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- Brexit: the European Commission takes stock of preparations and provides practical guidance to ensure a coordinated EU approach

### **EXPH: own initiative-paper: reflection on priorities for the future of healthcare in the EU**

This paper was prepared by the members of the Expert Panel on their own initiative based on an internal brainstorming on its work and future EU actions in healthcare and public health.

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### **EXPH: opinion on task shifting and health system design**

According to the Expert Panel, task shifting, when based on robust evidence and implemented effectively, can make a major contribution to health outcomes and to the sustainability of health systems. It is not, however, a panacea for all the challenges faced by health systems.

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### **EXPH: request for an opinion on options to foster health-promoting health systems**

The Expert Panel has been asked, among other things, to analyse the mechanisms to strengthen implementation of health promotion within health systems, and to identify the success factors for further integration, from a conceptual, organisation and financing point of view, as well as the main obstacles and challenges to address.

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### **HSPA: tools and methodologies to assess the efficiency of healthcare services in Europe**

This report from the Expert Group on Health Systems Performance Assessment (HSPA) aims to support national policy-makers in their efforts to achieve this objective. It gives an overview of the key theoretical concepts related to healthcare efficiency, and analyses country experiences assessing efficiency of care in Europe.

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### **European reference networks: launch of mutual collaboration between the ERNs and the stakeholders from industry and patients' associations**

Possible areas of cooperation between the European Reference Networks (ERNs) and other stakeholders, such as registries or clinical trials, were explored at the first meeting between members of the ERNs' working group on legal and ethical issues and relations with stakeholders and representatives from industry and patients' associations.

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### **Enlarging the European Reference Networks**

The ERN coordinators addressed several key aspects of the networks' development. The main discussions focussed on the on-going designation by Member States of affiliated partners, debating procedural aspects and the practical implications for ERNs. Several topics were then addressed related to the increase in operational activities and the development of the networks.

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### **European Commission: national contact points toolbox: glossary, checklist, FAQs and patients' manual**

This toolbox is intended for patients and National Contact Points (NCP) under the Cross-border Healthcare Directive, which are set up in every Member State to provide information to mobile patients. The toolbox contains relevant information on the legal framework of cross-border healthcare.

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### European Commission: Member State data on cross-border healthcare under Directive 2011/24/EU - 2017

In order to assess the impact of Directive 2011/24/EU, questionnaires were sent to all the Member States in 2015, 2016, 2017 and 2018 to collect information on patient mobility in the previous year. The data collected concern treatment for which prior authorisation was granted by the Member State of affiliation, and treatment for which prior authorisation is not required.

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### Council: informal meeting of European health ministers

The European health ministers met informally in Bucharest in the context of the Romanian presidency. The topics on the agenda included patient access to innovative drugs and patient mobility, particularly for patients with rare diseases or those below the age of 18, as well as access to innovative and expensive medicines.

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### Eurostat: data on access to care

According to data published by Eurostat, in 2017 almost 4 out of every 10 people (38 %) in the European Union consulted their general practitioner once or twice during the 12 months prior to the survey. 1.8% of children below the age of 16 had unmet medical needs, and more than half the population (55%) said that the amount that their household had to pay for medical care was not a financial burden.

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## 2 Health care services in the internal market

### European Court of Auditors: better management needed of cross-border healthcare

According to a report from the Court of Auditors, European patients are encountering difficulties when they try to benefit from the measures set out in the EU directive on cross-border healthcare. Few patients are well-informed about their right to receive medical care abroad. The electronic exchange of patient health data between Member States is subject to difficulties and delays.

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### European Parliament: labour mobility and recognition in the regulated professions

This study analyses the impact on labour mobility and employment of the 2013 revision of the Professional Qualifications Directive and related EU initiatives. It analyses trends in mobility and recognition, concentrating on the health sector and four country case studies. It reports findings from consultations with stakeholders at EU and national level and highlights best practice.

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### 3 Medicines and medical devices

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#### European Commission and Member States: signing of framework contracts with the pharmaceutical company Seqirus for the production and supply of influenza vaccines

Fifteen Member States, including Belgium, and the European Commission signed framework contracts with Seqirus for the production and supply of pandemic influenza vaccines under the 'EU joint procurement agreement to procure medical countermeasures. In case of an influenza pandemic, these fifteen Member States, which make up around half the European population, and the European Commission, will receive influenza vaccines.

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#### European Parliament: response to a parliamentary question on medicinal product shortages and parallel imports

The European Commission replied to a parliamentary question from John Stuart Agnew (ENF) on a possible study of the negative impact of parallel imports, given the particular nature of medicines and their markets. Such an evaluation could help to establish evidence-based regulation of the medicines trade, and could help Member States to plan their pharmaceutical stocks.

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#### European Parliament: response to a parliamentary question on medical devices

The European Commission replied to a parliamentary question from Dario Tamburrano (EFDD). This MEP asked: (1) how many medical devices are currently certified and will require a new certificate? (2) how many notified bodies have been accredited so far under Regulation 2017/745/EU; (3) how will the Commission avert the risk of a serious stoppage in the availability of medical devices for clinical use?

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#### Council of the EU: adoption of a regulation concerning the supplementary protection certificate for medicinal products

The Council of the EU adopted a regulation setting up an exception regime, exempting some medicines from the protection granted by a supplementary protection certificate (SPC), for exportation or storage. This exemption applies when generic or biosimilar medicines are produced solely for export to third countries where the original medicine is not protected, or where that protection has expired, or for stockpiling during the 6 months before the SPC expires.

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#### European Parliament: vote in favour of a new regulation on supplementary protection certificates

The European Parliament voted in favour of a new regulation on supplementary protection certificates (SPCs). The targeted revision of the patent-related rules on pharmaceuticals was proposed by the Commission, to help EU-based pharmaceutical companies tap into fast-growing markets, and to promote employment, growth and investment.

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#### EMA: the role of regulators in establishing added benefit of novel therapies

In this article published in Nature Reviews Drug Discovery, Hans-Georg Eichler, the EMA's senior medical officer, Harald Enzmann, chair of the EMA's human medicines committee and head of European and international affairs at the Federal Institute for Drugs and Medical Devices, and Guido Rasi, EMA's executive director, analyse the benefits and risks of different proposals regarding the role of regulatory agencies in establishing the added therapeutic benefit of novel treatments in light of the ongoing debate on medicines pricing.

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### **Eurobarometer: Europeans very sceptical about vaccinations**

According to the Eurobarometer survey published in relation with European Immunization Week, 48% of Europeans think that vaccines regularly have side-effects and 38% believe that vaccines can cause the disease against which they protect.

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### **European Commission: actions to address risks and challenges raised by pharmaceuticals in the environment**

A European Commission communication identifies several measures to address the multiple challenges that the release of pharmaceuticals poses to the environment. It lists six areas for action, concerning all stages of the lifecycle of pharmaceutical products, where improvements can be made. The text refers to pharmaceuticals for human and veterinary use.

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## **4 e-Health**

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### **European Commission: a new EU platform to support the diagnosis and treatment of rare diseases**

To mark Rare Disease Day, the European Commission launched a new online knowledge-sharing platform to support better diagnosis and treatment for more than 30 million Europeans suffering from a rare disease.

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### **European Parliament: Robots in healthcare: a solution or a problem? In-depth analysis**

This report summarises the presentations and discussions of a workshop on the use of robots and AI in healthcare. The first part of the workshop focused on the practical application of AI and robots in healthcare, whereas the second part examined the ethical implications and responsibilities of AI and robotic based technologies in healthcare.

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### **Albania and North Macedonia prepare to transpose the EU's legislative framework on digital health**

Albania and North Macedonia are eager to transpose the eHealth acquis, while Albania is setting up a digital agency and has started working on the digitisation of electronic health records. According to the roadmap set out by Council, accession negotiations are to be launched with both countries in June 2019. In this context, a meeting was organised in Brussels concerning the transposition of the Community digital health acquis, as part of a broader exercise relating to all European consumer protection and health rules.

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### **European guidelines for cross-border exchange of patient health data**

At its final conference, the CEN 'International Patient Summary' project presented the findings of its work, aiming to transform the current European guidelines on patient summaries, adopted by the eHealth Network, into European standards. These guidelines are considered an excellent basis for the establishment of international standards.

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➤ **Croatia will dispense ePrescriptions for Finnish citizens and will allow access to Czech patient summaries, while Croatian citizens travelling in Estonia will be able to receive their ePrescriptions there**

These exchanges will now be possible since the eHealth Network, comprising eHealth agencies in Europe, has agreed that Croatia can send and receive cross-border electronic prescriptions and receive patient summaries for citizens of other EU countries. This decision was supported by a positive vote in the eHealth Member State Expert Group.

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➤ **112 advertising technology companies are tracking EU citizens on public sector websites**

According to a study by the Danish company Cybot, more than 100 ad tech companies are systematically tracking European citizens when they consult public health websites on sensitive subjects such as pregnancy, sexual health, cancer or mental health. These data, once collected, can be resold via data brokers to companies both inside and outside the advertising industry.

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➤ **European Commission: reflection on the security of health apps**

A study prepared for the European Commission on the safety of non-embedded software shows that although no incidents have been reported to date, many countries are fully aware of the need to ensure some transparency on the safety/security of these applications. Professional medical organisations are organising activities to check the safety of health-related applications.

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➤ **European Commission: publication of 4 reports from the eHealth Stakeholders Subgroups**

DG CNECT has published a series of four reports prepared by eHealth Stakeholders subgroups. These reports are on the following topics: care continuum, citizen and health data, reimbursement, and e-standards and interoperability.

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## 5 Social policy

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➤ **EPSCO Council: adoption of the Joint Employment Report 2019**

Section 3.4 of this report looks at the implementation of employment guideline no. 8, which recommends to Member States to modernise their social protection systems, in order to promote equal opportunities, combat poverty and social exclusion. It gives an overview of the social situation in Member States by key indicators, and reports on measures taken by the Member States in the areas of social protection systems, notably long-term care and healthcare.

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➤ **Council: briefing from the Commission on the state of play concerning electronic exchange of social security information**

The Electronic Exchange of Social Security Information (EESSI) is an IT system that helps social security institutions in 32 European countries exchange information more rapidly and securely. The EESSI will make it easier to combat fraud and errors, and will benefit citizens who have lived and worked in several participating countries, who will see their social security benefits calculated more quickly and efficiently.

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## 6 Economic policy

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### European Commission: publication of the country-specific recommendations

The European Commission presented the 2019 country-specific recommendations (CSRs), giving economic policy guidance to all EU Member States for the coming 12-18 months. These recommendations are based on a detailed analysis of the country reports published in February, and on an assessment of the national programmes submitted in April.

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### EIB: support for upgrade of Utrecht's Diakonessenhuis hospital

The European Investment Bank and the Diakonessenhuis hospital in Utrecht have signed a loan agreement for EUR 43 million, supported by the European Fund for Strategic Investments, the main pillar of the Investment Plan for Europe.

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### EU Budget for 2021-2027: the Commission welcomes the preliminary agreement on InvestEU

The European Commission has welcomed the preliminary agreement on InvestEU. InvestEU supports various policy areas by providing a budgetary guarantee, in order to attract private investment. The areas covered include the financing of projects relating to hospitals, healthcare and long-term care.

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### Cyprus: sixth post-programme surveillance mission

European Commission staff visited Cyprus to conduct the sixth post-programme surveillance mission. The mission emphasises that by 2019 and 2020, the budget balance is expected to resume posting sizeable surpluses. The main risks relate to the fiscal impact of the healthcare reform.

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### Greece: third post-programme surveillance mission

The third post-programme surveillance mission to Greece examined the progress made on the key reforms launched under the programme, particularly progress in the implementation of the 15 specific reform commitments for mid-2019. As part of its strategy to modernise the healthcare sector, Greece undertook to ensure rollout of the primary healthcare system, in particular by opening at least 120 primary healthcare centres by the end of 2018, and 240 by mid-2020.

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## 7 Competition

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### Portugal: in-depth investigation into the Grupo HPA Saúde / Hospital São Gonçalo de Lagos merger

The Portuguese Competition Authority has decided to carry out an in-depth investigation into the merger involving the acquisition of Hospital São Gonçalo de Lagos by Grupo Hospital Particular do Algarve. This decision is based on indications of a risk that this merger could give rise to significant impediments of effective competition on the markets, both in relation to the provision of medical services in private hospitals in the Algarve, and to the supply of medical consultations in the areas of influence of the clinics operated by HSGL.

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**Denmark: the Competition Council publishes a study on excessive pricing in pharmaceutical markets**

Recently, the Danish Competition Appeals Tribunal upheld the Danish CD Pharma case concerning the drug Syntocinon, given to pregnant women during childbirth. This article explains the content of the case and the reasons why it was prioritised by the Danish Competition Council.

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**France: medicines distribution and biomedical laboratories: the Competition Authority publishes its opinion**

The Competition Authority has published the conclusions of its study on the health sector. The medicines distribution sector is facing radical changes. In order to maintain the high level of public health protection currently provided in France by the good coverage and quality of the pharmacy network, the Authority makes proposals to strengthen the role of pharmacists, and to make biomedical laboratories more efficient.

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## 8 Court of Justice of the European Union

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**Judgment: public procurement rules do not apply to services for the transport of patients provided, in emergency situations, by non-profit associations or organisations**

The Court ruled, in case C-465/17, that the care of patients in an emergency situation, carried out in a rescue vehicle by an emergency worker/paramedic, is covered by the CPV (Common Procurement Vocabulary) code corresponding to 'emergency/rescue services'. However, transport by qualified ambulance is not covered by the CPV code for 'ambulance services' unless it is possible to establish an emergency. This will be the case when it is necessary to transport a patient whose health is at risk of deterioration during that transport. That risk implies that the ambulance service must be provided by personnel properly trained in first aid.

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**Judgment: no supplementary protection certificate for new formulations of active ingredients already authorised**

In the Abraxis Bioscience case (C-443/17), the Court ruled that Article 3 of the regulation on supplementary protection certificates, must be interpreted as meaning that the marketing authorisation for a new formulation of an old active substance cannot be considered as the first marketing authorisation for this product in cases where this active substance has already been the subject of a marketing authorisation. This case follows an appeal made by Abraxis against the decision of the United Kingdom Intellectual Property Office refusing to grant an SPC for Abraxane.

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## 9 Infringement proceedings

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### Prescription medicines: the Commission urges Germany to comply with EU rules on free movement of goods

The Commission has sent a reasoned opinion to Germany regarding its rules on fixed prices for prescription medicines, which negatively affect the sale of products by pharmacies established in other EU Member States. The system of fixed prices under German legislation on medicinal products reduces pharmacies' ability to offer discounts, and therefore restricts trade among EU countries, and violates the principle of free movement of goods.

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### Recognition of professional qualifications: infringement proceedings against 26 Member States

The Commission has sent reasoned opinions to 24 Member States (including Belgium) and letters of formal notice to two Member States regarding the non-compliance of their national legislation and legal practice with EU rules on the recognition of professional qualifications. These opinions relate to crucial issues including the European professional card, the alert mechanism, the possibility of partial access to a professional activity and the proportionality of language requirements.

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## 10 Publications

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### OECD and EU: Improving forecasting of pharmaceutical spending – Insights from 23 OECD and EU countries. Analytical report

The OECD published a report entitled 'Improving Forecasting of Pharmaceutical Spending', together with 23 notes on EU/EEA countries. The report explores the various possible approaches to tracking pharmaceutical use and expenditure, and to anticipating changes in market dynamics. It looks at how EU/EEA countries use these approaches to set budgets and pharmaceutical expenditure caps, and to model future expenditure.

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### OECD: Using routinely collected data to inform pharmaceutical policies – Analytical report for OECD and EU countries

To assess the capacity of countries to generate evidence from clinical practice, and their impact on pharmaceutical policy development, the OECD, with the support of the European Commission, investigated countries' collection, uptake and use of routine data on prescribed and dispensed medicines. 19 EU/EEA countries responded fully to the OECD survey, and their responses were used to draw up the country notes.

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### WHO: Can people afford to pay for healthcare? New evidence on financial protection in Europe

This report, drawing on contributions from national experts in 24 countries, brings together data on unmet needs and financial hardship, to assess whether people living in Europe can afford to pay for healthcare. It shows that the proportion of people who forego needed healthcare, including prescribed medicines, is high in countries where financial protection is weak.

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**Study: Access to maternal health and midwifery for vulnerable groups in the EU**

This study, commissioned by the European Parliament, examines issues related to access of vulnerable social groups to maternal healthcare services and midwifery in the EU. It discusses the issues, analyses the causes, surveys the literature for best practices and makes policy recommendations, with a view to improving the situation of vulnerable women and contributing to a reduction in health inequalities.

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**Article: Brexit will cause significant harm to the NHS, but No-Deal Brexit presents by far the worst option**

This analysis, co-authored by the London School of Hygiene & Tropical Medicine, uses the available legal and political texts on four Brexit scenarios to assess the likely impact on 15 specific aspects of the British National Health Service.

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**ESPN: flash report on the healthcare reform process in Cyprus**

Less than three months before the launch of the long-awaited healthcare system, private doctors and hospitals are refusing to join the system. Although the system is expected to start as scheduled, these negative reactions raise doubts about its successful implementation, while the climate of controversy has created an explosive environment leading to the interruption of dialogue.

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**Article: evolution of the social situation and social protection in Belgium: increasing pressure on social protection adequacy**

This article analyses the evolution of the social situation in Belgium, based on European social indicators. The situation is monitored largely using social indicators taken from the EU survey on income and living conditions, and from the EU labour force survey.

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## 11 Brexit

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**Brexit: the European Commission takes stock of preparations and provides practical guidance to ensure a coordinated EU approach**

The European Commission has taken stock of the EU's intense 'no deal' preparations, and has issued practical guidance to Member States in five areas, including that of medicines and medical devices.

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