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European Hospital and Healthcare Federation

Newsletter

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"Artificial Intelligence in healthcare: is Europe ready?"	**Brussels, 18/03/2019**
19th International Conference on Integrated Care	**San Sebastian, 1-3/04/2019**
HOPE Agora 2019	**Ljubljana, 2-4/06/2019**

A Touch of Brussels for Nurses: ESNO-HOPE event

On 20 February 2019, HOPE organised in collaboration with the European Specialised Nurses Organisation (ESNO) prior to the ESNO congress 2019 #ESNO2019 an "Introduction to Brussels".

The workshop was intended for nurses interested in the European environment from a novice perspective or for those already familiar with a network. They could learn more on the mechanisms and dynamics of the European Union and Europe and how and where to engage. The idea is based on an EPHA project 'A touch of Brussels'.

It covered "Europe, how it works in a nutshell for healthcare professionals" and "How it works in context for specialist nurses" presenting the European Commission, agencies (EMA and ECDC) and two joint actions (AntiMicrobial Resistance; Vaccination) but also Health Workforce initiatives and nurses' engagement.

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

Read more on ESNO Congress 2019

ICT4Life Final Review in Luxembourg

On 8 February 2019 the ICT4Life Consortium met one last time for the project Final Review in Luxembourg with DG CONNECT (Communication Networks, Content and

Technology). All partners were represented for this intense meeting, and the Consortium members gathered also on 6 and 7 February in Luxembourg to finalise their presentations.

The objective of the final review was to assess:

- the degree to which the work plan has been carried out and whether all deliverables were completed;
- whether the objectives are still relevant and provide scientific or industrial breakthrough potential;
- how resources were planned and used in relation to the achieved progress, and if their use respected the principles of economy, efficiency and effectiveness;
- the management procedures and methods of the action;
- the beneficiaries' contributions and integration within the action;
- the expected potential scientific, technological, economic, competitive and social impact, and plans for using and disseminating results.

All the different work packages presented their achievements to the reviewers as well as perspective on how to exploit them and how to use the knowledge develop in further research or projects.

HOPE was in charge of WP8, the work package managing Dissemination and Exploitation of the project. Isabella Notarangelo presented the results achieved: all the key performance indicators were reached, and communication material has been produced and translated in several languages all along the project. Among them, a promotional video, leaflets, social media channels and a website. ICT4Life took part and organised in many events and created many valuable connection and collaboration with other EU-funded projects, European, national or regional organisations, SMEs, research entities and policy-makers.

The review was a success and the Commission representative and independent experts congratulated the team for the excellent work and results achieved. Some challenges remain regarding the post-project developments and the concretisation of the foreseen exploitation but the reviewers were confident the products developed have strong potential.

ICT4Life website

EURIPHI H2020 Project Kick-off Meeting

On 31 January 2019, HOPE took part in the kick-off meeting of EURIPHI, a Coordination and Supporting Action (CSA) falling under Horizon 2020 funding programme. The project aim is to introduce innovation and integrated solutions in health and care system in Europe, through cross-border value-based innovation procurement. The consortium, led by MedTech Europe, gathers 25 organisations, among Public Procurement Organisations covering more than 500 service providers throughout Europe; research organisations; associations and networks and private companies. An advisory committee of procurers and experts will further enlarge this initiative, ensuring that all the interests are taken into consideration to achieve effective results.

In the EURIPHI project, the partners involved or interested in value-based procurement and PPI/PCPs are teaming up around the novel approach of Most Economically Advantageous Tendering Value Based Procurement of Innovation Solutions (MEAT VBPPI) to achieve the following goals:

- Establish a sustainable Community of Practice using innovative procurement methods, such as MEAT value-based procurement of innovation and integrated solutions in health and care systems and develop legal guidance for efficient cross-border, value driven procurement with localized decision making;
- Adapt the existing tools, perform market consultations and deploy cross-border Value Based PPI/PCP testing as learning cases in the field of rapid diagnostics for infectious diseases and, new models of patient-centred integrated care;
- Developing an EURIPHI Network, a network of representatives of (regional) health authorities, policymakers, and payers who, in collaboration with other key stakeholders, will further prioritize investments and foster the deployment of Value Based PPI/PCP.

These key objectives are designed to build a foundation for future EU cross-border PPI/PCP.

For more details on the EURIPHI project or on MEAT Value Based Procurement and Innovation Procurement Schemes, please contact **info@euriphi.eu**.

FT Digital Health Summit - Enhancing the Impact of Innovation through Collaboration

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

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

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

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

Read more

NHS European Office – Information material

In February 2019, the NHS European Office website had been updated with the following new pieces of information:

- **New guidance on the regulation of medical devices:** The Medicines and Health Products Regulatory Agency has published guidance that sets out how medical devices will be regulated in the UK in a Brexit "no-deal" scenario. The guidance provides further detail on how the UK regulatory framework will operate after 29 March and what manufacturers and healthcare organisations need to do to ensure their devices are certified for use post-Brexit.
- **"No-deal" medicines availability:** NHSE publishes patient Q&A: NHS England has published further **guidance for patients** on how they can continue to access their medicines and medical products in the event of a "no-deal" EU Exit, with a **quick Q&A** for more information and **guidance to prescribers** of medicines on what action they should take when dispensing patients' medicines.
- **Health Minister updates MPs on "no-deal" medicines' supply:** Stephen Hammond, Minister of State for Health, has made a Written Ministerial Statement updating MPs on the Department for Health and Social Care's plans for the continuity of medicines and medical products in the event the UK exits the EU without a deal.
- **Sharing personal data post-Brexit:** NHS Improvement has issued new guidance (21 February 2019) to NHS organisations on the actions they need to take to ensure continuity of access to, processing and sharing of personal data in the event of a "no-deal" Brexit.
- **New guidance on the availability of medical devices post-Brexit:** NHS Improvement has issued new guidance (11 February 2019) to NHS providers and heads of procurement on the actions they need to take to safeguard the availability and supply of medical devices and clinical consumables in the event of a "no-deal" Brexit.
- **Updated guidance from NHS England on no-deal Brexit:** Professor Keith Willett, EU Exit Strategic Commander and Medical Director for Acute Care and Emergency Preparedness at NHS England, has written to clinical commissioning group (CCG) and trust chief executives outlining the operational response that NHS England and NHS Improvement are undertaking at a national and regional level in preparation for a "no-deal" Brexit scenario.

Romanian Presidency of the Council of the European Union

Preserving social security entitlements in the event of no-deal Brexit: Council approves draft contingency measures

The European Union is taking measures to safeguard the social security rights of citizens of EU member states in the UK and UK nationals in the EU 27 who have benefited from the right of free movement before the UK withdrawal from the Union.

On 22 February 2019, Member states ambassadors in the Council Permanent Representatives Committee (Coreper) approved the text of a draft regulation on establishing contingency measures in the field of social security coordination. Coreper will now inform the European Parliament that if it adopts its position at first reading in the same form, the Council should be able to approve the European Parliament position.

The measures are limited in time and scope and will be adopted unilaterally by the EU. The regulation will enter into force only if the UK leaves the Union with no withdrawal agreement in place.

The regulation will apply to the following persons:

- nationals of member states, stateless persons and refugees, to whom the legislation of one or more member states applies or has applied or who are or have been in a situation involving the United Kingdom before the date of application of the regulation, as well as their family members and survivors;
- nationals of the United Kingdom, to whom the legislation of one or more member states applies or has applied before the date of application of the regulation, as well as their family members and survivors;

The draft regulation is without prejudice to the existing social security conventions and agreements between the UK and one or more member states.

Read more on Brexit

EU measures in support of generic pharmaceuticals producers

On 20 February 2019, the Council of the European Union published a press release on new rules which should boost the competitiveness of EU producers of generic medicines and biosimilar products.

Member states ambassadors meeting on the same day in the Council Permanent Representatives Committee (Coreper) endorsed a deal reached on 14 February 2019 with the European Parliament on a draft regulation which introduces an exception to the protection granted to an original medicine by a supplementary protection certificate (SPC) for export purposes and/or for stockpiling.

Thanks to the exception, EU-based manufacturers of generics and biosimilars will be entitled to manufacture a generic or biosimilar version of an SPC-protected medicine during the term of the SPC either for the purpose of exporting to a non-EU market where protection has expired or never existed or (during the six months before the SPC expires) for the purpose of creating a stock that will be put on the EU market after the SPC has expired.

SPCs are intellectual property rights that extend patent protection (for up to five years) for medicinal products that must undergo lengthy testing and clinical trials before being authorised to be placed on the EU market. The aim of SPCs is to avoid that the term of patent protection would in actuality be curtailed by the period that elapses between the date of filing of the patent application and the date of the authorisation to place the product on the market in the EU.

The exception will operate only where:

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

Until a set date (three years from the entry into force of the regulation), the regulation will affect only SPCs that are applied for on or after the date of entry into force of the regulation. From then on, the regulation will also affect SPCs applied for before the entry into force of the regulation, but which have become effective after the entry into force of the regulation.

The agreed text, following the usual legal/linguistic scrutiny, will be submitted for formal adoption to the European Parliament and the Council.

European Semester Winter Package: assessing Member States' progress on economic and social priorities

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

Challenges vary significantly across countries and call for appropriate and determined policy action.

This review of country-specific challenges comes against the backdrop of a European economy that is expected to grow for the seventh consecutive year in 2019, but at a more moderate pace. Employment is at a record high and unemployment at a record low. Public finances have also improved across the board, although some countries are still facing high levels of debt. However, challenges remain. Productivity levels remain subdued, population ageing is intensifying and rapid technological change is having a significant impact on labour markets. Real household income remains below pre-crisis levels in some Member States. Youth unemployment has been significantly reduced, but is still unacceptably high in some Member States. At a time of more pronounced global uncertainty, it is crucial that EU Member States step up their action to boost productivity, improve the resilience of their economies and ensure that economic growth benefits all citizens.

Following the publication in November of the Annual Growth Survey and the recommendation on the economic policy of the euro area, which set out the priorities at European level, the 28 Country Reports published on 27 February zoom in on the national dimension of the European Semester. The reports provide a detailed analysis of country-specific economic and social challenges. They will serve as the basis for discussions with Member States of their national policy choices ahead of their national programmes in April, and will lead to the formulation in late spring of annual Country-Specific Recommendations.

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

Progress with Country-Specific Recommendations

The Country Reports assess Member States' progress in implementing the Country-Specific Recommendations of July 2018. Overall, Member States have achieved some or more progress with the implementation of more than two-thirds of the recommendations issued since the introduction of the European Semester in 2011. Member States have made most progress

on the recommendations on financial services, reflecting the priority given to the stabilisation and soundness of the financial sector in the aftermath of the financial crisis. Sound progress has also been achieved with regard to reforms facilitating job creation on permanent contracts and addressing labour market segmentation.

In recent years, one of the ways in which the Commission aims to help Member States step up their reform efforts is through its Structural Reform Support Programme (SRSP), which aims to provide technical support to all EU Member States, at their request, to help them design and implement growth-enhancing reforms. This also includes reforms highlighted in the Country-Specific Recommendations.

As part of November package, the Commission also adopted the Structural Reform Support Programme's **2019 Work Programme.** In 2019, the SRSP will provide technical support to 26 Member States to carry out more than 260 projects. This comes in addition to more than 290 projects selected in **2017 and 2018**.

European Semester 2019: Winter Package explained

Country Reports

Withdrawal of the United Kingdom and EU rules for batch testing of medicinal products- released by the Commission

On 21 February 2019, the European Commission released a Communication on the Withdrawal of the United Kingdom and EU rules for batch testing of medicinal products.

The information provided is intended to the EU27 Heads of Medicines Agencies and to the Executive Director of the European Medicines Agency (EMA).

In the possibility of United Kingdom becoming a third-country as of 30 March 2019, the pharmaceutical industry has been informed about the need to adapt processes and to consider changes to the terms of marketing authorisations in order to ensure their continuous validity and exploitation, once the United Kingdom has left the Union.

This contributed to a high level of preparedness of the sector. In particular, according to Article 51(1)(b) of Directive 2001/83/EC and Article 55(1)(b) of Directive 2001/82/EC, medicinal products imported into the EU have to undergo quality control testing (‘batch testing’) in the EU/EEA.

With regard to the batch release sites currently located in the United Kingdom marketing authorisation holders therefore need to comply with this requirement at the latest by the withdrawal date.

However, with regard to the quality control testing there may be objective reasons beyond control of the marketing authorisation holders that may prevent timely transfer of such testing activities to the Union by the withdrawal date.

In these cases, Article 20(b) of Directive 2001/83/EC and 24(b) of Directive 2001/82/EC provide that competent authorities may allow importers of medicinal products coming from third countries to have in justifiable cases certain of the controls carried out by third parties.

In applying these provisions, competent authorities may allow marketing authorisation holders, for a limited period of time, as a justified case, to rely on quality control testing performed in the United Kingdom (hereafter "the exemption").

Read more about the conditions and procedure for such exemption

Public Health

Falsified Medicines Directive launch

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

As of 9 February 2019, the Falsified Medicines Directive fully applies. From this date, the industry must affix a 2-D barcode and an anti-tampering device on the box of prescription medicines. The pharmacies – including on-line pharmacies – and hospitals will have to check the authenticity of medicines before dispensing to patients. This is the final step in the implementation of the Falsified Medicines Directive, adopted in 2011.

Medicines produced before Saturday 9 February 2019 without safety features may also remain on the market until their expiry date. But the new end-to-end verification system will require authorised persons (and in particular pharmacists and hospitals) to verify, throughout the supply chain, the authenticity of the products.

On Monday 11 February, Politico released an article (below) about the launch of the Falsified Medicines Directive Implementation with a contribution of HOPE CEO Pascal Garel.

Who pays for Falsified Medicines implementation?

While Saturday was the official launch of the Falsified Medicines Directive, today is the first day that it will really be tested as deliveries start rolling in. Drugmakers and distributors insist the rules aren't going to result in higher price tags for pills. But that doesn't mean that patients — or even taxpayers writ large — won't face higher costs.

Most hospitals are going to need to boost staffing to meet the requirements of the FMD. Their shipments of medicines often arrive by the pallet, not the parcel, and each box within that shipment needs to be scanned in.

"In terms of who pays … everybody's saying we swallow it," said the European Hospital and Healthcare Federation's Pascal Garel at a press conference by the European Medicines Verification Organisation (the body set up by the Commission to administer the directive). He was referring to earlier promises by EMVO's President Hugh Pullen, who also represents branded drugs lobby EFPIA, that drug prices would not go up because "the cost will be absorbed by the supply chain."

But those aren't the only costs, Garel noted. There's "an actual cost in most of the hospitals. Sometimes in terms of human resources, sometimes in IT service providers."

He continued, "Who pays at the end? The taxpayer… or the individual patients when they share the costs" of health care in a country. It's not possible to put a euro figure on those costs at this point, and it'll play out in different ways around the EU, Garel said. Calculating it will ultimately involve data from government payers, insurance companies, etc.

Hospital readiness: "Undoubtedly there will be hospitals that are not ready," said Rob Moss of the European Association of Hospital Pharmacists, though he added the "great majority" would be. However, he noted that diverting resources to people scanning in all the boxes on a pallet of medications would mean less time doing clinical pharmacy work or things like finding alternative supplies during shortages.

Feeling underappreciated: There was a palpable sense of frustration among some of the EMVO leaders that there was so much focus on the potential gaps in the European Medicines Verification System that underpins the directive. Indeed, its status today represents something of a come-from-behind victory compared to 10 months ago, when about a third of countries looked poised to miss major deadlines. Andreas Walter, EMVO's general manager, said the weekend's launch is a "cold start" for a "Ferrari [that] has to warm up."

Moss extended the metaphor in an interview. "It might be a big blow-up, it might be the Ferrari's slowly moving," he said. To describe the third possibility, he made the sound of a Ferrari skidding off the road.

EMVO Press Release on the launch of the European Medicines Verification System (EMVS)

"Improving patient safety with the Falsified Medicines Directive in the hospital pharmacy, status of implementation" - Roundtable

A meeting entitled "**Improving patient safety with the FMD in the hospital pharmacy, status of implementation**" was co-hosted by the EAASM and MEP José Inácio Faria (EPP, Portugal) on 19 February 2019 in the EU Parliament. It brought together 52 participants, including hospital pharmacists, patient safety organisations, EU Commission officials, Health Attachés of the Council of the EU, European and national agencies, industries

and academics to debate the challenges and potential practical solutions within the European hospital settings.

The roundtable aimed to create a positive and practical atmosphere and to help debate solutions that are supportive of the implementation of the verification of prescription packs in the hospital pharmacy setting. Keynote contributions came from MEP Faria, EAASM Executive Director Mike Isles, the European Medicines Verification Organisation, the Finnish Medicines Verification Organisation, DG Health and Food Safety of the European Commission, the European Association Hospital Pharmacists, and four national hospital representatives from Spain, France, Germany and the UK.

Cross-Border Healthcare Directive: Implementation must improve

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

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

Belgian MEP Ivo Belet addressed other MEPs, as well as Vytenis Andriukaitis, European Commissioner for Health and Food Safety, on cross-border healthcare and pointed out that, for patients in living border regions, it is often cheaper to get medical care in the closest hospital, which can actually be across a border. This is even more the case for those with chronic or rare diseases since they need specific care. There are still many barriers, with patients not being sure when they can be reimbursed, and not knowing the costs or where to go to find information. He stressed out that this is why the European Parliament is calling for one-stop-shops in all Member States in order to provide the necessary relevant information. The Commission, meanwhile, must continue to monitor implementation on an annual basis.

The Commission considers that 40% of the EU population lives in what can be defined as cross-border areas. Less than 27% are aware of the right to healthcare across borders. It was also reiterated that national information offices are important for citizens, and there certainly needs to be an improvement in implementation in all Member States.

Commissioner Andriukaitis welcomed the Parliament report and fully agreed with the views expressed which were in line with the Commission report from September 2018. He added that the Commission has examined the transposition of the Directive into national law and launched 26 infringement procedures.

The first phase is completed, with the EU Executive moving to in-depth analysis of compliance. The Directive allows Member States room for manoeuvre when it comes to transposition, but

the Commissioner acknowledged that there is evidence of discrimination against EU citizens, as well as too-complex administrative procedures.

The Commission has launched two cases on reimbursement and is now taking discussions with EU countries to find ways to simplify procedures. In the meantime, the Commission agrees that Member States should provide sufficient funding for the national contact and information points already mentioned.

Cross Border Directive Implementation Report

EuroGTP II Guide "Good Practices for evaluating quality, safety and efficacy of novel tissue and cellular therapies and products"

The EuroGTP II Guide "Good Practices for evaluating quality, safety and efficacy of novel tissue and cellular therapies and products" has been released on 4 February 2019.

Preparation of Tissue and Cellular Therapies and Products (TCTPs), including reproductive cells, intended for human applications must comply with high standards of quality and safety according to the requirements of the European Tissue and Cells Directives (EUTCD) in order to ensure a high level of health protection in the Union. This concept becomes even more important with new products that are applied for the first time in humans or are prepared with new and innovative methodologies.

By using the systematic approach proposed, the users of this guide will be able to:

a) Evaluate risks resulting from all aspects of T&C supply chain (from donor selection to clinical application) of the final product;

b) Design appropriate studies proportionate to the level of residual/unknown risk to confirm that the TCTP is safe and effective.

The project has developed good practices, principles and reference tools applicable to TCTPs and how to conduct adequate clinical follow up studies. The methodologies proposed in this guide aim to be systematic and consistent, in order to promote a standard approach to practices and recognition amongst the stakeholders.

EuroGTP II Guide

Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases – 2nd formal meeting

The Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases held on 14 February 2019 the second formal meeting.

The Steering Group had a discussion on the proposal by the Expert Group on Health Information to monitor the progress made towards achieving the World Health Organization's targets on non-communicable diseases by the EU Member States, Norway and Iceland. The Steering group also heard from the representative of DG ESTAT on the monitoring of the Sustainable Development Goals, and in particular the goal 3 related to health. The Steering Group noted the progress made in the prioritization, selection and implementation on best practices and research results. The Commission agreed to reflect on how the SGPP members could become more involved in the preselection of best practices and the results of research projects.

There was also a discussion on the sustainability of **Orphanet** and the Member States expressed intent to contribute to the sustainability plans based on the analysis of a survey among the SGPP which had been carried out in January this year. The Joint Research Centre presented an analysis of the survey carried out among the Member States on the Platform on Rare Disease Registries which was launched on 28 February on the Rare Disease Day. The European Investment Bank presented an update on the progress made related to fact finding on proton therapy centres. The Steering group agreed to review EU level activities on radionuclear medicine, in cooperation with DG ENER, at a forthcoming meeting of the Steering Group (particularly on issues around medical isotopes.)

The Steering Group also discussed the Joint Action CHRODIS plus and the possibility to connect the Steering Group to the outcomes of the Joint Action. Finally, the Steering Group had a reflection on possible new areas of work including joint procurement on orphan drugs, antimicrobial resistance, patient safety and dementia.

The Steering Group met also on 15 February 2019 with the Horizon2020 Programme Committee configuration SC1 to discuss synergies between the draft annual work plans for 2020 both on health and research.

Read more on the Steering Group

Repurposing of established medicines/active substances

HOPE was invited to the Commission Expert Group on Safe and Timely Access to Medicines for Patients (STAMP) that was holding its 10th meeting on 3 December 2018, in Brussels. Representatives from 22 Member States and the European Medicines Agency (EMA) participated in the meeting.

The Commission introduced the item explaining that the issue of repurposing of established medicines had been discussed in previous meetings of the STAMP. During the 9th meeting in June 2018 there had been a discussion on the proposal for a framework for repurposing existing medicines, which had been developed through the collaboration of the representative industry associations. Following discussion of the proposal the STAMP agreed that the proposal for the framework should be further developed through a working group.

The following Member States and stakeholder groups had volunteered to be part of the ad hoc working group: Belgium, the Netherlands, Norway, Spain, Sweden, the United Kingdom, the

EMA, Anticancer Fund, European Confederation of Pharmaceutical Entrepreneurs (EUCOPE), European Federation of Pharmaceutical Industries and Associations (EFPIA), European Organisation for Rare Diseases (EURORDIS), European Patients' Forum (EPF), European Society of Paediatric Oncology (SIOPE), International Association of Mutual Benefit Societies (AIM), Medicines for Europe (MfE). The working group was led by the UK and Spain and worked through exchange of emails and regular teleconferences.

The work had been split into two main areas: the proposal for a 'repurposing pathway' within the current regulatory framework (objective 1) led by SE, EMA and the UK and the topic of 'learnings and outstanding issues' to explore how the proposal for a framework would work in practice (objective 2) led by the Anticancer Fund. A third topic concerning possible supporting materials and communication had been discussed by the working group in a teleconference.

The UK introduced objective 1 by providing an overview of the interest in the issue of repurposing and explaining the scope of the proposed pathway and what it would look like, namely the core components. It was also explained that the main purpose of the meeting was to define the possible pathway, discuss outstanding issues and to agree on the next steps. It was emphasised that the pathway would use the existing regulatory framework and potential 'Champions' should be able to understand the regulatory process. A main goal would therefore be to provide support to academia and/or research organisations to help ensuring that the appropriate evidence meeting the regulatory requirements is collected. The overall aim would be to have new indications for existing medicinal products that are outside patent protection.

The participants also discussed the incentives and disincentives for repurposing. The industry representatives explained their written comments regarding the outstanding issues. They mentioned that having the data reported and presented in a way which was ready to be included directly in an application for an assessment of a new indication would reduce this potential barrier or disincentive for marketing authorisation holders. In addition, they mentioned that consideration would be needed with respect to potential need of additional risk minimisation measures, or obligations for post marketing studies.

The main outcome of the discussion about objective 2 was that good 'candidate' compound(s) to test the proposed repurposing framework should be identified before the next STAMP meeting in March 2019. The development of additional guidance and a template could be considered in the light of experience of the pilot.

The meeting also looked at EU activities relevant to timely patient access to innovative medicines. A representative of EMA gave a presentation on the experience of the EMA Committees on the application of the concept of "significant benefit" across the different provisions in the legislation, namely the additional year of marketing protection, orphan designation, derogation from orphan market exclusivity, paediatric investigation plan waiver, new active substance status, conditional marketing authorisation and accelerated assessment.

It was asked whether there is a harmonisation of understanding of the provisions. EMA explained that there can be differences as they serve different purposes, however they are reviewing the accumulated experience that learnings could be a basis to support consistent application of each provision (albeit some differences between provisions exist, based on the respective legal provisions and existing guidance). It was also noted that the health technology

assessment also assesses the benefit of medicines and there is an exchange of information between EMA and HTA bodies within the EUnetHTA project.

An update on activities relevant to timely access to medicines was provided:

- The Commission had launched studies to support the evaluation of the Orphan and Paediatric Regulations. The studies cover the topics of the regulatory system, incentives and access to medicines and are expected to be completed in 2019;
- The Austrian Presidency organised an informal meeting of Health Ministers during which the issue of availability of medicines, particularly for small markets, the benefit for patients, availability and prices was discussed;
- The Presidency also held a conference on the regulatory activities and research activities, exploring the relationship between public funding of research and the interest of the healthcare systems.;
- The new research programme Horizon Europe is being planned, it is proposed to have a health cluster in which health, including pharmaceutical related topics, would be covered.

Read more

Euripid Guidance Document on External Reference Pricing (ERP)

On 24 September 2018, the EURIPID Collaboration published their Technical Guidance Document on External Reference Pricing (ERP) to help national authorities avoid/mitigate any potential negative impacts of ERP on patients' access to medicines.

The document has been developed in cooperation with all national competent authorities of the EU, EEA-EFTA and EURIPID participating countries and the stakeholder representatives of the European pharmaceutical sector including consumers and patients.

Link

Communications networks, Content and Technology

European Electronic Health Record exchange format - Recommendation

On 6 February 2019, the Commission published a recommendation on the European electronic health record exchange format.

The ability to exchange health records across borders is intended to help citizens seeking treatment while abroad in the EU, such as for specialist advice, or falling ill while travelling, or for those citizens who have moved to another Member State and would like joined up medical records.

The exchange format, as described in the Commission **Recommendation**, would facilitate cross-border access to Electronic Health Records, while ensuring high of security and data protection, according to the European Commission.

A well-functioning access to existing data and the right infrastructure to provide timely information on existing health conditions, such as allergies and existing health conditions, and also, where needed, to an individual's recent laboratory or medical imaging results would help health practitioners and hospitals in another Member State to avoid repeating such tests, which can save patients' time and reduce hospital costs. Developing the secure exchange of electronic health records across the EU is a complex technical process but one which, in the long run, could support governments and innovators of the next generation of digital solutions and medical treatments.

Supported by the **Connecting Europe Facility** (CEF) Telecom programme, Member States have started work on the exchange of two kinds of medical information (patient summaries and e-prescriptions). In January 2019, the exchange of ePrescriptions became possible between Estonia and Finland, using the **eHealth Digital Service Infrastructure**.

A further 20 Member States are expected to be able to exchange this kind of information by the end of 2021. The Recommendation builds on these efforts and recommends that work on interoperability be further extended to laboratory results, medical images and hospital discharge reports, and puts forward recommended technical specifications for the exchange of this data.

What does the Recommendation consist of?

It proposes a set of common technical specifications for the transfer of health data in chosen health information domains such as Patient Summaries and e-Prescriptions, but also laboratory test, images and hospital discharge reports and the further elaboration of the exchange format through a joint coordination process.

EHR Recommendation

Agreement on Digital Europe programme for 2021-2027

The European Parliament and the Council of the European Union reached a provisional political agreement on the first-ever Digital Europe programme, part of the EU long-term budget presented by the Commission.

The programme, proposed in June 2018, will invest in five key digital sectors: high performance computing, artificial intelligence, cybersecurity and trust, advanced digital skills, and ensuring the wide use and deployment of digital technologies across the economy and society, in order to strengthen European industrial technological leadership.

The programme focuses on areas where no single Member State acting alone can guarantee success, and where public spending is likely to make the highest impact.

The Commission has also proposed to fund new digital infrastructure in the EU in 2021-2017 with a renewed Connecting Europe Facility.

Access the programme

AI and robots in the healthcare context – Workshop

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

MEP Alojz Peterle, (EPP, SI) explained that, in Japan, in care and nursing homes, robots number around 5,000 to help meet demographic challenges affecting most developing countries and generating a greater number of elderly in their populations. He suggested that a European agency for robotics could be useful, while pointing out that citizens are still uncomfortable with the idea that robots are being used in everyday life.

MEP Mady Delvaux then told the workshop about the **recommendations to the Commission on Civil Law Rules on Robotics** in respect of European values in the use of robots and AI. Two years after the report, the Commission created a **High-Level Expert Group on Artificial Intelligence**.

Attendees were also given an idea of some practical applications. For example, robotic applied to urology is already used in Europe. The technologies allow the movements of the surgeons to be miniaturised and very precise. In relation with surgery and frequent complications, there are many different kinds of surgical robots, and such innovative tools could make surgery safer and ultimately cheaper.

Robots in general service at healthcare establishments include back office, such as pharmacy dispensing, semi-autonomous service robots, which interact with more humans than before, and even autonomous robots. Many healthcare professionals have found that robotics can bring significant opportunities for improving safety, quality and efficiency.

Attendees were told about ‘Project Dream’, in which doctors try to use a robot in the treatment of children in the autism spectrum. Children in this autism spectrum have difficulties in learning social habits through observing human adults, but it turns out that they are very open with robots. The healthcare professionals wanted to see whether using robots would help teach social and psychological behaviour to children with such issues.

Another study has been undertaken related to using AI in the treatment of patients with major depressive orders. The clinical problem seems to be that, between sessions and after treatment, patients fail to follow the suggestions and recommendations of the therapist. It is impractical to have a therapist at the patient's home, but an artificial intelligence system could help as a therapist at home. In this case an avatar was used which was able to deliver different psychological tests and take in data. If the client had a problem, the avatar started going through basic methods to try to solve the situation.

In robotics, AI and healthcare Europe has processed and analysed medical data, including imaging, as part of 4P medicine (predictive, preventive, personalised and participative). This is becoming more and more important and includes telemedicine and virtual consultations in which the patient is not directly in contact with a medical professional.

There are several major barriers to the use of robots in healthcare, including the actual appearance of robots, plus changes to healthcare work, and new ethical and legal challenges. Changes to healthcare work can cause tensions between standardisation through automation and the unpredictable nature of healthcare work. With regard to new ethical and legal challenges, the workshop heard that there are currently no existing liability and ethical frameworks in a rapidly evolving field. Moreover, cybersecurity is a big concern and protecting patient data and personal data is essential in healthcare.

1 Million Genomes Declaration - Hungary signed

On 15 February 2019, Hungary joined the EU Member States driven initiative on linking genomic data bases across borders, becoming the 20th country to join this cooperation mechanism.

The signature by Hungary took place shortly before the 3rd Meeting of the Representatives of the Signatories of the Declaration 'Towards access to at least 1 Million Genomes in the EU by 2022'. These EU Member States have committed to collaborate on the secure and authorised access to national and regional banks of genomic and other health related data. To reach this goal, they are working on bringing together their existing infrastructures and expertise.

The Declaration on genomics cooperation: 'Towards access to at least 1 Million Genomes in the EU by 2022', was launched on Digital Day 2 (10 April 2018) and has been signed already now by 20 Member States (Austria, Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, Finland, Greece, Hungary, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Portugal, Slovenia, Spain, Sweden and the UK). The initiative is also open to countries of the European Economic Area and the European Free Trade Association. It is part of the EU's agenda for the **Digital Transformation of Health and Care**, as set out in its recently adopted Communication.

This cooperation mechanism is aimed to ensure that in 2022 there will be at least a cohort of 1 Million sequenced genomes accessible for research and personalised medicine in the EU.

2018 Declaration Genome

Implementation of the European emergency number 112 - 2018 Report

On 11 February 2019, the Commission published the 2018 report on the implementation of the European emergency number.

This annual report provides an overview of the state of play on the implementation of the 112 European emergency number in 2018 in the EU countries. The data for this report on the implementation of the European emergency number 112 was collected in 2018 throughout the EU Member States. The report gives the data on emergency calls, answering time, access for disabled users, caller location and awareness levels, and finally, determines the state of play of the implementation of emergency communications.

Main findings of the report

- Calls to “112” increased by 5% in one year, while the total number of emergency calls dropped 2.5%. Calls to “112” represented 48% of the calls placed in case of an emergency.
- Accuracy of caller location continued to improve in the reporting period. Advanced Mobile Location (AML) handset-based caller location solution took off in Malta and Slovenia. Currently AML is fully deployed in Belgium, Estonia, Finland, Ireland, Lithuania, Malta, Slovenia and the United Kingdom. The Commission contributes to this development by financing AML deployment in Germany, Denmark, France, Croatia, Hungary, Portugal and Sweden, thereby raising the number of AML countries to fifteen.
- 73% of emergency calls were made from a mobile phone, up 3% from last year. This confirms that a growing number of people would benefit from handset-derived caller location, as mandated by the European Communications Code.
- 23 Member States reported less than 10 seconds for the answering time needed to get in contact with emergency services.
- 23 Member States reported the implementation of alternative access to emergency services for users with disabilities through SMS. Meanwhile, some emergency applications deployed can provide much better location information and additional features. The information received from Member States reveals a number of potential implementation issues as regards equivalent disabled access to emergency services. In addition to the basic problem of lack of availability of any appropriate service that ensures two-way interactive communication (EL), there are Member States where solutions meeting minimum requirements are not deployed throughout the whole territory (PL, IT, ES) or are not available at all times of the day (CZ). In addition, user location information for disabled users is not available in 15 Member States
- 26 Member States reported a currently deployed public warning system. The technologies deployed are: sirens in 16 Member States; TV, Radio or social media alerts in 10 Member States; specific applications in 5 Member States; SMS alert in 5 Member States and Cell Broadcast in 4 Member States

Report on the implementation of the European emergency number 112

Transformation of Health and Care in the Digital Single Market - Factsheet

On 5 February 2019, the EU Commission released a factsheet on the Transformation of Health and Care in the Digital Single Market.

The European Commission considers that digital solutions for health and care can increase the well-being of millions of citizens and radically change the way health and care services are delivered to patients, if designed purposefully and implemented in a cost-effective way.

Full factsheet

Internal market

Medical Devices Coordination Group

A meeting between MDCG and Stakeholders MDCG – Medical Device Coordination Group (Medical Devices Regulation/In Vitro Devices Regulation) was organised on 14 February 2019 in Brussels.

The main item was the implementation of the MDR/IVDR. Medtech Europe and COCIR were extremely vocal about concerns that things will not be ready on time to implement. They are worried, particularly about the preparedness of Notified Bodies to implement. At the moment only one Notified Body has been MDR designated, and that is one from the UK. 30 more are in process, and 10 more will apparently apply this year. They are also worried about the development of the implementing acts: 2 have been published, but around 16 more need to be out before implementation.

Medtech Europe also spent a lot of time talking about Brexit and worries of a no-deal scenario. They were asking for contingency plans and in case of a no deal, a 2-year grace period. The European Commission was going to be holding a session the following day with MDCG EU 27 members to discuss Brexit and no deal scenarios.

The report from NB-Med also said that MDD certification renewal process, and MDR initial certification with assessments by 2020 will be impossible.The Joint Research Centre gave a presentation on the new scientific bodies and expert panels which will be up and running soon. They have reached out to the medical profession and BioMed Alliance is chairing a task force.

On Unique Device Identifier (UDI), the MDCG subgroup on UDI will be up and running from 1 May 2019. There will also be a subgroup on nomenclature and there is overlap with two taskforces (implant card and regulatory guidance). The 4 applications from 4 UDI issuing entities are being evaluated but that should be concluded by the end of February 2019. The scope of the work is very technical at the moment, but HOPE will get involved as an end-user. In terms of communications, the European Commission has revamped their webpage and then will be publishing a leaflet for Healthcare Institutions.

Medical Devices - Common Specifications for products without a medical purpose - informal consultation of stakeholders

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

In order to allow manufacturers to demonstrate the conformity of such products, common specifications will be adopted. In accordance to Art. 1(2) of the MDR such common specifications will address at least the application of risk management and, where necessary, clinical evaluation regarding safety.

A first draft of an Implementing Regulation on common specifications for devices without an intended medical purpose has been developed by the Commission in collaboration with Member States. The text has not been endorsed by the MDCG, and neither should it be seen as a final version agreed among all Member States and the European Commission. However, this draft version has been informally transmitted to stakeholders in order to gather further information at this stage of the process.

Pharmaceuticals – Big Data

Recommendations for a path towards understanding the acceptability of evidence derived from '**Big data**' in support of the evaluation and supervision of medicines by regulators were published on 15 February 2019 as part of a **summary report of the Heads of Medicines Agencies (HMA) - EMA Joint Big Data task force** .

Massive amounts of data are generated on a daily basis through wearable devices, electronic health records, social media, clinical trials or spontaneous adverse reaction reports. There is no doubt that insights derived from this data will increasingly be used by regulators to assess the benefit-risk of medicines across their whole lifecycle. However, in order to benefit from and make prudent use of the data collected, regulators need a deeper understanding of the data landscape.

The recommendations and associated actions set out what needs to be addressed, but the mechanisms by which this may be achieved requires further focused work over the coming year. Stakeholders are invited to submit feedback and observations on the recommendations to inform the upcoming work of the group.

Stakeholders and members of the public are invited to submit their comments on the core recommendations in the summary report (not to exceed 1,000 words) to **bigdatasec@dkma.dk** until 15 April 2019. In particular, views on prioritisation of future actions would be welcomed.

Further information and related documents are available by clicking **here**.

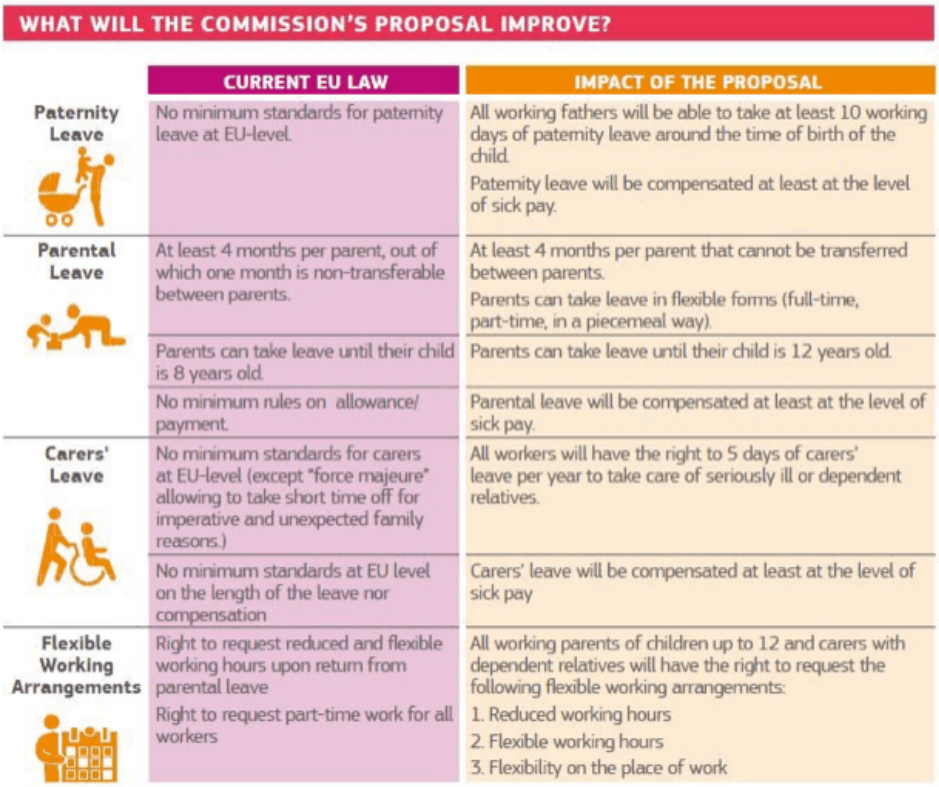
Work-life balance directive – Compromise

The European Parliament and the Council reached in February 2019 a provisional agreement on the European Commission's proposal for a new Directive on work-life balance for parents and carers. To address the challenges that working carers and parents face in reconciling work and family responsibilities, the European Commission proposed the 'Work-life Balance' Initiative in April 2017. This initiative is a key deliverable of **the European Pillar of Social Rights**.

The Directive on work-life balance sets a number of new or higher standards for parental, paternity and carer's leave, and the right to request flexible working arrangements. It takes account of the needs of small and medium-sized companies and makes sure that they are not disproportionately affected. The new Directive is complemented with policy and funding measures, supporting Member States in enforcing existing dismissal protection legislation, developing formal care services and addressing economic disincentives for second earners to work.

The provisional agreement now has to be formally adopted by both the European Parliament and the Council.

Read more on work-life balance



Long term care - Commission Workshop

The European Commission Directorate General EMPL organised a workshop "Taking stock of EU action in the area of long-term care", which took place on 29 January 2019.

With the ageing population, the need for long-term care is growing. While the provision of long-term care is the responsibility of Member States, common challenges and the cross-border

dimension emphasise the value added of the EU-wide response. The European Pillar of Social Rights (principle 18) states that everyone has the right to affordable long-term care of good quality, in particular home-care and community-based services. To implement this principle, a number of actions have to be taken at the regional, national and EU levels.

The aim of the workshop was to gather expert knowledge and evidence to set the scene for future discussions on long-term care. 25 participants representing expertise in this area, EU level NGOs and social partners, will have the possibility to present their research, projects or members' activities during the event, discuss policy and practice in the field of long-term care and provide expert knowledge to the European Commission.

The workshop marks the start of a series of workshops that aim to inform possible future EU initiatives in the field of long-term care. The right to affordable and good quality long-term care, in particular home-care and community-based services, is promoted in the European Pillar of Social Rights (Principle 18). Five expert workshops in Brussels, taking place between January and June 2019, will discuss which potential EU actions can support Member States to implement this Principle.

Cohesion Policy Investments in Health - Conference

HOPE was invited to the European Commission conference « Cohesion Policy Investments in Health » organised on 19 February 2019 in Brussels.

Two Commissioners made the opening statements: Vytenis Andriukaitis, European Commissioner for Health and Food Safety, and Corina Creţu, European Commissioner for Regional Policy. The Commissioners said that health systems are evolving towards more education, health promotion and disease prevention and shifting away from hospital and institution-centred care to community-based care and towards integration of health and social care. They also mentioned that with the new policy objectives that allow for integrated investments in health, social inclusion and education, the Commission **proposal** for the 2021-2027 Cohesion Policy provides the conditions to support these changes.

The Commissioners launched a pilot project as well to improve cross-border emergency services in the Pyrenees between the border regions of France, Spain and the Principality of Andorra. A presentation of pilot project on cross-border healthcare in the Pyrenees « When medical emergencies erase borders » was delivered by Jean-Louis Valls, Director of the Communauté de Travail des Pyrénées, Interreg V-A Espana – France – Andorra.

Doctors in border regions cannot attend patients in need of urgent medical attention from across the border. To overcome this situation, the project "When medical emergency systems erase borders" aims to ensure mutual prior recognition of doctors on both sides of the border.

The second phase of the pilot project is now launched and is set to ensure bilateral agreements between the Orders of Doctors of the Spanish and French border regions. As a result, 15 million inhabitants of the Pyrenees will benefit from better emergency services as a result. The project is supported by the European Regional Development Fund and will be completed mid-2019.

The results of this project will serve as an example to possibly replicate in other border regions in the future. The Commission supports tackling obstacles linked to the governance of cross-border issues and, in its legislative proposal for Cohesion Policy 2021-2027, suggests setting aside 15% of any Interreg cross-border cooperation programme to this purpose.

They also announced that health will be this year's new category for the **RegioStars Awards.** Every year the RegioStars reward the best and most innovative Cohesion Policy projects in Europe in five thematic categories, including a topic of the year. This year's edition will seek to reward quality health projects, to inspire Member States and regions. The **online application platform** is open from today until 9 May 2019. An independent jury will assess the applications and crown the winners during the RegioStars awards ceremony, to take place in Brussels in October 2019.

Factsheet – Cohesion Policy investments in health

Study financed by the EU Health programme - **European Structural Funds for Health**

Competition

Report on Competition enforcement in the pharmaceutical sector (2009-2017)

On 28 January 2019, the European Commission adopted the Report 'European competition authorities working together for affordable and innovative medicines' on competition enforcement in the pharmaceutical sector. The Report covers the period 2009-2017. The Report was drawn up in close co-operation with the national competition authorities of the 28 EU Member States. It explains how competition authorities in the EU are working together and how their enforcement actions contribute to affordable and innovative medicines.

Report

DigitalHealthEurope: get support for your digital transformation of health and care activities

The new Horizon 2020 project DigitalHealthEurope will provide comprehensive, integrated and centralised support to the Digital Health and Care Innovation initiative in the context of the Digital Single Market Strategy.

This co-ordination and support action was launched on 1 January 2019. It will work over a two-year period with a 17-member consortium supported by more than 50 associated experts. Its kick-off meeting took place in Bonn, Germany, on 24-25 January 2019.

The project will mobilise actions that boost innovation and advance the three Digital Single Market priorities for the digital transformation of health and care, as outlined in the 2018 Communication:

- citizens' secure access to and sharing of health data across borders;
- better data to promote research, disease prevention, personalised health and care;
- digital tools for citizen empowerment and person-centred care.

Deploying digital solutions is at the forefront of the project's approach. To this end, successful initiatives will be identified and analysed, using assessment tools. Highly impactful and replicable initiatives will be selected and given the opportunity to scale up, with the aid of instruments such as matchmaking and a twinning support scheme.

The call for twinnings will be made public in the summer of 2019. Up to 46 pairs of organisations will receive funding for twinning.

Organisations will receive structured advice on EU funding instruments and financing sources as well as from a deployment support service. The results will contribute to capacity building and "building blocks" for the scaling of innovative practices.

The project will create multi-stakeholder collaborative platforms that directly reflect the digital transformation priorities. The platforms will work towards producing white papers and recommendations in the following three areas: better citizen access and control of data, better use of data infrastructure platforms to support secondary uses of health data, and active cooperation between patients and health and care professionals and providers.

The results will include a roadmap, advice and recommended actions. Taken together, these will deliver a common vision of EU coordination and support for digital transformation of health and care beyond 2020.

Project website

Active and Assisted Living Programme: 2019 Call for proposals now open

The Active and Assistive Living (AAL) Association has opened its February 2019 Call for proposals: 'Sustainable Smart Solutions for Ageing Well'. This year the aim of the call is to support innovative, transnational and multi-disciplinary collaborative projects. It will close on 24 May 2019.

The AAL Call 2019 has the following key features:

- it is open to developing ICT-based solutions targeting any application area(s) within the AAL domain. The solutions need to be embedded in the strategies of the participating end-user organisations, service providers and business partners.
- it allows for more flexibility regarding the scope, size and duration of the proposed projects (including small collaborative projects),

More information on the call main features and objectives

EuDonOrgan - Why Organ Donation Matters to Us All

HOPE participated to the EU-funded project EUDONORGAN conference titled Why Organ Donation Matters to Us All organised on 18 February 2019 in Brussels. The event was hosted by the European Parliament in collaboration with the Belgian Ministry of Health.

The conference brought together patients, advocacy groups, leading professionals and transplant authorities for a unique exchange of views on their common aim: increasing organ donation and transplantation in the EU.

This is one of six EU-funded awareness raising events being held across the EU to increase interest and support for organ donation among health professionals and the general public.

The event was followed by a short commemoration for deceased donors in Belgium, in front of the BELDONOR bus on the esplanade of the European Parliament.

More information:

- **"Why Organ Donation Matters to Us All": EUDONORGAN Social Awareness Event on Organ Donation**

Reports

- *World Health Organization (WHO)*

Antibiotic resistance: using a cultural contexts of health approach to address a global health challenge (2019)

This policy brief published in February 2019 has been developed in response to the contemporary challenge of antibiotic resistance (ABR). ABR poses a formidable threat to global health and sustainable development. It is now increasingly recognised that the systematic neglect of cultural factors is one of the biggest obstacles to achieving better health outcomes and better standards of living worldwide.

Using a cultural contexts of health approach, the policy brief explores the centrality of culture to the challenge of ABR. The brief examines how the prescription and use of antibacterial medicines, the transmission of resistance, and the regulation and funding of research are influenced by cultural, social and commercial, as well as biological and technological factors. The brief moves beyond the ready equation of culture with individual behaviours and demonstrates how culture serves as an enabler of health and provide new possibilities for change.

Link

Guidelines for the care and treatment of persons diagnosed with chronic hepatitis C virus infection (2018)

These guidelines published in July 2018 and available online since February 2019, aim to provide evidence-based recommendations on the care and treatment of persons diagnosed with chronic hepatitis C infection. They update the care and treatment section of the WHO Guidelines for the screening, care and treatment of persons with hepatitis C infection issued in April 2016. The 2017 Guidelines on hepatitis B and C testing update the screening section.

These guidelines are intended for government officials to use as the basis for developing national hepatitis policies, plans and treatment guidelines. These include country programme managers and health-care providers responsible for planning and implementing hepatitis care and treatment programmes, particularly in low- and middle-income countries.

Link

WHO Mental Health Gap Action Programme Operations Manual

The WHO Mental Health Gap Action Programme (mhGAP) published online at the beginning of 2019, aims at scaling up mental health services in non-specialised health settings to achieve universal health coverage.

The mhGAP operations manual is an integral component of the mhGAP package and supports district health managers and others responsible for integrating mental and physical health services. The manual offers practical guidance and necessary tools for planning, preparing, implementing, monitoring and evaluating mhGAP.

Link

➢ *OECD (Organisation for Economic Co-operation and Development)*

Using routinely collected data to inform pharmaceutical policies

In February 2019 the OECD adopted a report and country fiches on "Using routinely collected data to inform pharmaceutical policies". Under the EU Health Programme grant, the report describes best practices in the use of information routinely collected in health systems to improve knowledge on the performance of medicines in real settings and increase spending efficiency. It is based on research, a survey of OECD and EU countries, and interviews.

Link

Pharmaceutical Innovation and Access to Medicines

On 29 November 2019 the OECD published a report on Pharmaceutical Innovation and Access to Medicines. This report reviews the important role of medicines in health systems, describes recent trends in pharmaceutical expenditure and financing, and summarises the approaches used by OECD countries to determine coverage and pricing. It then highlights current issues for policy makers, such as the increasing prices of new medicines; concerns about the value of spending in some therapeutic areas; challenges in anticipating the arrival of very effective medicines for highly prevalent diseases; sharp price increases in off-patent products; and the apparent misalignment of current incentives for the development of treatments for certain conditions.

Link

Excessive Pricing in Pharmaceutical Markets -Note by the European Union

On 27-28 November 2018 a written contribution from the European Union was submitted for Item 9 of the 130th OECD Competition Committee meeting.

Affordable access to many drugs is made difficult by high prices. At the same time, serious questions are being asked about the degree of innovation and value offered by increasingly costly treatments. A number of competition enforcement actions against excessive pricing have recently taken place in the pharmaceutical sector, despite competition authorities usually being reluctant to intervene directly against high prices. In common with other instances of application of competition law in the pharmaceutical sector, these cases require a deep understanding of market dynamics and sectoral regulation, and of the various regulatory responses that may be deployed to address high prices.

In November 2018, the OECD held a discussion on excessive prices at the intersection between competition law and regulated sectors such as pharma.

Link

➢ *Other*

Integrating is caring: A paradigm shift in health

On 19 February 2019, the European Policy Center (EPC) published a report entitled “Integrating is caring: A paradigm shift in health”.

In this Policy Brief, Simona Guagliardo, together with Claire Dhéret, argues that the integration of healthcare services in the EU is a policy worth pursuing. It has the potential to address the needs of an ageing European population, to tackle the rising cost of healthcare systems and deliver better health outcomes. The biggest barriers are related to the complexity and rigidity of the organisational structures of many European healthcare systems and to the level of engagement of health and care practitioners and patients.

Even though the EU has limited competencies in health, Guagliardo and Dhéret demonstrate that it can play a decisive role in overcoming the hurdles in the transition to integrated care, by collecting strong, evidence-based data, encouraging knowledge-sharing and capacity-building and creating a framework that facilitates the mobilisation of financial resources.

Link

Legislative Approaches to Immunization Across the European Region

In December 2018, in light of recent outbreaks of measles and other vaccine-preventable diseases in Europe, the Sabin Vaccine Institute reviewed the immunization legislation in the region, in partnership with the O'Neill Institute for National and Global Health Law at Georgetown Law and with the contribution of the European Region Legislative Landscape Review Steering Committee.

Report

Articles

HTA programme response to the challenges of dealing with orphan medicinal products: Process evaluation in selected European countries

Challenges commonly encountered in HTA of orphan medicinal products (OMPs) were identified in Advance-HTA. Since then, new initiatives have been developed to specifically address issues related to HTA of OMPs.

This study published in February 2019 aimed to understand why these new HTA initiatives in England, Scotland and at European-level were established and whether they resolve the challenges of OMPs. The work of Advance-HTA was updated with a literature review and a conceptual framework of clinical, regulatory and economic challenges for OMPs was developed. The new HTA programmes were critiqued against the conceptual framework and outstanding challenges identified.

The new programmes in England and Scotland recognise the challenges identified in demonstrating the value of ultra-OMPs (and OMPs) and that they require a different process to standard HTA approaches. Wider considerations of disease and treatment experiences from a multi-stakeholder standpoint are needed, combined with other measures to deal with uncertainty (e.g. managed entry agreements). While approaches to assessing this new view of value of OMPs, extending beyond cost/QALY frameworks, differ, their criteria are similar. These are complemented by a European initiative that fosters multi-stakeholder dialogue and consensus about value determinants throughout the life-cycle of an OMP.

New HTA programmes specific to OMPs have been developed but questions remain about whether they sufficiently capture value and manage uncertainty in clinical practice.

Link

Artificial intelligence, bias and clinical safety

This analysis, firstly published online in January 2019, is written with the dual aim of helping clinical safety professionals to critically appraise current medical AI research from a quality and safety perspective and supporting research and development in AI by highlighting some of the clinical safety questions that must be considered if medical application of these exciting technologies is to be successful.

In medicine, artificial intelligence (AI) research is becoming increasingly focused on applying machine learning (ML) techniques to complex problems, and so allowing computers to make predictions from large amounts of patient data, by learning their own associations. Estimates of the impact of AI on the wider economy globally vary wildly, with a recent report suggesting a 14% effect on global gross domestic product by 2030, half of which coming from productivity improvements. These predictions create political appetite for the rapid development of the AI industry, and healthcare is a priority area where this technology has yet to be exploited. The digital health revolution described by Duggal et al. is already in full swing with the potential to "disrupt" healthcare. Health AI research has demonstrated some impressive results, but its clinical value has not yet been realised, hindered partly by a lack of a clear understanding of how to quantify benefit or ensure patient safety, and increasing concerns about the ethical and medico-legal impact.

Link

Demand-side determinants of rising hospital admissions in Germany: the role of ageing

In this study published on 9 February 2019, the authors investigated the relationship between changes in demand-side determinants and changes in hospital admissions. The authors used longitudinal market-wide data, including a novel detailed measure of population morbidity. To assess the effect of ageing, the authors interacted age with shifts in the population structure for both the surviving population and the population in their last year of life.

One of the main results is that changes in morbidity had the largest impact on changes in hospital admissions. Changes in the size of the surviving population had the second largest impact, which differed substantially across the age spectrum. There was a large response in admissions to changes in the size of the population aged 60–79 years. The end-of-life effect had the smallest impact and began to play a greater role only in the population aged 80 years and older. In many studies, end of life presumably approximates high morbidity. The results demonstrated robustness in several tests. Estimations in separate major diagnostic categories have been performed and changes included in personal preferences. The authors argue that the determinants included in the estimations capture the vast majority of change on the demand side. Taken together, the findings provide evidence that these determinants explain one-fifth of changes in hospital admissions.

Link

Stakeholders' perceptions of policy options to support the integration of community health workers in health systems

Community health workers (CHWs) are an important component of the health workforce in many countries. The World Health Organization (WHO) has developed a guideline to support the integration of CHWs into health systems. This study published on 18 February 2019 assesses stakeholders' valuation of outcomes of interest, acceptability and feasibility of policy options considered for the CHW guideline development.

A cross-sectional mixed methods (quantitative and qualitative) study targeting stakeholders involved directly or indirectly in country implementation of CHW programmes was conducted in 2017. Data was collected from 96 stakeholders from five WHO regions using an online questionnaire.

Outcomes of interest and policy options proposed were rated highly by most stakeholders. This finding helps to reinforce their usefulness in meeting the expectations of the CHW guideline end-users to properly integrate CHWs into health systems.

Link

Parental digital health information seeking behaviour in Switzerland: a cross-sectional study

Digital media are increasingly abundant and used to seek health information, however, to date very little is known on parents' seeking behaviour in the context of child's health and development outside English-speaking and Scandinavian countries.

By investigating the prevalence of, and reasons for use, the authors studied parents' perception of the Internet as a resource for improving their health-related knowledge. The survey was conducted in a random sample of Swiss-German parents with at least one child aged less-than 2 years old and included questions on use of print, digital, and personal information sources, as well as different information situations. Results published on 21 February 2019 show that the internet has become a highly frequented source of information for Swiss-German parents on children's health with largely valuable perceptions of its utility. Digital media are used in addition to and not in replacement of print media and personal contacts. Increasing parental guidance by health and public health professionals could improve parental digital health utilisation and empower parents in the new role they adopt.

Link

Antimicrobial resistance: Towards higher patient safety in European hospitals - Roundtable

On 5 February 2019, HOPE took part in the event "Towards higher patient safety in European hospitals. Innovation in hygiene and sanification to reduce healthcare associated infections and antimicrobial resistance" hosted by the Interest Group "European Patients' Rights & Cross-Border Healthcare" and in particular by MEP Brando Benifei (S&D Group) in the European Parliament.

It took place in the frame of a two-day event devoted to patient safety, organized on the 4-5 February in Brussels by Active Citizenship Network, the European network of Cittadinanzattiva, with the support of Copma. The main message of the event was that in order to effectively fight against healthcare associated infections (HAIs) and antimicrobial resistance (AMR), it is necessary to adopt innovative solutions together with a decisive action aiming at raising awareness of this issue among the public. Therefore, it is pivotal to engage groups advocating for patients' rights.

The event was moderated by Brian Maguire, Journalist at EURACTIV. After a welcome address given by MEP Brando Benifei and Mariano Votta, Director of Active Citizenship Network, and overview of the issue was presented by Charles Price, Policy Officer for Antimicrobial Resistance and Healthcare-associated infection, European Commission Directorate for Public Health and Daniele Celotto, European network to promote infection prevention for patient safety (EUNETIPS).

Recent data released by the European Center for Infectious Diseases (ECDC) have reported that the problem of antibiotic-resistant infections is worsening. In Europe, about 33,000 deaths per year are caused by this kind of infections, and almost a third of these occur in Italy. Here, despite the high incidence of this phenomenon, there is a very low level of awareness of the risks associated with HAIs and AMR. Proper prevention practices, together with the adoption of innovative solutions, could significantly curb HAIs, and consequently economically benefit the national health system. As a matter of fact, the costs for treating each single infection range from 5.000 to 9.000 euros.

The role of innovation in hygiene and sanification was addressed by Elisabetta Caselli, PhD - Section of Microbiology, University of Ferrara and Luca Arnoldo, Hygiene and Public Health, University of Udine. An eco-sustainable probiotic-based cleaning system (Probiotic Cleaning Hygiene System, PCHS) was presented for the first time to the European Commission, as well as to numerous stakeholders and leaders of civic and patients' associations coming from 13 countries. This system exploits microbial biocompetition and reduces HAIs by 52%, guaranteeing long-lasting, stable conditions of hygiene in hospital environments, thus benefitting both patients and the healthcare system as a whole.

The issue was then discussed by a panel composed of: Denis Herbaux, Director PAQS (a Belgium); Giuseppe Banfi, European University Hospital Alliance (gathering 9 university hospitals); Esther Calbo, European Regional and Local Health Authorities (EUREGHA, gathering 14 European regions); and Melina Raso, Health First Europe. Denis Herbaux underlined the importance of education and training of healthcare professionals on patient safety and good practices in European hospitals.

Cittadinanzattiva's General Secretary Antonio Gaudioso stressed out that 7,800 people die in Italy every year due to antibiotic-resistant infections contracted during hospitalization, almost twice the number of deaths caused by car accidents. In Italy, one in 15 patients contracts an infection during hospitalization which was not clinically apparent nor incubated at the time of entry. Additionally, the Pit Health Report of Cittadinanzattiva reports that nosocomial infections have been increasing in the last year (4.9% in 2017 compared to 4.3% in 2016), especially among immunosuppressed patients. Likewise, the number of complaints for the conditions of healthcare facilities has been rising, growing from 30.5% in 2015 to 33.4% in 2017. In particular, citizens complain when they are treated in structures characterized by crumbling environments, poor hygiene conditions, or lacking maintenance.

Event page

Health Access – European Parliament

A conference "EU collaboration in health for better access: Taking stock and looking to the future" was organised on 20 February 2019 in the European Parliament.

The meeting started with a keynote address of Anne Bucher, Director General for Health and Food Safety, European Commission followed by an introduction: Universal access to healthcare for all: access through inclusion by several speakers: Ann-Isabelle Von Lingen, Policy Officer, European AIDS Treatment Group (EATG); Dorota Sienkiewicz, Policy Coordinator, EuroHealthNet; Elisabeth Kasilingam, Manager Director, European Multiple Sclerosis Platform (EMSP) & European Patients' Forum (EPF) board member.

The panel discussion "What have we achieved in improving equal access to quality healthcare?" reflected on the key topics raised by the Patient Access Partnership and the MEP Interest Group on Access to Healthcare over the years, to assess the progress made in putting access to healthcare in the focus of health policies at EU and international level; to serve as a basis for the agenda of the next mandate of the MEP Interest Group on Access following EU Elections 2019. The panellists were first Members of the European Parliament: Cristian Silviu Buşoi MEP (EPP, Romania); Karin Kadenbach MEP (S&D, Austria); Lieve Wierinck MEP (ALDE, Belgium). A second group was made up of Ghebremedhin Ghebreigzabiher, Health Attaché of Italy; Ewa Piasecka, Health attaché of Poland; Ana Carla Pereira, Head of Unit Modernisation of Social Protection Systems, DG EMPL, European Commission; Martin Seychell, Deputy Director General for Health, Units B & C, DG SANTE, European Commission;

Santiago Calvo-Ramos, Policy analyst from the Unit: Sustainability of public finance, DG ECFIN, European Commission.

The panel discussion “What are the future priorities towards better access to healthcare for patients?” based on lessons learned and past achievements, the Patient Access Partnership and the MEP Interest Group on Access discussed with the healthcare community the key priority areas for cooperation in health. The discussions will inform the agenda of the MEP Interest Group on Access in its new mandate following EU Elections 2019.

Antimicrobial resistance: actions taken across Europe - EUPHA e-collection

The European Journal of Public Health published in February 2019 papers on antimicrobial resistance. **This e-collection** provides concrete examples of how the strategic objectives of the AMR global action plan can be operationalised in the region, showcasing some successes but also highlighting some of the challenges, in particular around changing prescribing and consumption behaviour.

28th Congress of the European Association of Hospital Managers (EAHM)

The Belgian Association of Hospital Managers is hosting the 28th Congress of the European Association of Hospital Managers (EAHM) in Ghent on 12-13 September 2019. The conference theme is “Innovative Healthcare Strategies”.

The programme is organised around six topics and six hospitals. The six topics are: smart building and logistics; innovation and technology; big data and digital health; healing architecture; finance and health economics; health management. And the six hospitals are: AZ Delta Roeselare – Menen; AZ Zeno - Knokke; AZ Maria Middelares Gent; AZ Groeninge Kortrijk; AZ Delta Chirec Brussels ; ZNA Cadix Antwerpen.

More information

"Artificial Intelligence in healthcare: is Europe ready?"

Brussels (Belgium), 18 March 2019

Background

Artificial intelligence is already changing healthcare. Managing medical records, interpreting scan's results or monitor the use of medications is just some of few examples of how artificial intelligence is used today.

But new possibilities bring also new issues such as ethical, safety and liability, and transparency towards users. Is Europe ready to embrace the change of artificial intelligence in healthcare and how will it respond to the challenges ahead?

Aim of the event

Hear from different sectors (patients', healthcare professionals', academia, industry, etc.) about the challenges and opportunities brought by artificial intelligence in healthcare. Identify recommendations and priorities to be addressed by European and national policy-makers.

Read more

19th International Conference on Integrated Care

San Sebastian (Spain), 1-3 April 2019

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

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

- Integrated health and social care for people at home

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

The Scientific Committee is now welcoming abstracts of good practice, projects, development of policy and research and theory in the areas of the conference themes. The international committee is made up of recognized experts in the field of integrated care from around the world and they support the development of the programme that reflects of the challenges and opportunities experienced by people and organisations that are working towards more coordinated and people-centred services. All accepted abstracts will be published in the **International Journal for Integrated Care.**

Read more

HOPE Agora 2019

Ljubljana (Slovenia), 2-4 June 2019

The HOPE Agora 2019 will take place on 2-4 June 2019 in Ljubljana, Slovenia, and will discuss the topic “Evidence-informed decision-making in healthcare management”. It will close the HOPE Exchange Programme 2019 which will run from 6 May 2019 to 4 June.

Every year HOPE runs an exchange programme to promote the sharing of knowledge and expertise within Europe and to provide training and experience for hospital and healthcare professionals.

Read more