# European Health Care News

## Newsletter No.43 - September 2017

Ose European Social Observatory

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## 1 Public health

### European Commission: health programmes

Around 820 projects and actions have so far received financial support from the European Union under the three multiannual health programmes. The European Commission launched a database containing information on these projects.

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### European Commission: new action plan to tackle antimicrobial resistance

The Commission has adopted a new action plan to tackle antimicrobial resistance (AMR). The action plan is based on a 'one health' approach that addresses resistance in both humans and animals. In parallel the Commission adopted EU guidelines on the prudent use of antimicrobials in human health.

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### EXPH: three opinions at the request of the Commission

The Expert Panel on effective ways of investing in health (EXPH) is preparing three opinions, on 1) innovative payment models for high-cost innovative medicines, 2) benchmarking access to healthcare in the EU and 3) tools and methodologies for assessing the performance of primary care. The purpose of the opinions is to support the Commission in its policy initiatives.

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### European Parliament: compliance of Irish legislation with Directive 2011/24/EU on cross-border healthcare

In response to a Parliamentary question, the Commission provided clarification on compliance of Irish legislation with Directive 2011/24/EU on cross-border healthcare.

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### European Parliament: briefing paper on the European Reference Networks on rare diseases

The European Parliament Think Tank brought out a briefing paper on the European Reference Networks.

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### Stakeholder organisations urge greater EU action on health

More than 100 organisations representing stakeholder organisations in the health sector wrote a letter to Commission President Juncker expressing their serious concerns about the future place of health in European policies and programmes, in the light of the White Paper on the future of Europe.

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### Council: European pillar of social rights

The EU Health ministers welcomed the Commission proposal for a European pillar of social rights. They agreed with the objective of providing timely access to affordable, preventive and curative healthcare of good quality, provided that Member States' competencies in health policy are respected.

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## 2 Healthcare services in the internal market

### European Parliament: draft report on the proposal for a directive on a proportionality test before adoption of new regulation of professions

In his draft report on the proposal for a directive on a proportionality test before adoption of new regulation of professions (the 'draft proportionality test directive'), the rapporteur proposes that health professions be excluded from the scope of the directive. He submitted this draft report to the IMCO Committee (Internal market and consumer protection), which is responsible for discussing the proposal.

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### European Parliament: draft opinion of the ENVI Committee on the draft proportionality test directive

The rapporteur of the opinion from the ENVI Committee (environment, public health and food safety) to the IMCO Committee proposes in her draft opinion that health professions should be excluded from the scope of the directive.

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### European Parliament: proposed amendments to the draft proportionality test directive

In the ENVI Committee, amendments were proposed during the preparation of the Committee's opinion. Several amendments propose the exclusion of health professions from the scope of the directive.

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### Council: general approach adopted for the draft proportionality test directive

The Competitiveness Council (COMPET) adopted a general approach for the draft proportionality test directive. This text will form the basis for negotiations with the European Parliament on the proposal.

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### Fedcar: position paper on the draft proportionality test directive

FEDCAR, the European Federation of dental competent authorities and regulators, proposes that health professionals be excluded from the scope of the proposed directive, or, alternatively, that a much more balanced approach be taken in the criteria for the proportionality test, in accordance with the case law of the Court of Justice and the 'acquis communautaire'.

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### European Commission: study on cross-border health services: potential obstacles for healthcare providers

The Commission (DG SANTE) published a study on cross-border health services: potential obstacles for healthcare providers. This study was produced by a consortium made up Ecorys, Erasmus University Rotterdam, Spark Legal Network and Consultancy Ltd.

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### European Parliament: research on health tourism in the EU

This study defines and explores health tourism and its three main components: medical, wellness and spa tourism. It finds that health tourism comprises around 5% of general tourism in the EU and contributes approximately 0.3% to the EU economy.

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## 3 Medicines and medical devices

### European Commission: public consultation on EU blood, tissues and cells legislation

The purpose of the consultation is to gather views on the extent to which the 2002 directive setting standards for quality and safety of human blood, and the 2004 directive setting standards for tissues and cells, have met their original objectives and whether they remain fit for purpose.

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### Council: Conclusions on Member States-driven voluntary cooperation between health systems

These conclusions, adopted by the ministers responsible for public health in the EPSCO council, focus on cooperation for greater affordability and access to health technologies, price-setting and reimbursement of medicines, in the provision of highly specialised healthcare and in enhancing the expertise of health professionals.

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### European Commission: replies to the public consultation on the paediatric regulation

The Commission published a summary of the replies from stakeholder groups to the consultation on the paediatric regulation.

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### Eurostat: the EU is the world's leading exporter of pharmaceutical products

According to an article by Eurostat, the EU's statistical office, on international trade in pharmaceuticals, the EU, in 2016, was by far the largest world trader in medicinal and pharmaceutical products.

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### EMA: new EudraVigilance system for monitoring suspected adverse reactions

The EMA launched a new and improved version of EudraVigilance, the European information system on suspected adverse reactions to medicines which are authorised or being studied in clinical trials in the European Economic Area (EEA).

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### EMA and EUnetHTA: coordination of data requirements for medicine developers

The European Medicines Agency (EMA) and the European Network for Health Technology Assessment (EUnetHTA) are stepping up their efforts to provide developers of medicines with simultaneous, coordinated advice on their development plans, and to facilitate alignment of data requirements.

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### European Commission: report on the activities of the Expert Group on safe and timely access to medicine for patients (STAMP)

The report gives an account of the activities of STAMP. Discussions are on-going on the following topics:

- repurposing of authorised medicines;
- off-label use of medicines;

- instruments for early access to medicines, including compassionate use schemes.

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### European Commission and the EMA: impact of Brexit on centrally authorised medicines

The European Commission and the European Medicines Agency (EMA) published a question and answer document concerning the impact of Brexit on medicines with a market authorisation obtained via the centralised procedure.

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### EMA prepares for Brexit

The EMA has developed a business continuity plan to deal with the implications of the UK's withdrawal from the European Union and the Agency's relocation. 43 staff members have been reallocated to Brexit preparations, which means that other activities have had to be put on hold, such as the development of a publicly accessible web portal with information on medicines, and the development of a transparency roadmap for the EMA.

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### EMA: public consultation on personalised medicines and companion diagnostics

The EMA has released for public consultation a concept paper on the development and lifecycle of personalised medicines and companion diagnostics.

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### European Ombudsman: strategic inquiry into EMA arrangements for pre-submission activities

The European Ombudsman is conducting a strategic inquiry into the arrangements that the European Medicines Agency (EMA) has in place for engaging with individual medicine developers before the Agency receives applications for marketing authorisations from them ('pre-submission activities'). According to the Ombudsman, these activities may influence the final decisions of the EMA.

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## 4 e-Health

### Estonian presidency: consultation on the 'Digital Health Society' declaration

Together, the Estonian presidency of the Council of the European Union and ECHAlliance invited stakeholders interested in the development of digital health to take part in the consultation on the 'Digital Health Society' declaration.

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### European Parliament: study on the benefits of eHealth

The study, 'Transforming eHealth into a political and economic advantage' was commissioned by MEP Michał Boni. It examines the eHealth development rate in European countries, and the various ways in which eHealth and mHealth solutions can contribute to more cost-efficient healthcare systems.

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### European Commission: public consultation on the transformation of health and care in the digital single market

The aim of the consultation is to investigate the need for and scope of policy measures to promote digital innovation. It seeks to collect information on the following areas:

1) Cross-border portability of personal health data
2) Sharing of data and infrastructure to advance prevention, treatment, and personalised medicine in three areas:
   - Rare and complex diseases;
   - Preparedness for upcoming epidemics and infectious threats;
   - The use of data for pharmacovigilance and assessment of effectiveness of products placed on the market.
3) Measures to encourage widespread uptake of digital innovations.

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### Estonian presidency: report on obstacles to free movement of electronic health records

The report 'Mapping out the obstacles of free movement of electronic health records in the EU in the light of the single digital market' was commissioned by the Estonian government and financed by the EU. It investigates the situation in a number of countries and makes recommendations on how possible obstacles can be removed.

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### European Commission: report from the mHealth working group

The stakeholders' working group on mHealth assessment guidelines, set up by the Commission in 2016, recently concluded its work. A report, including a few case studies on mHealth, is now available.

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### European Parliament: possible uses of Big Data in healthcare

This publication from the European Parliament Think Tank looks at how Big Data can be used in the context of healthcare.

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### Informal Council: digital solutions in healthcare

At the 20 July informal meeting in Tallinn, EU health ministers discussed the future of digital solutions in health. The ministers identified areas for closer cooperation between Member States and possible actions at the EU level to overcome the main challenges of data-driven digital innovation in healthcare.

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## 5 Social policy

### European Commission: information system for electronic exchange of social security information

The Commission launched the EESSI (Electronic Exchange of Social Security Information System), a new IT platform that will connect electronically around 15,000 social security institutions in the EU Member States, as well as Iceland, Liechtenstein, Norway and Switzerland. It should simplify the exchange of data needed for the processing of cross-border social security cases.

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### European Commission: consultation on access to social protection for workers in non-standard jobs

The Commission is starting a consultation with the social partners on a possible initiative to address difficulties in accessing social protection for people in all types of employment, particularly for those in self-employment and non-standard employment.

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### European Commission: Employment and Social Developments in Europe 2017

The 2017 edition of this annual review of employment and social developments in Europe presents a detailed analysis of key employment and social issues in the European Union.

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### Eurostat: monitoring social inclusion in Europe

This study analyses the data from the EU Statistics on Income and Living Conditions (EU-SILC) to gain new insights into issues related to income, deprivation and work. Healthcare data are analysed in the chapter on public services.

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### European Parliament: petitions on alleged gender discrimination

In Germany, spouses of civil servants have fewer rights on retirement in terms of statutory health insurance than women married to non-civil servants. Several women lodged a petition, claiming to be victims of gender discrimination. In its reply, the Commission found that the petitions were unfounded, since the cases in question referred to unequal treatment between women.

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## 6 Economic policy

### European Parliament: question on the reimbursement of cancer medicines in Greece

In response to a question from a Greek MEP, the Commission replied that the EU institutions, on the basis of the Memorandum of Understanding, have agreed with the Greek authorities that pending availability of HTA assessment in Greece, decisions on the reimbursement of innovative medicines will be taken on the basis of the decisions taken following a HTA assessment in six Member States.

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## 7 Court of Justice of the European Union

### Judgment: causal link between the administering of a vaccine and a disease

Case C-621/15 concerns a person who claimed to suffer from various serious conditions due to the administering of a vaccine against Hepatitis B. In its judgment, the Court finds that, in the absence of a scientific consensus, the existence of a defect in the vaccine, and the causal link between that defect and a disease, may be established by factual evidence constituting serious, specific and consistent presumptions.

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**Judgment: no justification for requirement that medicinal products derived from plasma should be prepared from plasma collected in the same Member State**

In case C-296/15, the Court finds that a clause in the tender specifications for a public contract which, in accordance with the law of the Member State to which the contracting authority belongs, requires medicinal products derived from plasma, which are the subject matter of the public procurement at issue, to be obtained from plasma collected in that Member State, is not in compliance with EU legislation.

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**Opinion of the AG: refusal to grant dental technicians partial access to the profession of dentist is justified**

In the opinion of the Advocate General in case C-125/16, national legislation which requires that dental technicians pursue their profession under the supervision of dentists is pursuing a legitimate objective of public health protection, which is appropriate for attaining the objective pursued and does not go beyond what is necessary in order to attain it.

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**Opinion of the AG: software to support prescribers in their prescription of medicines is a medical device**

In the view of the AG in case C-329/16, software used to support the prescribing of medicines does constitute a medical device, since this software provides the doctor with information which is important to detect contraindications, drug interactions and excessive doses.

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## 8 Competition

**European Commission: investigation into agreement between Teva and Cephalon on generic drug**

The European Commission has informed the pharmaceutical concern Teva of its preliminary view that the agreement concluded with Cephalon was in breach of EU anti-trust rules. Under the agreement, Teva undertook not to market a cheaper, generic version of Cephalon's drug for sleep disorders, modafinil.

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**EESC: opinion on application of state aid rules to services of general economic interest**

The European Economic and Social Committee (EESC) brought out an opinion on application of state aid rules for compensating the provision of services of general economic interest (Decision 2012/21/EU and Community Framework). Hospitals, healthcare and long-term care are included in the scope of this legislation.

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**Hungary: five suppliers of medical suture products fined for bid-rigging**

The Hungarian competition authority is fining five suppliers of medical suture products for bid-rigging, exempting one of them under the leniency provisions.

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**European Commission: statement of objections sent to Merck and Sigma-Aldrich for breaching EU merger rules**

The Commission has sent a statement of objections to Merck and Sigma-Aldrich for

breaching EU merger rules by providing incorrect or misleading information.

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### European Commission: acquisition of Actelion Pharmaceuticals by Johnson & Johnson approved

The European Commission has approved under the EU merger regulation the proposed acquisition of Actelion Pharmaceuticals by Johnson & Johnson. The decision is subject to conditions ensuring that clinical development of their innovative insomnia drugs will not be adversely affected by the merger.

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## 9 Infringement proceedings

### Hungary: Infringement procedure for restrictions on the establishment of pharmacies concluded

In reply to a parliamentary question concerning a Commission infringement procedure against Hungary for restrictions on the establishment of pharmacies, the Commission states that it concluded the infringement procedure in June 2017 having established that, under EU law, there were insufficient strong legal arguments to take the case further.

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## 10 Publications

### European Commission and OBS: implementation in the European Union of the right to healthcare under the UN Convention on the rights of the child

The European Commission and the European Observatory on health systems and policies (OBS) published a report, 'Implementation of the right to health care under the UN Convention on the Rights of the Child'.

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### 'Vulnerable' project: literature review on unmet medical needs in the EU

This literature review discusses the unmet needs for medical care among people in vulnerable and isolated situations in the EU.

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### OECD: variations in hospital length of stay and cost

Through international comparison work, this paper helps policy makers understand the scope and nature of differences in length of stay/costs across hospitals in OECD countries. It also explores whether the varying characteristics of hospitals or of health systems can explain differences in efficiency.

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### Article: the role of the European Structural and Investment Funds (ESIF) in financing the health system in Lithuania

This article assesses the extent to which ESIF support assisted the implementation of the ongoing health system reform, and whether this has led to improvements in healthcare.

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### Report: the impact of biosimilar competition in Europe

This document describes the effects on price, volume and market share of the arrival and presence of biosimilar competition in the European Economic Area (EEA). The report was produced by QuintilesIMS at the request of the European Commission.

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### Eurohealth: article on the proposal for a directive on a proportionality test for the regulation of professions

This article analyses the Commission proposal to introduce a proportionality test before new regulations are adopted or amendments made to existing legislation on professions. Healthcare professions account for a large share of the regulated professions.

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### Observatory for patient mobility: annual report 2015-2016

Every year, Belgian care institutions provide care to non-Belgian patients. In its fourth annual report, the Observatory for patient mobility, set up by NIHDI and the FPS Public health, provides an overview of developments in 2015-2016. The report shows that the number of hospital admissions of foreign patients receiving care in Belgium has been stable for several years.

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### Book: Research Handbook on EU Health Law and Policy

This book, 'Research Handbook on EU Health Law and Policy', edited by T. K. Hervey, C. A. Jonge and L. E. Bishop, from the University of Sheffield, offers an up-to-date analytical overview of the most important topics in EU health law and policy. It outlines the direction of travel of policy and suggests a research agenda for the future.

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## 11 Miscellaneous

### Parliamentary question on the use of EU funds in Hungary for the project 'energy rationalisation in hospitals'

According to the MEP putting the question, the use of EU funds in Hungary is extremely controversial, and there are claims that contracts are often awarded to the same commercial circles. The Commission was asked if it is aware of such practices and what action it would take.

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### EU loan to develop a new device to identify infectious pathogens

A € 20 million EU loan will help a Barcelona-based start-up to develop and commercialise a device capable of identifying within an hour a range of infectious pathogens.

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### EIB: loan to ETZ hospital in the Netherlands

The European Investment Bank (EIB) and ETZ Hospital (Elisabeth-TweeSteden Ziekenhuis) signed a €43 million loan agreement to help with the modernisation of the hospital's sites in Tilburg and Waalwijk (The Netherlands).

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**EIB: loan to the Amphia Hospital in the Netherlands**

The European Investment Bank (EIB) decided to grant a loan of a maximum amount of € 100 million to the Amphia Hospital in Breda, the Netherlands.

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**EIB: loan to a hospital in the Veneto region, Italy**

The European Investment Bank (EIB), under the so-called 'Juncker plan', signed a €29 million loan to support the construction and operation of a healthcare institution in Treviso. Ospedal Grando will operate under a 21-year concession agreed with the local health authority.

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**EIB: loan for brain cancer treatment**

The EIB and German medical device company MagForce have signed a financing agreement which will allow the company to borrow up to €35 million over the coming three years. The financing will enable a Europe-wide roll-out of a brain cancer treatment.

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**EIB: loan for the expansion of a private healthcare network in Romania**

The European Investment Bank (EIB) is providing a € 15 million loan for the expansion of a private healthcare network in Romania. The agreement is backed by a guarantee from the European Fund for Strategic Investments (EFSI).

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**Brexit Health Alliance: negotiation priorities**

The Brexit Health Alliance was set up by stakeholders in the British NHS to give them a strong, collective, evidence-based voice in the discussions on Brexit. In a document, they set out the alliance's five negotiation priorities.

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**UK: plans to charge foreign patients for non-urgent medical care**

The British government is planning to require NHS hospitals to charge foreign visitors and migrants upfront for non-urgent medical care. This would apply to patients from inside and outside the European Economic Area.

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**Brexit: negotiating proposal on EU citizens living in the UK and UK nationals living in the EU**

According to this UK negotiating proposal, the UK intends to protect the healthcare arrangements set out in the European Regulation on the coordination of social security systems for citizens who benefit from these arrangements before a specific date.

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