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- European Commission: setting up of a steering group on health promotion, disease prevention and management of non-communicable diseases
- European Commission: audit report on the anti-microbial resistance policy in Belgium
- ECDC: fall in measles cases in the EU/EEA
- EXPH: draft opinion on vaccination programmes and health systems in Europe
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- European Commission: study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards
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- European Commission: financial support to improve reception conditions for migrants in Greece
- European support for Bavarian Nordic's vaccine production

## 1 Public health

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### **European Commission: combatting HIV/AIDS, viral hepatitis B and C and tuberculosis**

The Commission staff working document provides an overview of EU policy initiatives and activities to help Member States end the AIDS and tuberculosis epidemics by 2030, and to fight hepatitis and other communicable diseases.

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### **European Commission: setting up of a steering group on health promotion, disease prevention and management of non-communicable diseases**

The objective of the steering group is to help Member States meet the sustainable development goals related to health and to reduce premature mortality from non-communicable disease.

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### **European Commission: audit report on the anti-microbial resistance policy in Belgium**

The European Commission published the audit report on its visit, together with the European Centre for Disease Prevention and Control (ECDC), to Belgium, to discuss its antimicrobial resistance policy.

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### **ECDC: fall in measles cases in the EU/EEA**

According to the ECDC, the overall number of measles cases in the EU/EEA is falling, but the case load is still high in some countries.

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### **EXPH: draft opinion on vaccination programmes and health systems in Europe**

The Expert Panel on effective ways of investing in health (EXPH) published a draft opinion on vaccination programmes and health systems in Europe.

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### **European joint action on vaccination**

The European joint action on vaccination involves 21 European countries, as well as international institutions, universities and a wide range of stakeholders. The aim of this joint action is to promote sustainable European cooperation against diseases preventable by vaccination.

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## 2 Medicines and medical devices

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### **European Commission: conference on future cooperation on Health Technology Assessment (HTA)**

During a conference in July, more than 300 policymakers, care providers, patient representatives and other experts discussed future cooperation on Health Technology Assessment (HTA).

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🔹 **European Commission: study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards**

This study has been conducted in response to the Council conclusions of 17 June 2016, in which the Commission was invited to conduct an analysis on the impact of pharmaceutical incentives and rewards on innovation, availability and accessibility of medicinal products.

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🔹 **European Commission: good practice for clinical tests with genetically modified human cells**

A good practices document has been drawn up by the national competent authorities and the Commission services, reporting on good practices for the assessment of GMO-related aspects in the context of clinical trials with genetically modified human cells.

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🔹 **European Commission: the Pharmaceutical Committee discusses shortages of medicines**

This meeting, with experts from EU Member States, was a response to calls from the Council and European Parliament to the Commission to monitor the obligation of marketing authorisation holders to ensure continuous supply of medicines. Two documents were adopted: a summary of the measures taken by Member States to ensure continuous supply, and a paper on the obligation on marketing authorisation holders.

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🔹 **Reinforced EU/US collaboration on medicines**

Senior officials from the European Commission (EC), the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) agreed, inter alia, to encourage early parallel scientific advice on advanced therapies and generic medicines. The parties are also working together on methodologies to optimise the use of Real-World Evidence (RWE), to support regulatory decision-making throughout the life-cycle of the product.

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🔹 **STAMP discusses the repurposing framework for medicines and the use of Real-World Evidence**

The Commission expert group on safe and timely access to medicines for patients ('STAMP') discussed the proposal for a repurposing framework for medicines, and the use of RWE and big data.

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🔹 **European Commission: use of the website on the online pharmacies logo and on falsified medicines**

The Commission's website on the online pharmacies logo and on falsified medicines aims to enable citizens to identify legitimate pharmacies, and to provide information on the potential dangers of using online pharmacies. In response to a question from the European Parliament, European Commissioner Andriukaitis reported that the site was visited 573,294 times between 2016 and 2018.

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🔹 **European Commission: fine-tuning of the intellectual property rules**

The Commission is proposing a targeted adjustment to the intellectual property rules, to help Europe's pharmaceutical companies tap into fast-growing global markets: the so-called 'export manufacturing waiver' for supplementary protection certificates.

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🔹 **EMA: 100th meeting of the management board**

The EMA management board is warning that unless the Agency receives sufficient staff resources, given the growing workload and the preparations for Brexit, its ability to

implement current and upcoming legislation may be impaired.

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#### **EMA: work programme to improve the availability of medicines in the EU**

An EU-wide task force published its work programme for 2019/20, and is preparing stakeholder workshops to improve the availability of medicines in the EU.

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#### **European Commission: consultation on the draft guidelines on good clinical practice for advanced therapy medicinal products**

The European Commission is organising a targeted stakeholder consultation on the draft guidelines on good clinical practice for advanced therapy medicinal products.

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#### **European Commission: consultation on duplicate marketing authorisations for biological medicinal products**

The European Commission is organising a targeted stakeholder consultation on duplicate marketing authorisations for biological medicinal products.

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#### **EPSCO Council: Health Technology Assessment (HTA)**

During the Employment, Social Affairs, Health and Consumer Affairs (EPSCO) Council on 21-22 June 2018, the ministers held a debate on the proposed regulation on health technology assessment. The discussions focused on the choice between a mandatory approach and a more voluntary approach. The Presidency concluded that the debate indicated a prevailing preference for a voluntary approach.

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### **3 Health care services in the internal market**

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#### **European Commission: study on cross-border health services: enhancing information provision to patients**

According to this study, European patients are generally not aware of the possibility of gaining access to health services in other EU Member States, but the situation is improving.

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#### **European Commission: cross-border healthcare: facts and figures**

The Commission published data on cross-border patient mobility, based on Member State data for 2016.

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#### **European Commission: report on the use of the European Professional Card and alert mechanism**

According to the report, 1,529 physiotherapists, 1,037 general care nurses and 396 pharmacists applied for a European Professional Card (EPC) in 2016-2017. In total, 13,597 alerts were issued by the authorities over the same period, mainly concerning professionals who have been restricted or prohibited from practising their profession in their Member State.

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**European Commission: notice on Brexit and the EU rules in the field of regulated professions**

The Commission published a notice to stakeholders on the withdrawal of the United Kingdom and the EU rules in the field of regulated professions and the recognition of professional qualifications.

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**European Parliament: petition on introducing uniform EU-wide language exams for specialist professions**

The petitioner is of the view that certain Member States are increasingly introducing new language proficiency requirements with the motive of protecting their labour markets. He is therefore calling for the introduction of uniform language proficiency requirements for certain professions, with an EU-wide system.

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**European Commission: communication on the retail sector**

The Commission published a set of best practices to support Member States' efforts to create a more open, integrated and competitive retail sector, also indicating the areas where changes may be needed. The authorities are encouraged, among other things, to introduce rules which will level the playing-field with e-commerce, for example, by ensuring that non-prescription medicines can be sold in shops other than pharmacies.

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**European Commission: proposal for a mechanism to resolve legal and administrative obstacles in a cross-border context**

The purpose of this proposal is to establish a mechanism to apply, for a common cross-border region, in a given Member State, the legal provisions of the neighbouring Member State, if applying its own laws would present a legal obstacle to implementing a joint project. It could be used, inter alia, for health services.

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## 4 e-Health

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**European Commission: EU country reports on Big data, the general data protection regulation and health**

The EU-funded AEGLE project took stock of the situation in each country of medical data processing for the purposes of scientific research, since the implementation of the General Data Protection Regulation (GDPR). They also published some lessons learned from working with big data analytics for diabetes.

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**European Parliament: petition on alleged breach of privacy with respect to sensitive data related to citizens' health**

The petitioner condemns an alleged violation of European legislation by Italy, which in November 2017 allegedly granted private companies the use of the health data of private citizens without their prior consent.

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### **European Commission: recommendation on a European Health Record**

In an interview, Roberto Viola, Director General of the Commission's Communication DG (DG CONNECT), announced that the Commission is preparing a recommendation on a harmonised electronic European health record, which would be linked to an electronic identity card. The recommendation will also discuss content-related standards for documents, images, complex datasets and multimedia recordings.

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### **European Parliament: framework for the free flow of non-personal data in the European Union**

The Parliament voted on the proposal for a regulation on a framework for the free flow of non-personal data in the European Union. This Regulation would also cover anonymised data used for research.

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### **European Commission: project to develop ICT infrastructure for the coordination of care**

The EU-funded C3-Cloud project, with a budget of almost €5 million, will establish an ICT infrastructure facilitating a collaborate care and cure cloud to enable continuous coordination of patient-centred care activities by a multi-disciplinary care team or informal care givers.

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### **Innovative Medicines Initiative: new calls for proposals**

The new topics of the Innovative Medicines Initiative (IMI) aim to make clinical trials more digital, more patient-centric, contribute to medicine safety, and apply blockchain technologies to the drug development and health sectors.

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### **European Commission: 9.2 billion euro for digital programme**

Healthcare initiatives figure among the priorities of this programme.

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## **5 Social policy**

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### **EPSCO Council: revision of the regulations on the coordination of social security systems**

The Council has agreed on its negotiating position (general approach) concerning the revision of the regulations on the coordination of social security systems (883/2004 and 987/2009). The revision includes amendments to five areas, including long-term care.

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### **European Commission: review of employment and social developments in Europe - 2018**

The report 'Employment and Social Developments in Europe' describes positive trends and challenges, particularly concerning automation and digitalisation. It also discusses developments in the fields of social protection and healthcare.

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## 6 International agreements

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### **ECOFIN Council: country-specific recommendations endorsed**

The Council adopted the recommendations on the economic and budgetary policies of the Member States. These recommendations are drawn up in connection with the 'European Semester'. Several Member States received recommendations on their healthcare policy.

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### **European Commission: post-programme surveillance report, Cyprus**

This report presents the findings of the fourth post-programme surveillance mission to Cyprus, and identifies the remaining challenges to the Cypriot economy. Challenges for the healthcare system are also discussed.

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## 7 Competition

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### **Greece: fine for GSK for reducing the supply of medicines to wholesalers**

The Greek competition authority has imposed a fine on a pharmaceutical laboratory (GSK), for reducing the supply of medicines to wholesalers.

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## 8 Court of Justice of the European Union

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### **Judgment: supplementary protection certificate for medicinal products**

In its judgment in case C-121/17, the Court rules on the interpretation to be given to Regulation (EC) no. 469/2009 concerning the supplementary protection certificate for medical products, for a product made up of several active ingredients with a combined effect.

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### **Opinion of the Advocate-General: off-label use of Avastin**

Avastin is authorised for the treatment of particular forms of cancer. It is also used to treat a disease of the retina, although the market authorisation does not refer to this therapeutic indication. According to the Advocate-General in case C-29/17, a national legal provision can allow the reimbursement of a medicinal product used for a therapeutic indication which is not covered by the market authorisation.

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### **Judgment: application of patent legislation to the parallel importation of a medicine from a Member State which has recently joined the EU**

In case C-681/16, the Court found that the holder of a supplementary protection certificate for a medicinal product may oppose the parallel importation of a medicinal product from a

new Member State where the legal systems of that state did not provide for the possibility of obtaining equivalent protection at the time when the application for the basic patent was lodged.

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### **Judgment: VAT exemption for financial services to dentists**

DPAS designs, implements and manages dental plans in the United Kingdom. These plans are sold by DPAS, through the dentists, to the dentist's patients. According to the judgment in case C-5/17, the VAT exemption set out in directive 2006/112/EC does not apply to the services provided by DPAS.

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## **9 Infringement proceedings**

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### **Commission calls on 27 Member States to comply with EU rules on the recognition of professional qualifications**

The Commission is sending letters of formal notice to 27 Member States regarding the conformity of their legislation and practice with the EU directive on the recognition of professional qualifications (2005/36/EC). The particular issues here are the introduction of the European Professional Card, the alert mechanism, the possibility to have partial access to a professional activity, the proportionality of language requirements and the setting up of assistance centres. The Commission is also raising issues relating to the transparency and proportionality of regulatory obstacles in professional services.

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## **10 Publications**

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### **Article: The implementation of EU rules on cross-border care: moving towards convergence?**

The article 'The implementation of European Union (EU) rules on cross-border care: moving towards convergence?' studies the implementation of the EU patients' rights in cross-border healthcare directive in Germany and Norway.

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### **OECD: Review of the Lithuanian health system**

This report analyses the performance of Lithuania's health system. According to the report, the main challenge to the system is that health outcomes still place Lithuania among the lowest ranked in the OECD.

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### **WHO: Medicines reimbursement policies in Europe**

The World Health Organisation (WHO)'s report 'Medicines reimbursement policies in Europe' examines the various policies which increase access to affordable medicines. It discusses diverse national practices and identifies key aspects of policy frameworks that protect vulnerable groups from unaffordable out-of-pocket payments for medicines.

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**OECD: Delivering quality health services: a global imperative**

This report describes the current situation regarding universal health coverage and the global quality of care, and outlines the steps needed to improve the situation.

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**OECD: Health Statistics 2018**

The online database OECD Health Statistics 2018 offers the most comprehensive source of comparable statistics on health and health systems across OECD countries.

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**WHO: country reviews on financial protection and affordability of healthcare**

These reviews assess the affordability of healthcare for patients in European countries.

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**European Commission: Informal care in Europe: exploring formalisation, availability and quality**

The report 'Informal care in Europe: exploring Formalisation, Availability and Quality', produced by LSEconsulting for the European Commission, explores the trend in European countries to formalise the role and status of informal carers.

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**Bruegel: The macroeconomic implications of healthcare**

In the study 'The macroeconomic implications of healthcare', published by the Bruegel think tank, the authors find significant differences in efficiency between countries.

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**OBS: analyses of the Estonian, Greek and Spanish health systems**

These studies, published by the European Observatory on health systems and policies (OBS), review recent developments in organisation and governance, health financing, health care reforms and health system performance.

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**European Commission: Boosting investment in social infrastructure in Europe**

This report by the High-level Taskforce on Investing in Social Infrastructure in Europe looks at investment in social infrastructure in Europe, such as healthcare, education and affordable housing.

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## 11 Miscellaneous

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**WHO conference: health systems for prosperity and solidarity**

The WHO high-level regional meeting 'Health Systems for Prosperity and Solidarity: leaving no one behind' was held in conjunction with the tenth anniversary of the signing of the Tallinn Charter. Presentations from the conference and background documents are available online.

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➤ **European Commission: financial support for healthcare for asylum seekers in Italy**

The Commission awarded € 9 million in emergency assistance to Italy, to improve access to healthcare in reception facilities for asylum seekers and beneficiaries of international protection.

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➤ **European Commission: financial support to improve reception conditions for migrants in Greece**

The European Commission awarded € 37.5 million to Greece to improve reception conditions for migrants, including healthcare provision.

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➤ **European support for Bavarian Nordic's vaccine production**

The European Union is supporting biotech company Bavarian Nordic with a € 30 million euro loan from the European Investment Bank (EIB), to finance a vaccine-production facility.

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