Union in the event of future outbreaks.

The draft conclusions draw on the results of the Ebola conference organised jointly by the Commission and the Luxembourg Presidency in Luxembourg from 12 to 14 October 2015.

More information:

<http://data.consilium.europa.eu/doc/document/ST-14751-2015-INIT/en/pdf>

INFRINGEMENT PROCEDURE AGAINST POLAND OVER BLOOD QUALITY AND SAFETY OF HUMAN BLOOD

On 10 December 2015, the Commission referred Poland to the Court of Justice of the EU (CJEU) for failing to fully transpose Directives 2002/98/EC, 2004/33/EC and 2005/61/EC regarding quality and safety of human blood. Indeed, Poland had to transpose Directives 2002/98/EC, 2004/33/EC by 8 February 2005 and Directive 2005/61/EC by 31 August 2006 and communicate the relevant texts to the Commission which Poland did not do.

The Commission therefore considers that Poland has failed in transposing the Directives, especially regarding the eligibility of donors (the Polish rules are less protective than the EU rule), the import of blood and blood components from third countries (the Polish legislation does not contain the EU rules on traceability and tests of the products) and regarding the control of blood establishments.

EUROPEAN COMMISSION INITIATIVE ON BREAST CANCER – LAUNCH OF A NEW WEB HUB

On 4 December 2015, the European Commission launched a web hub to centralise all the information on its initiative on Breast Cancer (ECIBC). The ECIBC will ensure that all breast services across the EU are harmonised. It will provide support for the implementation of guidelines that will encompass all stages of breast cancer care pathway, from screening to diagnosis and treatment to end-of-life care.

The web hub will be available to patients and stakeholders. Moreover, it will provide information to women on the compliance of their cancer care with European guidelines.

More information (ECICB Website): <http://ecibc.jrc.ec.europa.eu/>

COMMISSION REPORT ON THE IMPLEMENTATION OF DECISION ON SERIOUS CROSS-BORDER THREATS TO HEALTH

On 7 December 2015, the Commission published an implementation report for Decision 1082/2013/EU on serious cross-border threats to health.

The report, among others, includes an assessment of the operation of the Early Warning and Response System (EWRS) and of the epidemiological surveillance network.

The Commission concludes that the Decision has overall improved health security in the EU and the protection of EU citizens from communicable diseases and other events. The alert notification, risk assessment and cross-border management, as well as the coordinated response at EU level seem to be efficient. However, the Ebola epidemic proved to be a challenge for the system.

The establishment of the EWRS, the epidemiological surveillance network, the European Centre for Disease Prevention and Control (ECDC) and the Health Security Committee (HSC) has proven to be effective and to improve the quality of the response to the threat. Moreover, these structures have functioned efficiently during the Ebola outbreak, the Middle East respiratory Syndrome caused by coronavirus (MERS CoV) and the poliomyelitis threat. Each of them has a specific task in the response and management of health threats as they complement each other. Indeed, the EWRS is crucial in the alert notification process, the ECDC provides timely risk assessment and the HSC centralises the preparedness and response planning of Member States in order for the Member States and the Commission, in collaboration with the ECDC and the WHO Europe office to discuss them. Furthermore, those structures also collaborate with other mechanisms in different fields that have an impact on health (for instance animal health or food safety).

According to the Commission, the collaboration and discussion between Member States within the HSC have proven to be efficient, especially during the Ebola crisis. As the EU does not have the competence to take public health measures on serious cross-border threats, this platform helped coordinate Member States' responses to the Ebola outbreak, therefore improving the efficiency of those responses.

More information:

http://ec.europa.eu/health/preparedness_response/docs/report_decision_serious_crossborder_threats_22102013_en.pdf



NEXT PHASE OF EU-US eHEALTH/HEALTH IT– CONSULTATION

The European Commission has launched, on 7 December 2015 a public consultation on the updated Roadmap that guides the EU and US cooperation on eHealth.

The consultation will gather comments and input from stakeholders that will be used to finalise the update of the Roadmap and validate it. The updated roadmap will help the collaboration between the EU and the US through European Commission DG CONNECT and the United States Department of Health and Human Services. This collaboration enters in the framework of the EU eHealth Action Plan 2012-2020.

This consultation seeks to gather views from Member States' authorities, businesses, academia, organisations involved in eHealth, health professionals and any other interested stakeholders.

The deadline for responding to the survey is 10 March 2016.

More information:

<https://ec.europa.eu/digital-agenda/en/news/public-stakeholder-consultation-next-phase-eu-us-cooperation-ehealthhealth-it>

CYBERSECURITY – AGREEMENT REACHED IN TRILOGUE

On 7 December 2015, an agreement was reached in trilogues between the European Parliament, the European Commission and the Council on the Network Information Security Directive.

The objective of the proposed Directive is to improve the security of the Internet and the private networks and information systems. The proposed text sets up stricter obligations for operators of essential services and digital services providers in order to manage cyber risks. The Directive will also provide a more uniform set of rules across the EU for digital services providers.

Moreover, the proposed text would also set up a national authority in charge of cyber security designated by Member States.

The next step will be for the Internal Market and Consumer Protection Parliamentary Committee (IMCO) to formally approve the text.

More information:

<https://ec.europa.eu/digital-agenda/en/cybersecurity>



COMPLIANCE WITH STATE AID REGULATIONS – MEMBER STATES' REPORTS

The European Commission published the Member States' reports on their compliance with the rules on State aid for the provision of services of general economic interest (SGEI) for the period 2012-2014.

The report aims at bringing more transparency in the support for the provision of public services as every citizen can see which sectors have received state support during this time period, including hospitals and healthcare services.

The 2011 EU state aid rules on public service compensation allow Member States to compensate companies that provide a public service as long as the company is not overcompensated. This effort is made in order to not have a distortion of competition between companies.

More information:

http://ec.europa.eu/competition/state_aid/public_services/reports_2012_2014_en.html



DATA PROTECTION – AGREEMENT REACHED IN TRILOGUE

On 15 December 2015, after months of negotiations an agreement was reached in trilogue on the general data protection Regulation.

The proposal for a general data protection Regulation was published by the Commission in January 2012. The draft legislation aims to strengthen current EU data protection rules and to ensure a more harmonised approach to data protection and privacy across the European Union. It contains provisions which could have an important impact on the provision of healthcare services and research.

The LIBE Committee (Committee on Civil Liberties, Justice and Home Affairs) of the European Parliament voted on the text on 17 December.

Formal votes in the European Parliament's Plenary session and at the Council of Minister will take place in 2016.

The final compromise text is available at:

<http://www.statewatch.org/news/2015/dec/eu-council-dp-reg-draft-final-compromise-15039-15.pdf>



EUROPEAN SEMESTER – OUTCOME OF EPSCO COUNCIL

The European Semester 2016 opened on 26 November 2015 with the presentation of documents containing the 2016 annual growth survey, the draft joint employment report (JER) and the alert mechanism report (AMR). This time, the package also included the draft eurozone recommendation, which up until now had been adopted at the same time as the specific country-based recommendations in May or June. On 7 December 2015, the Employment, Social Policy, Health and Consumer Affairs Council (EPSCO) held an exchange of view on the European Semester.

Ministers pointed out that re-launching investment, pursuing structural reforms and responsible fiscal policies were the priorities areas that would help strengthening the recovery and fostering convergence. They welcomed the fact that this year the employment and social dimensions of the alert mechanism report are strengthened throughout the economic package.

The annual growth survey 2016 maintains and updates the existing priorities, taking account of the progress made and new challenges. This year's priorities are re-launching investment, pursuing structural reforms to modernise our economies and responsible fiscal policies. This year's package places a strong emphasis on social and employment performance and the importance of social investment.

During the EPSCO Council, Ministers approved the employment and social aspects of the draft eurozone recommendation. The recommendation will be adopted in 2016, after the economic aspects have been approved by the ECOFIN (Economic and Financial Affairs) Council and it has been endorsed by the European Council.

More information on the European Semester:

<http://www.consilium.europa.eu/en/policies/european-semester/2015/>

NEW EURES NETWORK APPROVED

The Permanent Representatives Committee approved an agreement reached with the European Parliament for the re-establishment and re-organisation of the existing EURES (European employment services) network. The objective of EURES (to facilitate the free movement of workers within the EU) will be facilitated with this strengthened and modernised EURES portal. In order to reach this objective, the participation to EURES has been extended as well, including private (i.e. profit-making) employment organisations. EURES will regroup available job vacancies, applications and CV's, therefore giving a single point of research for job-seekers and employers and increasing the transparency of the information. Furthermore, EURES will regroup all the information on cross-border work for employers and frontier workers in Europe.

More information on EURES: <https://ec.europa.eu/eures/public/language-selection>



VAT RULES FOR HEALTH SERVICE PROVIDERS – JUDGEMENT

The Court of Justice of the European Union (CJEU) delivered on 29 October 2015 a judgement on the case C-174/14 Sudaçor — Sociedade Gestora de Recursos e Equipamentos da Saúde dos Açores SA v. Fazenda Pública.

With this judgement, the CJEU clarified the conditions of application of the Value-Added Tax (VAT) to companies that have an activity of planning of healthcare services under Article 1(9) of Directive 2004/18/EC on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts.

The autonomous region of Açores created a company, the Sociedade Gestora de Recursos e Equipamentos da Saúde dos Açores SA, to take care of the planning and the managing of the regional health service. The Public Treasury drew up a report on the company estimating that it did not fall under the scope of companies governed by Public law and had therefore to pay taxes, including the VAT. The company brought the case before the Administrative and Tax Court because it estimated that it was providing a public service. The Administrative and Tax Court established that the service provided by the company was of an economic nature. It therefore had to pay taxes in order to avoid any distortion of competition.

After losing the case, the company filed an appeal to the Court who decided to ask questions to the CJEU whether a limited company owned entirely by a public entity and providing services could be considered as 'governed by public law' and whether the company could be considered as a taxable person according to the Directive.

The CJEU stated that when a company provides a region with services in respect of the planning and management of the regional health service under the programme agreements concluded between that company and that region, that company was considered as a non-taxable person. The company is defined as a body governed by public law and therefore does not have to pay the VAT.

More information:

<http://curia.europa.eu/juris/document/document.jsf?text=&docid=170742&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=437024>

DATA PROTECTION – OBLIGATION OF INFORMATION OF PUBLIC ADMINISTRATIONS BEFORE EXCHANGING PERSONAL INFORMATION – JUDGEMENT

The Court of Justice of the European Union (CJEU) delivered on October 2015 a judgement on the case C-201/14 Smaranda Bara and Others v Președintele Casei Naționale de Asigurări de Sănătate, Casa Națională de Asigurări de Sănătate, Agenția Națională de Administrare Fiscală (ANAF).

With this judgement, the CJEU clarified the interpretation of Article 124 TFEU and Articles 10, 11 and 13 of Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

Smaranda Bara and others earn an income under the status of self-employed. The National Tax Administration Agency (ANAF) transferred data regarding the income of Smaranda Bara and others to the National Health Insurance Fund (CNAS) who asked the applicants the payment of arrears of contributions to the health insurance regime. The applicants brought the case before the Court of Appeal of Cluj which asked the CJEU whether an administration had to obtain the consent of the person concerned before transferring personal data to another administration.

The CJEU concluded that Directive 95/46/EC forbids the public administrative body of a Member State from transferring personal data to another public administrative body without the consent of the person concerned.

More information:

<http://curia.europa.eu/juris/document/document.jsf?text=&docid=168943&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=497309>

PUBLIC PROCUREMENT – REQUIREMENT FOR HEALTH SERVICES TO BE PROVIDED IN A PARTICULAR MUNICIPALITY – JUDGEMENT

The Court of Justice of the European Union (CJEU) delivered on 22 October 2015 a judgement on the case C-552/13 Grupo Hospitalario Quirón SA v. Departamento de Sanidad del Gobierno Vasco, Instituto de Religiosas Siervas de Jesús de la Caridad.

With this judgement, the CJEU clarifies the conditions of application of public procurement law, more precisely, Article 23(2) of Directive 2004/18/EC on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts.

As the public health care system in the Basque Region is very busy, and in order to reduce the waiting time for patients, local authorities can outsource some patients to private health care centres who make available to public health service their infrastructure and technical and human resources. The surgical procedures and other medical treatments are however carried out by surgeons attached to the public health service.

The Department of Health approved a tender for an outsourcing of resources for patients covered by the public hospital in Basurto, in the municipality of Bilbao, and Galdakao. The contract stated that,

in order to stay close to patients and to minimise travel costs for hospital personnel, the hospital to be selected had to be in the municipality of Bilbao.

The Grupo Hospitalario Quirón, which owns hospitals in the municipality of Erandio, challenged both calls for tender, arguing that the geographical requirement was contrary to the principles of equal treatment, freedom of access to public procurement procedures and free competition.

The CJEU ruled that article 23(2) of Directive 2004/18/EC precludes the automatic exclusion of tenderers who are not in a geographic zone, especially when that zone is not necessarily where the patients reside.

More information:

<http://curia.europa.eu/juris/document/document.jsf?text=&docid=170308&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=494407>



HEALTH PROGRAMME – NEW CALLS FOR TENDERS LAUNCHED

The Consumers, Health, Agriculture and Food Executive Agency (Chafea) launched new calls for tenders within the EU Public Health Programme.

These calls concern:

- development of 2 studies on vaccines: a study on the added value of the strategic and life-course approach to vaccination and a study on shortcomings related to low vaccination coverage in health care workers;
- development of a behavioural survey for HIV/AIDS and associated infections and a tailored training for healthcare professionals and community based health workers to facilitate the access and improve the quality of prevention, diagnosis of HIV/AIDS, STI and viral hepatitis and health care services for men who have sex with men (MSM);
- development of actions to strengthen the capacity of Member States' health authorities to effectively use European Structural and Investment Funds (ESIF) in health and produce a study on building knowledge on, and assessment of, ESIF interventions in health within the period 2014-2020;
- provision of services in support of the implementation of the Decision no 1082/2013/EU on serious cross-border threats to health, by creating conditions to strengthen and enhance coordination between Member States, international level and the Commission in order to ensure a coherent and consistent policy approach to effectively manage responses to serious cross-border threats to health across the EU.

The deadline of these calls for tenders is 9 February 2016.

More information: <http://ec.europa.eu/chafea/>

eSTANDARDS – CONSORTIUM MEETING AND PUBLICATION OF DELIVERABLE ON THE CASE FOR FORMAL STANDARDISATION IN LARGE-SCALE eHEALTH DEPLOYMENT

On 2 and 3 December 2015 HOPE attended the eStandards project consortium meeting in Brussels.

eStandards project is financed under Horizon 2020, the EU research and innovation programme. The project started in May 2015 and will run for two years with the main objective of advancing eHealth interoperability and global alignment of standards for health information sharing.

The project brings together the leading standards organisations in Europe and health stakeholders including HOPE.

The meeting was an opportunity for partners to discuss the current state of play of activities and plan the work ahead. Within Work Package 6 on socio-economic aspects of standards-driven eHealth interoperability, HOPE presented an overview of the initiatives implemented so far in Europe as regards ICT standardisation and public procurement. Partners will build on this work to achieve the work package objective which is to explore and analyse sociological and economic aspects of standards-driven eHealth interoperability in an attempt to suggest ways to reduce the upfront or hidden costs and re-establish trust between the standard organisations, the users, and the industry.

Achievements to date were also presented. Among these, there is the collection of case studies on the concurrent use of eStandards and the publication of a deliverable on the case for formal standardisation in large-scale eHealth deployment. This deliverable aims at exploring what are the main benefits ICT standardisation can bring from the perspective of citizens, health workforce, eHealth market players and the health system. The report concludes with a number of implications at the policy level for both the direct users and stakeholders of standards, as well as the standards development and profiling organisations, highlighting the need for collaboration and coordination at all levels.

More information on eStandards: <http://www.estandards-project.eu/>

The deliverable "The case for formal standardisation in large-scale eHealth deployment" is available at:

www.estandards-project.eu/index.cfm/download/deliverable-3-1-the-case-for-formal-standardization-in-large-scale-ehealth-deployment/

JOINT ACTION HEALTH WORKFORCE – CONFERENCE ON PLANNING AND EDUCATING HEALTH WORKFORCE WITHOUT BORDERS, 18-19 FEBRUARY 2016, VARNA

A two day conference will be held by the Joint Action on Health Workforce Planning and Forecasting on 18 and 19 February 2016 in Varna, Bulgaria to tackle the challenges of health workforce across Europe and even beyond. The conference aims to foster active networking and interactive encounters of Joint Action partners, stakeholders, professional organisations, decision makers and experts in the field of health workforce.

The event will focus on the following topics:

- the challenges of health professionals' mobility in relation to the topic of education;
- the effects of a changing demography on the health workforce needs with the presentation of several country cases;
- the presentation of future perspectives on education supported by horizon scanning analysis and demonstration of countries' best practices.

The event will provide an opportunity to strengthen the partnerships and networks with Joint Action's partners and health workforce stakeholders and experts as 350 attendees are expected.

More information and registration: <http://healthworkforce.eu/events/18022016-varna/>

MID-TERM EVALUATION FOR THE 3RD HEALTH PROGRAMME 2014-2020 – CONSULTATION

The Commission plans to launch a mid-term evaluation of the Health Programme 2014-2020 in early 2016 in accordance with its obligations under the Regulation n° 282/2014.

A roadmap has been established in order to conduct this evaluation and the European Commission DG SANTE is seeking feedback from the stakeholders in the field. Feedbacks should be sent to SANTE-HEALTH-PROGRAMME@ec.europa.eu

The deadline of the public consultation is 14 January 2016.

More information:

http://ec.europa.eu/health/programme/docs/midterm_evaluationreport_en.pdf

The Roadmap "Mid-term evaluation of the 3rd Health Programme 2014-2020" is available at:
http://ec.europa.eu/smart-regulation/roadmaps/docs/2015_sante_68o_evaluation_mid-term_health_programme_en.pdf

HEALTH EQUITY 2020 – FINAL CONFERENCE

On 4 December 2015, HOPE attended the final conference of the European project Health Equity 2020 at the Committee of the Regions in Brussels.

Health inequities are very much present in Europe and have been for several decades. Despite the efforts of public institutions like the WHO to decrease those inequities, some fractions of the population have worse health outcomes than others.

The meeting started with a presentation of the policy matrix and of the toolkit that were developed under that project. The toolkit is a very practical and concrete set of tools that public authorities can use to assess their needs, their capacity, set priorities, chose actions and assess the impact of those actions.

The exchange of best practices was also put forward and all the partners of the project agreed that each region need to make that assessment and decide what is best for them. Indeed, the case studies presented showed that different regions, starting from different points, managed to reduce their health inequities by using the toolkit and putting in place policies that suited them.

Finally, Dr. Andor Ürmös, from the Regional and Urban Policy unit of DG REGIO highlighted that the EU was encouraging policies for reducing inequities through structural funds.

More information: <http://www.healthequity2020.eu/>

REPORTS AND PUBLICATIONS



WHICH PRIORITIES FOR A EUROPEAN POLICY ON MULTIMORBIDITY? – COMMISSION PUBLICATION

In December 2015, the Commission published a report summarising an event that HOPE attended organised on 27 October 2015 by the Commission on the priorities to tackle multimorbidity.

More information: http://ec.europa.eu/health/ageing/docs/ev_20151007_frep_en.pdf

HOW CAN COUNTRIES ADDRESS THE EFFICIENCY AND EQUITY IMPLICATIONS OF HEALTH PROFESSIONAL MOBILITY IN EUROPE? – WHO PUBLICATION



There are many inequalities in the repartition of the healthcare workforce in Europe. Considering that healthcare professionals are a key contributor to the performance of health systems, this problem has consequences for the efficiency and equity of health systems.

Member States of the WHO have adopted the Global Code of Practice on the International Recruitment of Health Personnel. However, the freedom of movement and of establishment that exists within the EU poses a problem as it is only the healthcare professional that decides to move without considerations for the needs of the source and destination countries.

The authors of the study have detailed the merits and drawbacks of health professional mobility on the equity and efficiency in destination and source countries and for the EU in general.

More information:

http://www.euro.who.int/_data/assets/pdf_file/0008/287666/OBS_PB18_How-can-countries-address-the-efficiency-and-equity-implications-of-health-professional-mobility-in-Europe.pdf?ua=1

HIV/AIDS SURVEILLANCE REPORT IN EUROPE – WHO/ECDC PUBLICATION



WHO and ECDC published in November 2015 a joint surveillance report on the state of HIV in Europe.

According to their research, 2014 was the year with the highest number of new HIV cases in Europe ever. This report aims at calling for better prevention, diagnosis and treatment and includes a specific approach to the treatment of migrants and refugees.

Some of the conclusions of the report are that the growth of the HIV epidemic is driven by the eastern part of the Region and that two-third of the newly infected population is composed of native-born Europeans. The report calls on European countries to take action against the raise of

the epidemic.

Furthermore, it exposes certain risk factors of HIV like the social isolation of refugees and migrants; it establishes sex between men as the main transmission mode in EU/EEA; it warns against the dangers of late diagnosis and mentions the new global HIV guidelines that improve prevention and treatment.

More information: <http://ecdc.europa.eu/en/publications/Publications/hiv-aids-surveillance-in-Europe-2014.pdf>

DELIVERING PUBLIC SERVICES: A GREATER ROLE FOR THE PRIVATE SECTOR? AN EXPLORATORY STUDY IN FOUR COUNTRIES – EUROFUND PUBLICATION

Since the 1970's many Member States have limited the welfare system and extended the delivery of public services to the private sector. The authors studied four countries: Lithuania, Spain, Sweden and the UK, in order to examine how the private sector became more prominent there and the quality, effectiveness and accessibility of the services rendered from a user perspective. They focused on healthcare, long-term care, early childhood education and care and employment services.

They found out that some Member States (the UK and Sweden) turned to the private sector in the hope that it would increase the quality and efficiency of the services while others (Lithuania and Spain) were more attracted by the financial aspect of the transition. Furthermore, the authors pointed out the importance of monitoring and evaluating those private entities in order to ensure high quality services and transparency. Indeed, it is important to monitor and evaluate those private structures in order to ensure a uniform quality of services between private and public structures. Moreover, sharing the findings of those evaluations will benefit all the system as it will allow a constant state-of-the-art quality of services. Furthermore, this process allows a calculation of the costs involved when service provision is contracted to private entities.

More information:

http://www.eurofound.europa.eu/sites/default/files/ef_publication/field_ef_document/ef1538en.pdf

HEALTH PROFESSIONAL MOBILITY IN THE EUROPEAN UNION: EXPLORING THE EQUITY AND EFFICIENCY OF FREE MOVEMENT – HEALTH POLICY PUBLICATION

On a global level, the migration of healthcare workforce is regulated by the WHO Global Code of Practice on the International Recruitment of Health Personnel. In the EU however, the principle of freedom of movement governs the health workforce migration. The objective of this principle was to create a space where professionals could move easily and work wherever they wanted. But the questions of equity and efficiency often arise.

The authors of the article aimed at assessing the efficiency of the free movement to “equitably strengthen health systems” through a matrix which looks at the effects of health professional mobility in terms of efficiency and equity. The analysis was conducted from three points of view: from the EU’s point of view, from destination countries and source countries’ points of view.

They established that both destination and source countries experience both positive and negative effects. However, they also stated that those effects are complex because it is hard to identify migration waves as they are constantly moving. Despite this difficulty, the authors stated that there is a disproportion in consequences of migration movements. Indeed, wealthier Member States of the EU benefit more from those movements than less advantaged ones. This disparity may also cause to increase the already existing gap.

The final conclusion is that the WHO principles put forward in the Global Code are also relevant within the EU and should be paid attention to.

More information:

<http://www.healthpolicyjrnl.com/article/So168-8510%2815%2900214-6/pdf>

HEALTH WORKFORCE GOVERNANCE: PROCESSES, TOOLS AND ACTORS TOWARDS A COMPETENT WORKFORCE FOR INTEGRATED HEALTH SERVICES DELIVERY – HEALTH POLICY PUBLICATION

A competent health workforce is a vital resource for health services delivery, dictating the extent to which services are capable of responding to health needs. In the context of the changing health landscape, an integrated approach to service provision has taken precedence.

For this, strengthening health workforce competencies is an imperative, and doing so in practice hinges on the oversight and steering function of governance. To aid health system stewards in their governing role, this review seeks to provide an overview of processes, tools and actors for strengthening health workforce competencies. It draws from a purposive and multidisciplinary review of literature, expert opinion and country initiatives across the WHO European Region’s 53 Member States. Through this analysis, the authors observe distinct yet complementary roles can be differentiated between health services delivery and the health system. This understanding is a necessary prerequisite to gain deeper insight into the specificities for strengthening health workforce competencies in order for governance to rightly create the institutional environment

called for to foster alignment. Differentiating between the contribution of health services and the health system in the strengthening of health workforce competencies is an important distinction for achieving and sustaining health improvement goals.

More information:

http://ac.els-cdn.com/S0168851015002468/1-s2.0-S0168851015002468-main.pdf?_tid=3d29b8ca-a49e-11e5-9d88-00000aacb360&acdnat=1450343704_ac58263e7c1e8237a36d943coa31528e

THE "TEMPORARY RECOMMENDATIONS FOR USE": A DUAL-PURPOSE REGULATORY FRAMEWORK FOR OFF-LABEL DRUG USE IN FRANCE – HEALTH POLICY PUBLICATION

After the 2012 Mediator (also known as befluorex) scandal, France established the "Temporary Recommendations for Use" (RTUs), a regulatory framework for controlling off-label drug use, which is aimed at regulating the use of pharmaceuticals outside the scope of a marketing authorisation (MA) by establishing a framework for patient monitoring and data collection. This is intended to ensure that the benefit/risk ratio is favourable for the indication approved by the RTU. The granting of an RTU enables the reimbursement of off-label drug use and encourages pharmaceutical companies to expand their marketing authorisation.

Between 2012 and 2014 the regulatory framework for RTUs was amended twice in order to allow the bypassing of an MA for economic reason, when a licensed alternative drug exists. The primary purpose of the RTU framework is to implement an original national control for off-label uses that respond to a public health need. The secondary purpose is more controversial. Indeed, it promotes off-label use. This has raised legal issues and a ground for litigation between pharmaceutical firms and health authorities.

On the one hand, RTUs provide an interesting example for other countries that are exploring the possibility of regulating off-label drug use. On the other hand, the processes surrounding the implementation of RTUs illustrate the difficulties of public policies to balance public health needs, safety and economic goals.

More information:

<http://www.healthpolicyjrn.com/article/S0168-8510%2815%2900225-0/pdf>



eHEALTH IN THE NURSING AND SOCIAL CARE ECOSYSTEM – 7TH EUROPEAN INNOVATION SUMMIT

On 10 December 2015, HOPE attended an event on eHealth Services in the Nursing and Social Care Ecosystem at the European Parliament, in the framework of the 7th European Innovation Summit.

The event, organised by the Knowledge4Innovation Forum, in collaboration with the European Federation of Nurses, presented the results of the ESN4CARE project that developed 5 key areas and guidelines for the deployment of eHealth services. The 5 areas are prevention, clinical practices, advanced roles, integrated care and nurse ePrescribing.

Some important points were raised such as the issue of data protection, patient empowerment, digital security of healthcare and digital health literacy.

More information on ESN4CARE: <http://www.ens4care.eu/>

LIFTING THE DARK CLOUD: WHAT CAN EUROPE DO TO REDUCE THE BURDEN OF DEPRESSION IN THE WORKPLACE?

On 9 December 2015, HOPE attended an event on the topic of depression in the workplace in Brussels organised by the European Brain Council.

Depression is one of the biggest costs borne by society. Indeed, 1 person in 10 across Europe will have an episode of depression throughout their life and depression will cost 0.5 trillion Euros a year to Europe if nothing is done to decrease the spread of the disease.

S Regarding the case of depression in the workplace, the speakers highlighted the fact that there is a need for early diagnosis and treatment. However, a major obstacle is the reluctance of employees to communicate about their disease because of a fear of the stigma. David Kinder, a British civil servant that suffered from depression testified to his experience and how he managed to set up mechanisms, in collaboration with his employer, to alleviate the stigma around mental illness and to create a safe space for employees to communicate about it.

The overall conclusion of the event was that there is an urgent need to raise awareness about mental illness, in particular depression. There is a need for a holistic approach that includes actions at individual level, at community level, in the workplace and at public health level. There is a need for support from the employer and guidelines for the staff that are written by people who experienced depression.

eHEALTH IN EUROPE: REALITY AND CHALLENGES AHEAD – STOA WORKSHOP

On 1 December 2015, HOPE attended the workshop organised in the European Parliament by STOA, the Parliament's own Science and Technology Options Assessment unit. STOA provides the Parliament's Committees access to independent, outside expertise, when issues have a technological and scientific dimension.

The workshop was chaired by MEP Eva Kaili (S&D, Greece) and former MEP John Bowis, who stressed the importance of telemonitoring. Telemonitoring allows patients to manage their own health and has positive economic impact enabling people to remain longer in the workplace.

Peter Zilgalvis from the European Commission DG CNECT highlighted the Commission's current and future actions in the area of eHealth. To evaluate the intermediate achievements of the eHealth action plan 2010-2020 and issues to be addressed, the Commission commissioned a study to Deloitte and will also launch a public consultation in the first quarter of 2016. The input received will feed the development of a Staff Working Document.

The Commission is also taking some follow-up actions to the mHealth green paper. These include the creation of two working groups on code of conduct for mobile apps and mobile apps data validity and reliability and the development of a 2016 work plan setting out priority areas for ICT standardisation.

This was followed by presentations of countries' experiences, namely the Greek eHealth network, eHealth services for people with congestive heart failure in Veneto region (Italy) and patients affected by diabetes in Slovenia. The service deployed in Veneto region turned out to be very successful in reducing the number of hospitalisations, bed days and specialist visits for congestive heart failure patients.

Presentations then focused on the challenges related to deployment of eHealth in Europe. Panos Stafylas from the United4Health EU co-funded project shared some findings such as the reduction of hospital services' use by patients affected by chronic heart failure, chronic obstructive pulmonary disease and diabetes benefiting from the eHealth services deployed. The project will present some recommendations to policymakers during the final conference scheduled for January 2016.

Presentations are available at:

<http://www.europarl.europa.eu/stoa/cms/cache/offonce/home/events/workshops/ehealth;jsessionid=7856F6A548D49B0608099C614FF0A239>

CROSS-BORDER HEALTHCARE AND PATIENTS' RIGHTS – MEPS INTEREST GROUP

On 2 December 2015, HOPE attended the launch meeting of the MEPs Interest Group on European Patients' Rights and Cross-border Healthcare. The secretariat of the group is provided by Active Citizenship Network, a platform of more than 100 civic and patient organisations.

The meeting was attended by several MEPs, namely David Borrelli (EFDD, Italy), Therese Comodini Cachia (EPP, Malta), Piernicola Pedicini (EFDD, Italy) and Elena Gentile (S&D, Italy), all

declaring their commitment in making sure the Directive on the application of patients' rights in cross-border healthcare is correctly implemented so that patients can truly benefit from the right to freely circulate in the EU to receive healthcare.

They also highlighted some challenges such as: unequal level of implementation of the Directive and quality of information available across Member States, involvement of patients and delivery of real tangible benefits to them.

Invited to present the European Commission's perspective on the matter, Annika Nowak, member of the cabinet of Commissioner for Health and Food Safety Vytenis Andriukaitis, explained actions taken by the Commission to ensure the implementation of the Directive. These include 26 infringement procedures against Member States for not having completely transposed the Directive into national legislation. Almost all infringements are closed now and the Commission is going one step further, checking national legislations' compliance with the provisions of the Directive. One infringement for compliance has been launched by the Commission in September.

The discussion continued with a statement from Prof. Alceste Santuari from the European Association of Health Law. He pointed out to the fact that the Directive created more obstacles for patients willing to travel abroad to receive healthcare. Indeed, prior authorisation (not present in the initial text of the Directive and introduced later by Member States to ensure control over national health expenditures) is a real issue.

He also stated that the European Court of Justice might again play a role in promoting the rights of citizens. The correct implementation of the Directive might indeed be challenged in light of article 35 of the EU Charter of Fundamental Rights establishing the right to access to healthcare.

It followed several statements from stakeholders representing health professionals and patients. They highlighted the importance for patients to be correctly informed about the possibilities to go abroad to receive treatment and of their engagement to ensure Member States are made accountable for the correct implementation of the Directive.

HOPE took the opportunity to publicise the work done by the HoNCAB project (www.honcab.eu) and raise awareness about the existence of a Network of Hospitals exchanging good practices and experiences on cross-border healthcare.

An open call will be launched to set the agenda of the next meetings, which will focus on the points of the European Charter of Patients' Rights promoted by Active Citizenship Network.

More information on the Interest Group is available at:
<http://www.interestgroup.activecitizenship.net/>

NEW MEDTECH EUROPE CODE OF ETHICAL BUSINESS PRACTICE

On 2 December 2015, at their General Assemblies held in Brussels members of the European Diagnostics Manufacturers Association (EDMA) and of the European Medical Technology Industry (Eucomed), have approved a new and common MedTech Europe Code of Ethical Business Practice that will replace the EDMA and Eucomed codes of business practice.

The new MedTech Europe Code regulates all aspects of the industry's relationship with healthcare professionals and healthcare organisations, such as company-organised events, arrangements with consultants, research and financial support to medical education, amongst others. The Code also introduces a common independent enforcement mechanism. The new MedTech Europe Code of Business Practice will become binding for EDMA and Eucomed corporate members on 1st January 2017.

The new MedTech Europe Code of Business Practice is available at:

http://www.medtecheurope.org/sites/default/files/resource_items/files/20151202_MedTechEuropeCode.pdf

Accompanying Q&A on the MedTech Europe Code of Ethical Business Practice:

http://www.medtecheurope.org/sites/default/files/resource_items/files/Questions%20%26%20Answers%20%28Q%26As%29%20on%20the%20MedTech%20Europe%20Code%20of%20Ethical%20Business%20Practice.pdf

INAUGURAL CONFERENCE OF THE EUROPEAN INSTITUTE FOR INNOVATION THROUGH HEALTH – 10 MARCH 2016, PARIS



The Inaugural Conference of the European Institute for Innovation through Health Data (i~HD) will take place on 10 March 2016 in Paris, France.

i~HD is a not-for-profit European institute, with a mission to guide and catalyse the quality, interoperability and trustworthy uses of health data, for optimising health and knowledge discovery.

This Inaugural Conference will mark the parallel launch of a novel European platform to support multi-centre clinical research. This operational platform, the result of the European project EHR₄CR (Electronic Health Records for Clinical Research), can connect securely to the data within multiple hospital EHR systems and clinical data warehouses across Europe, to enable a trial sponsor to

predict the number of eligible patients for a candidate clinical trial protocol, to assess its feasibility and to locate the most relevant hospital sites.

The role of i-HD, as a not-for-profit Institute, is to provide independent governance oversight of such services now, and as these expand to connect with many more hospitals across Europe. The conference will present this platform and its pharma-led adoption programme, and detail the i-HD governance services that reflect state-of-the-art in the trustworthy re-use of health data for research. The audience will also learn about Europe's largest "big data" project in health: EMIF (European Medical Information Framework). The views of patients on the benefits of reusing their data for research will be presented by Mary Baker, past President of the European Brain Council.

The conference will also spotlight the challenges and state-of-the-art approaches to improving the quality and semantic interoperability of clinical data. i-HD will play an important future role in the development and quality labelling of semantic interoperability standards, bringing together clinical and research domain experts, with patients, to help ensure that future standards support patient care, learning health systems and clinical research.

The audience will be healthcare providers from across Europe, representatives of the pharma industry, patient associations, health professional associations, the health ICT industry and standards bodies. The event is being hosted by the Assistance Publique - Hôpitaux de Paris, INSERM and the UPMC Cordeliers Campus. Participation is upon invitation only, but free, although participants will need to cover their own travel costs. Persons who are interested are kindly invited to pre-register via the conference website (www.i-hd.eu/jic2016) to receive an invitation. Via the form it is also possible to recommend colleagues.

More information: <http://www.i-hd.eu/jic2016/>

EXPLORING THE MIGRATION-DEVELOPMENT NEXUS: GLOBAL HEALTH ASPECTS OF THE IMPLEMENTATION OF THE WHO CODE OF PRACTICE

On 9 December 10, HOPE participated to the debate on policy coherence for development in the context of the implementation of the WHO Global Code of Practice on the International Recruitment of Health Personnel, which placed emphasis on policy coherence between health, migration and development policies, representing one of the key challenges when it comes to the global dimension of the WHO Code implementation.

The raising issues that need to be further discussed regard the actions Europe should put in place in order to ensure quality and accessible health systems without luring away developing countries' talents. Furthermore, how should Europe ensure that, if international migration continues to grow, source countries are also able to profit from the departure of the brains they have produced? The discussion was thus aimed to find answers on how Europe could face the global dimension of health workforce migration, avoiding further "brain drain" which negatively impacts on the health systems of migrating professionals' countries of origin. Only a coherent, cross-sectorial approach including, inter alia, health, development, migration and employment policies will generate long-term positive results, according to what emerged from the discussion and from evidences of the project Health Workers for All and All for Health Workers (HW4All). The last one represents a key civil society

initiative raising awareness of the principles of the 2010 WHO Global Code of Practice on the International Recruitment of Health Personnel in 8 countries.

INTERNATIONAL DAY OF PERSONS WITH DISABILITIES

The 3rd of December 2015 was the 23rd International Day of Persons with Disabilities. Created in 1992 by the United Nations, the International Day of Persons with Disabilities' goal is to promote awareness and mobilise support for critical issues relating to the inclusion of persons with disabilities.

This year's theme was "Inclusion matters: access and empowerment for people of all abilities" and designated three focus areas (sub-themes) on the accessibility of cities, the availability of data and statistics and on the inclusion in society of persons with invisible disabilities.

More information: <http://www.un.org/en/events/disabilitiesday/>

AGENDA



UPCOMING HOPE CONFERENCES

HONCAB FINAL CONFERENCE

18 February 2016, Brussels (Belgium)

HoNCAB project started in 2012 with the aim to obtain a better understanding of the financial and organisational requirements arising from the implementation of the cross-border healthcare Directive, thus preparing hospitals to the new applying conditions. The project also set up a Hospital Network (Hospital Network for Care Across Borders in Europe) which brings together hospitals interested in sharing experiences and good practices but also critical issues and possible solutions when providing care to cross-border patients.

HoNCAB project is organising its final conference on 18 February 2016 in Brussels to present the main results obtained and to launch the created Hospital Network for Care Across Borders in Europe. The conference will bring together European policymakers, healthcare providers and main health stakeholders to discuss findings and future steps as regards cross-border healthcare in Europe.

As leader of the project dissemination activities, HOPE is assisting in the organisation of the final conference.

More information about HoNCAB: www.honcab.eu

Conference agenda and registration will be available at the beginning of 2016 at: <http://honcab.eu/final-conference/>

FIRST eSTANDARDS CONFERENCE IN CONHIT

21 April 2016, Berlin (Germany)

eStandards project is financed under Horizon 2020, the EU research and innovation programme. It started in May 2015 and will run for two years with the main objective of advancing eHealth interoperability and global alignment of standards for health information sharing.

eStandards will organise its first conference on 21 April in Berlin. The event is organised under the ConhIT conference, one of Europe's leading events for health IT.

The event will offer participants the opportunity to debate the first version of the eStandards Roadmap for essential standards development: strategic options and policy instruments.

Registration: <http://bit.ly/1TMYDyy>

More information on eStandards: <http://www.estandards-project.eu/>

8TH EUROPEAN CONFERENCE ON RARE DISEASES & ORPHAN PRODUCTS

26-28 May 2016 – Edinburgh (United Kingdom)

The European Conference on Rare Diseases & Orphan Products (ECRD) is organised in partnership with HOPE from 26 to 28 May 2016 in Edinburgh. It is the unique platform/forum across all rare diseases, across all European countries, bringing together all stakeholders - patients' representatives, academics, researchers, healthcare professionals, industry, payers, regulators and policy makers.

ECRD provides the state-of-the-art of the rare disease environment, monitoring and benchmarking initiatives. It now brings together over 80 speakers and more than 800 participants, covering six themes of content over two days: from the latest research, to developments in new treatments, to innovations in healthcare, social care and support at the European, national and regional levels. Registrations for ECRD 2016 will be opening at the end of November.

A call for posters is now open and will close on 31 January 2016. Patient groups, academics, healthcare professionals and all other interested parties having conducted research or studies on rare diseases or public health projects are encouraged to submit a poster abstract to the ECRD 2016.

More information: www.rare-diseases.eu

More information on the call for posters: <http://www.rare-diseases.eu/abstracts/>

HOPE AGORA 2016
THE FUTURE OF HOSPITALS AND HEALTHCARE

6-8 June 2016 – Rome (Italy)



HOPE will celebrate its 50th anniversary on 6, 7 and 8 June 2016 in Rome, the city where it was founded. This celebration will engage hundreds of healthcare professionals, HOPE Board members, Liaison Officers and National Coordinators.

Throughout its 50th anniversary HOPE will be hosting in the Agora 2016 a diverse mix of events: meeting former Presidents and the former Secretary-General, listening to the views on the future of key European associations, discussing with healthcare professionals, learning from each... These events will review past achievements while focusing on the present and future role of healthcare services. HOPE Agora 2016 wants to bring to surface different perspectives in an open and stimulating exchange with representatives from national governments, European institutions, national competent authorities, industry, healthcare professionals, academia and patient groups, with the objective of working towards a shared vision for the future.

HOPE Agora will also conclude the HOPE Exchange Programme, which in 2016 will reach its 35th edition. This 4-week training period starting on 9 May 2016 is targeting hospital and healthcare professionals with managerial responsibilities. During their stay, HOPE Exchange Programme participants are discovering a different healthcare institution, a different healthcare system as well as other ways of working. The topic of the HOPE Exchange Programme 2016 is "Innovation in hospitals and healthcare: the way forward". The topic of 2016 is a follow up of the Programme 2015 "Hospitals 2020: hospitals of the future, healthcare of the future", which was all about innovations in management and organisation of hospitals and healthcare services.

Programme and information: <http://www.hope-agera.eu/>

Online registration open on 15 February 2016: http://www.hope-agera.eu/?page_id=1243



Happy New Year
Best wishes for 2016

